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Using Academic License Agreements To Promote Global Social Responsibility

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I. Abstract

The impetus to use academic innovations to enhance peoples' lives in the developing world, which we term promoting Global Social Responsibility or "GSR," got its start with healthcare and the need to ensure affordable access to life saving medicines even during their period of patent protection in the developed world. However, academic innovation has the potential to advance living standards in the developing world in other ways in addition to healthcare, and it is equally important that academic institutions commit themselves to realizing this broader potential and adopt licensing approaches that anticipate these broader considerations.

The purpose of this article is to present (a) a business and licensing paradigm; and (b) a number of sets of simple, readily implementable language that academic institutions can choose from if they wish to ensure that inventions emanating from their research programs are used to improve the human condition in developing countries.

We show how current academic licensing best practices leave academic institutions vulnerable to a repetition of the Zerit® story that attracted such negative publicity for Yale and Bristol-Myers Squibb in 2001.

We show that it is possible to achieve socially positive licensing outcomes without detracting from academic institutions' ability to license their innovations and get them developed. Our research has shown that the academic community is at the very earliest stages of including social responsibility in its licensing practices, and we identify the leading institutions and the approaches they are following to achieve these ends. We also show that the pharmaceutical industry is starting to move in the direction we advocate of its own volition.

Finally, we identify the risks from inaction—the potential for congressionally mandated amendments to the Bayh-Dole Act that we believe will make it significantly harder to license academic inventions in the first place.

II. Acknowledgements

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III. Introduction

Starting in 2001 and driven by the controversy (discussed in detail below) surrounding the licensing by Yale to Bristol-Myers Squibb of what became the very important antiretroviral drug Zerit®, academic institutions identified the need to address the issue of affordable access to their innovations in developing countries in their licensing agreements.

The issue received new impetus in 2003 when the Bill and Melinda Gates Foundation launched its Grand Challenges in Global Health, and included a requirement for a Fair Access Policy as part of the proposal, to ensure that the resultant products would indeed benefit the world's poor.

More recently, this principle was enunciated as Point 9 in the Stanford University "Nine Points to Consider" document;[1] the document included model

1. *http://otl.stanford.edu/industry/resources/whitepaper-10.pdf.*

language for a number of the points, but did not include model language for global health; and the need to address global health issues was incorporated into the Massachusetts Association of Technology Transfer Offices ("MATTO") Joint Invention Agreement.[2]

Two groups that have devoted considerable effort to raising awareness of this issue are the Technology Managers for Global Health ("TMGH") group within the Association of University Technology Managers ("AUTM") and the Center for the Management of Intellectual Property for Health Research ("MIHR") in Oxford, UK. Both groups received support from the Rockefeller Foundation, and in addition TMGH leveraged a considerable amount of volunteer effort both from within and from outside AUTM. MIHR produced a more than 2,000 page handbook[3] which comprehensively addressed all aspects of global health. The handbook included a section with form license agreements.

However, the only licensing language to achieve social responsibility objectives in the handbook was developed by an independent working group based at Yale University and convened by Universities Allied for Essential Medicines ("UAEM"), a student organization discussed in more detail in Section XII below. UAEM has done an effective job of disseminating this language. In general, the members of UAEM are students, and while many are in law schools, they are not experienced licensing professionals. Their proposed license structure, also discussed in more detail in Section XII, appears likely to make it more difficult to license academic inventions in the first place, which would be counter-productive.

A thoughtful analysis of the issue of global health in academic licensing and one licensing approach was recently proposed in the UK.[4]

We therefore set out to analyze the issue and to identify the underlying business and licensing paradigms needed to achieve affordable access to essential medicines and other innovations in developing countries. We wanted to identify a range of options of simple, readily adoptable and implementable language that academic institutions can incorporate in their form term sheets and license agreements. We also discovered that many of these options have been contributed by academic institutions that have already implemented them and are testing their acceptability in the marketplace.

IV. Yale, Bristol-Myers Squibb and Zerit®

The events that first thrust the issue of universities' intellectual licensing practices and their ability to impact global health onto center stage actually started in the early 1960's at the Detroit Institute of Cancer Research (now the Barbara Ann Karmanos Cancer Institute) where Dr. Jerome Horowitz, working on the then prevalent theory that cancer was caused by viruses, synthesized a number of compounds that would inhibit DNA replication in the expectation that they would cure cancer. The compounds included:

- AZT
- ddC
- ddI
- d4T

The theory was of course incorrect for the overwhelming majority of types of cancer and so the compounds were ineffective against cancer and were shelved.

When the HIV epidemic emerged in the early 1980's, Horowitz' work was dusted off and several of his compounds were evaluated against HIV and found to be effective. AZT (Burroughs Wellcome), ddC and ddI (NIH) were all discovered by following this line of enquiry.

Drs. Tai-Shun Lin and William Prusoff of Yale University worked with another Horowitz compound, d4T (stavudine), with funding from the NIH and Bristol-Myers Squibb, and evaluated d4T's activity against HIV.

Prusoff and Lin found d4T to be effective and Yale filed for a method of treating patent on December 17, 1986 and U.S. patent 4,978,655 issued on December 18, 1990. Bristol-Myers had received an exclusive option to an exclusive license to any patents that emerged from the work as part of the sponsored research agreement and exercised their option and signed a license on January 12, 1988. As is normal in academic licenses, Yale gave Bristol-Myers the right to file in foreign countries in Yale's name and Bristol-Myers duly filed corresponding applications in major western countries such as Europe, Japan, Canada, etc. Critically, they decided to include S. Africa, Mexico and Egypt in their filings.

Bristol-Myers commenced clinical development

2. *http://www.masstechtransfer.org/category/news.*

3. "Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices" (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, California, U.S.A. Available online at *www.ipHandbook.org.* Vol. 1, 89, (2007).

4. "Making Drugs Available at Affordable Prices: How Universities' Technology Transfer Offices Can Help Developing Countries," Mark Anderson, *Journal of Intellectual Property Law and Practice*, 2007, Vol 2 # 3, 145-152.

of stavudine and received FDA approval on June 24, 1994. The product was trademarked Zerit®. It became a critical component of the "triple cocktail" that turned HIV infection from a death sentence to a manageable, chronic condition. In 1998 it became the most frequently prescribed anti-retroviral in the world.[5]

In 2000, Zerit® was on the list of essential medicines that the world's poor needed access to compiled by Toby Kasper, the head of the Access to Essential Medicines Program for Medécins Sans Frontiéres. Kasper had met Amy Kapczynski, then a first year Law School student at Yale (and currently an Assistant Professor at the University of California, Berkeley Boalt Hall School of Law) at an AIDS conference in Durban in July 2000, and immediately realized that Amy could help put pressure on Yale from within.[6] Her first recruit to the cause was Dr. Prusoff, the inventor of Zerit®. Then she obtained the support of Dr. Michael Merson, Dean of Yale's School of Public Health, and former head of the World Health Organization's HIV/AIDS program.

On February 14, 2001, MSF wrote to Yale and asked 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.

On February 28, 2001, Yale replied saying they were unable to agree to the request because they had granted an exclusive license to Bristol-Myers Squibb (BMS), under the terms of which, only BMS could respond to the request.

Kapczynski alerted reporters at the Yale Daily News to the story, which published its first story on the subject on March 2, which served to mobilize opinion on campus. A group of students in the Graduate Student Union—which had already been campaigning against Yale's relationship with corporate sponsors—circulated a petition calling on the school to "ease its patent" and collected 600 signatures from students, professors and researchers on campus. The students also criticized Yale for its close ties to BMS—the company had donated $250,000 to Yale in 1999.

On March 9, MSF responded to Yale pointing out that Yale's own policy stated that a key objective of their technology transfer program was intended to be for "the benefit of society in general" and that d4T was not reaching those who need it in South Africa, and suggesting that Yale had the ultimate power over their patent and could breach their contract with BMS if need be.

On March 12, the *New York Times* ran a story "Yale Pressed to Help Cut Drug Costs in Africa" on the front page of its Technology section.

The impact was immediate. On March 14, Bristol-Myers issued a statement saying:

> 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.

In June 2001, Bristol-Myers signed an "agreement not to sue" with Aspen Pharmacare, South Africa's leading generic manufacturer.

The high visibility of the Zerit® story gave considerable momentum to an evolving change in the world pharmaceutical paradigm whereby the concept of tiered pricing for patent protected drugs started to be established, under which drugs could be sold at generic prices in developing countries during their period of patent protected exclusivity and at high prices in developed countries.

V. The Extent of Academic Innovation's Ability to Contribute to Enhancing Conditions in the Developing World

The ability of academic licensing practices to influence the quality of life in developing countries was first identified with the Zerit® case discussed above. The full extent of academic research's ability to lead to new drugs has only recently begun to be quantified. A study currently underway at Boston University has identified 131 vaccines, small molecule drugs, biologic drugs and in vivo diagnostics that have been discovered in whole or in part at academic institutions, patented, licensed and have reached the public since 1980[7]; so clearly the licensing approaches that

5. *http://mondediplo.com/2002/02/04stavudine.*

6. *http://archive.salon.com/news/feature/2001/05/01/aids/print.html*; accessed 1/2/07, on which much of this account is based.

7. For a preliminary report on this study, see: "The Role of Public Sector Research in the Discovery of New Drugs," Jonathan J. Jensen, Katrine Wyller, Eric R. London, Sabarni K. Chatterjee, Fiona E. Murray, Mark L. Rohrbaugh, and Ashley J. Stevens, Poster at Annual Meeting, Association of University Technology Managers, San Francisco, CA, March 2007.

were followed for these drugs are of enormous importance. Unfortunately, all were licensed years before global social responsibility issues were identified, and, by and large, these genies are out of the bottle. Universities cannot unilaterally change the terms of exclusive licenses, and any changes will have to be made voluntarily by the drug companies. Outterson and Kesselheim have described this as a "Generic Open" or GO license.[8] As we discuss in more detail in Section XII below, a number of companies are starting to do precisely this.

Although healthcare was the first area where it was realized that academic innovation could make an impact on living standards, there are other areas of academic innovation with similar potential:

- Nutritional products;
- Agricultural innovations, e.g., those providing resistance to diseases prevalent in Developing Countries or which enhance efficiency of production, preservation or nutritional value of crops commonly grown in Developing Countries;
- Sustainable high technology innovations such as inexpensive computers, cell phone networks, solar power devices, irrigation technology, water purification and so forth.

VI. The Problem with Current Academic Licensing Best Practices

The issue that the Yale/Bristol-Myers Squibb/Zerit® case highlighted is that academic license agreements generally allow the licensee to determine in which foreign countries to file for patent protection. What caused the problem with Zerit® was that Bristol-Myers Squibb elected to file for patent protection in South Africa and then asserted that patent.

Seven years after the Zerit® case first highlighted this problem, most academic license agreements still give the licensee complete discretion as to where to file patents. Indeed, most academic institutions will only file for foreign patent protection if there is a licensee in place to reimburse the costs of the filings and welcome a licensee filing foreign patent applications because these filings increase the size of the sales base on which royalties will be paid.

It is therefore imperative that institutions start to include a safeguard in their license agreements so that licensee agreements signed today do not cause problems in the future when the products that result from them are ready for the marketplace.

VII. Business and Licensing Paradigm

An examination of the different segments of the pharmaceutical industry clearly identifies the importance of competition on drug pricing. The pharmaceutical industry in fact consists of two quite distinct segments:[9]

- The research based pharmaceutical industry, which develops new medications, obtains extensive patent protection and exclusivity, and markets the drugs for the duration of their patent lifetime at monopoly, premium prices that reflect the medical value they deliver;
- The generic pharmaceutical industry, which develops equivalents of the patent protected products and launches them as their patents expire. The Hatch-Waxman Act[10] supplied the regulatory framework for the generic industry, including creating the Abbreviated New Drug Application ("ANDA"), in which generic companies only have to show that their product is bioequivalent to the approved product. In the first six months after patent expiration only the first generic competitor to file an ANDA is allowed to enter the market and prices fall somewhat. After expiration of this 6 month period of semi-exclusivity, additional ANDA's can be approved, allowing additional companies to enter the market and prices rapidly fall to one based on cost of production plus a reasonable profit margin ("cost+") basis, which frequently results in price reductions of 70 to 85 percent.

It appears therefore that an effective business paradigm for universities to utilize to ensure affordable access to medicines in developing countries is for them to license the underlying patents in a way that establishes generic competition (or at least the potential for generic competititon) in developing countries so that products are sold at cost+ pricing during their period of patent protection in the developed world.

Some would argue that this was the way the pharmaceutical industry operated before the Trade-Related Aspects of Intellectual Property Rights

8. "Market-Based Licensing For HPV Vaccines In Developing Countries" K. Outterson and A. S. Kesselheim," Health Affairs, 27, 130-144, January 2008.

9. For a more extensive discussion of this issue, see "Valuation in Global Health Licenses," Ashley J. Stevens in "Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices" (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, California, U.S.A. Available online at *www.ipHandbook.org.* Vol. 1, 89, (2007).

10. PL98-417 "Drug Price Competition and Patent Term Restoration Act of 1984."

("TRIPS") agreement of 1994, which forced India, traditionally the "pharmacy of the developing world" to recognize composition of matter patents on pharmaceuticals. Irrespective of the accuracy of this view, certainly it is not the way the pharmaceutical industry has operated post-TRIPS, and it represents a dramatic change in the pharmaceutical industry's business model.

Such pricing is not going to be able to justify the private sector investment of $200 million to $1 billion needed over 10 to 15 years to show that a new drug is both safe and effective. While a philanthropically-funded business model is starting to emerge to fund development of medicines which treat diseases which only afflict the developing world,[11] the licensing challenge for drugs which treat diseases that afflict both the developed and the developing world is how to achieve competition in developing countries while preserving their patent monopoly in developed countries.

VIII. Make Social Responsibility a University Policy

We recommend that academic institutions make Socially Responsible Licensing a formal, stated institutional policy. Several benefits will follow from this.

First and foremost, it is the right thing to do and it is important for academic institutions to be seen by their stakeholders to be out in front on such a major issue of public policy.

Second, it will strengthen the licensing officers' hands in negotiations if they can point to an institutional requirement to include socially responsible licensing terms in the agreement.

Finally, it can be a positive in philanthropic activities, helping form the basis for public health initiatives in developing countries. For example, the University of California Berkeley has recently received three substantial donations for this purpose[12] that it attributes in part to its strong leadership in socially responsible licensing. Interestingly, the most recent, a $1.8 million gift, was from Gilead Sciences, a pharmaceutical company which, as noted above, has implemented one of the most reaching global health initiatives of any pharmaceutical company.

The University of California at Berkeley has had a Social Responsibility Program since 2003[13] and the University of British Columbia has drafted Principles for Global Access.[14] Imperial Innovations PLC has made global access a licensing policy.[15] The University of Vermont has adopted a Global Social Responsibility Policy that anticipates going beyond healthcare to encompass other sustainable technologies.[16]

IX. General Issues and Concerns

There are several issues that the licensee will have irrespective of the specific licensing approach that is being used.

A. Which IP Should be Covered by Social Responsibility Provisions?

It is frequently the case that the licensee of a drug whose basic patents are owned by an academic institution makes further inventions in the course of developing the drug. Research carried out by Professor Bhaven Sampat at Columbia[17] in collaboration with UAEM suggests that about half of the NDAs in the FDA Orange Book which list a public sector patent also list at least one private sector patent that also covers the drug, and UAEM and Professor Sampat feel there are a variety of reasons why this may be even be an underestimate.

A number of the licensing frameworks proposed below achieve their objectives through the terms of access to the university's patents. If the licensee develops their own IP that is an additive to but independent of the university's IP (i.e., the licensee's patents are not continuations-in-part of the university's patents), these mechanisms may not be effective. The licensee will indeed be incented to develop patents that are independent of the university's patents because they will have their own, independent 20 year term, thereby extending the effective patent life of the drug.

Using the university's patents to "reach through" and impose terms on the licensee's independently developed patents will likely be strongly resisted by the licensee. For instance, licensing university–patented drug targets under terms that paid royalties on drugs discovered using the target was highly controversial in the 1990's.

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11. See for example, the Institute for OneWorld Health at *http://www.oneworldhealth.org/.*

12. See *http://www.berkeley.edu/news/media/releases/2007/10/30_SPSprogram.shtml; http://blumcenter.berkeley.edu/ and http://ls.berkeley.edu/?q=node/499.*

13. *http://ipira.berkeley.edu/docs/sociallyresponsible11-07.pdf.*

14. *http://www.uilo.ubc.ca/global_perspective.asp.*

15. Tony Hickson, Personal Communication.

16. Todd Keiller, Personal Communication.

17. B. Sampat, Unpublished Working Paper, Columbia University (2007).

One possible approach to this problem would be to explicitly limit the reach through to the licensee's patents for purposes of implementing the social responsibility protections. One contractual approach to implement this might be to include in the definition of Patent Rights the following:

> Solely for purposes of implementing the Social Responsibility Purpose, (and, for avoidance of doubt, not for purposes of determining royalties payable to University) Patent Rights shall include all patents owned or controlled by Licensee that are co-listed with Patent Rights solely or jointly owned by University in the Orange Book maintained by the U.S. Food and Drug Administration.

B. What is a Developing Country?

This question is not as simple as it may seem at first blush. While there are countries that are unequivocally "developed"—the U.S., Canada, the European Union, New Zealand, Australia, the members of the OECD, many oil producing Arab countries for example—and there are countries that are equally unequivocally "developing"—say Botswana or Myanma—there is a vast grey area in between. Countries such as Brazil, India, China and South Africa today, and doubtless numerous others over the ten to fifteen years before a compound licensed today will reach the market, have prosperous middle and upper classes which can and should afford to pay market rates for drugs, but also have large poor populations who cannot.

Therefore, an approach which defines "Developed Countries" and defines developing countries as every country except Developed Countries would be problematic and would probably be the subject of intense negotiation.

There are lists of countries produced by international agencies that can be used to define where competition is to be encouraged, and the license can be written to allow later, updated versions of these lists to govern. Suitable license agreement languages include:

> • Those countries listed on the United Nations Conference on Trade and Development list of "Least Developed Countries," as such list may change from time to time or any subsequent list that may be agreed to by the University and Licensee.
>
> • Those countries listed by the World Bank as Low-Income and Lower-Middle-Income Countries, as such list may change from time to time.[18]
>
> • Those countries eligible for support from the Global Fund for Children's Vaccines (GAVI) or successor organization, which at the effective date of this Agreement are those countries with a Gross National Product of less than U.S. $1,000 per capita per year, and at the effective date of this Agreement include the countries listed in Appendix XX.

However, many of these lists exclude South Africa, which is generally included in humanitarian terms (and is even included within the list of countries eligible for aid under the President's Emergency Plan for AIDS Relief ("PEPFAR").[19]

Another approach is to allow competition only for supply to the Public Sector, broadly defined:

> "Public Sector" means the government of a Developing Country, or any entity empowered by the government of a Developing Country, to act for said government in matters applicable to this Agreement, organizations within the United Nations system including the World Health Global Organization and UNICEF, and other nonprofit agencies which may purchase drugs or vaccines for delivery, manufacture and/or sale in Developing Countries, including but not limited to:
>
> a. Organizations which are members of the International Committee of the Red Cross and Red Crescent;
>
> b. International charitable agencies (also known as Non-Governmental Organizations or NGO's) including but not limited to Oxfam, Médecins Sans Frontières, and so forth;
>
> c. Organizations substantially supported by philanthropic organizations including but not limited to the Bill and Melinda Gates Foundation, the Rockefeller Foundation and so forth, specifically including global product development and distribution public-private partnerships including but not limited to Global Fund for Children's Vaccines, Aeras Global TB Vaccine Foundation, International AIDS Vaccine Initiative, Global Alliance for TB Drug Development, etc.

One of the situations that may prove problematic is if the country has a national health service that covers both rich and poor and procures the country's entire supply of drugs.

Relatively few developing countries have robust generic drug manufacturing capacity, and those countries which are such as India, China and Brazil,

18. This is probably the most inclusive list.

19. *http://www.pepfar.gov/about/.*

are important suppliers to the developing world. It is critically important therefore that the mechanisms used address not only the countries of sale, but also the countries of manufacture.

C. Product Diversion ("Black Market Imports")

Licensees may have a concern that their sales in developed country markets may be undermined by low priced products from developing countries being diverted back into those developed countries.

This concern is legitimate and needs to be addressed. One solution is to require that products subject to competition be produced in a trade dress (dosage size, shape, color, flavor, trade name, trademark, service mark, etc.) different from that used by the primary licensee. This principle was incorporated in the 1994 TRIPS Agreement. The EU has established an Anti-Diversion Regulation to protect against this problem.

While research by Outterson[20] has shown that there is little evidence of product diversion having occurred with products made available at No Profit Prices, Glaxo has used a distinctive trade dress apporach to protect some of its AIDS drugs, and has received regulatory approval for red versions of *Epivi®r* and *Combivi®r* tablets in over 25 countries.[21] Through 2005, over 200 million doses of *Epivi®r* and *Combivi®r* have been shipped under this program in special tri-lingual packs. Glaxo has nine ARVs registered under the EU's Anti-Diversion Regulation.

X. Licensing Frameworks

We have identified four licensing frameworks that will facilitate availability and/or affordability in developing countries. One of these can be implemented through a number of different approaches:

1. Contractually requiring availability in developing countries.
   - Requiring the licensee to include developmental milestones.
2. Contractually requiring availability and affordability in developing countries without specifying the way this will be obtained.
   - Require the licensee to develop the product in developing countries and to sell it using cost+ pricing.
3. Specifying desired outcomes of availability and affordability in developing countries and including an enforcement mechanism to achieve competition if the specified outcomes do not occur.
   - Reserving a march-in right to grant additional licenses to be exercised if the product is not made available in developing countries in a timely manner or if prices in developing countries are too high.
4. Specifying mechanisms to achieve competition.
   - Excluding developing countries from the license and issuing non-exclusive licensee in developing countries separately.
   - Granting only non-exclusive rights in developing countries.
   - Requiring the licensee not to patent in developing countries.
   - Requiring the licensee to grant sublicenses in developing countries at low or zero royalty rates.
   - Requiring the licensee to commit to not assert the licensed IP in developing countries.

Next we show with specific examples that the mechanisms to include global social responsibility safeguards can be implemented with relatively simple additions to standard forms of license agreements.

This learning allows licensing officers to focus on the business negotiation of agreeing a license; social responsibility protections become just another business term and element of the overall negotiation.

We do not in this article discuss the merits of one approach relative to another. Only time and experience will tell which approach or approaches are (a) most acceptable to prospective licensees and (b) most effective in promoting affordable access in developing countries. What is important is that institutions start including these approaches in their license negotiations and experimenting to see what works. The lessons from these "early adopters" will be shared at academic licensing conferences over the next few years.

The licensing frameworks and approaches listed above were developed by us in the process of developing global socially responsible protections to include in Boston University's licenses. We then tested our hypotheses by determining what other institutions were doing. We contacted institutions which we knew were already incorporating global social responsibility principles in their license agreements and asked them to share their language with

20. "Counterfeit Drugs: The Good, The Bad And The Ugly" Kevin Outterson and Ryan Smith, *Albany Law Journal of Science and Technology*, 16, 526-543 (2007).

21. *http://www.gsk.com/responsibility/cr_report_2005/access-to-medicines/dc-preferential-pricing.htm.*

us. We also posted an enquiry on the techno-l listserv on Wednesday, January 16, 2008.

Our conclusions were three-fold:

1. We found examples of almost all of the licensing approaches listed above being used by at least one institution.

2. The relatively small number of replies we received in response to the techno-l posting plus discussions in various academic licensing conferences leads us to believe that relatively few institutions have yet incorporated global social responsibility into their day-to-day licensing practices.

3. Based on the relatively small number of institutions we have identified, the most common approach utilized to date seems to be a continuation of exclusive licensing coupled with the reservation of a "march in" right—the right of the institution to grant additional licenses in developing countries, either at the institution's sole discretion or, if defined objectives have not been met, by the primary licensee.

XI. Contractual Approaches

The approaches below combine examples that have either been provided to us by other academic institutions with whom we have spoken or were developed by us to implement the licensing options we identified from theoretical considerations. All of the institutions cited gave permission for their names to be used.

A. Term Sheet

It is imperative that the concept of Social Responsibility be introduced into the negotiations from the outset. We therefore recommend that the concept be referenced (though, for simplicity, the precise mechanism not be spelled out) in the institution's standard Term Sheet.

Implementation:

• Include in "Exclusivity":

Non-commercial rights, Government Rights and Humanitarian Rights reserved.

B. License Agreement Preamble

No matter which licensing approach is being used, as a general proposition it is probably helpful to include in the "WHEREAS" clauses a general statement of purpose, such as:

WHEREAS, It is the policy of the University that its activities in licensing University intellectual property take into consideration Global Social Responsibility Objectives to fulfill unmet needs in Developing Countries, [such as those of neglected patient populations or geographic areas], and Licensee acknowledges and agrees to carry out its activities under this Agreement in a manner designed to fulfill such needs, as set forth below;

or

WHEREAS, University and Licensee understand and accept that it may serve the public good for there to be competitive sources of Licensed Product in certain markets, with appropriate safeguards to Licensee's economic interests in other markets as more fully specified herein, and that the result of this will be the availability of drugs at affordable prices to poor segments of the world's populations.

C. Specific Licensing Approaches

Framework 1: Require Developing Country Development.

This approach requires the licensee to develop the product for developing countries. Failure to do so would be a material breach of the license, which would at a minimum reopen discussion of license terms and in the extreme could lead to termination. The National Institutes of Health is using this approach through its "White Knight" mechanism.

Implementation:

• Include in Milestones:

Within six (6) months of New Drug Application/Biologic License Application approval in the United States or its equivalent in Europe, Licensee shall send a written report to the Public Health Service detailing the potential Public Sector market to fulfill the public health need for the approved drug or vaccine in Developing Countries, including the impact of any approved competing drug or vaccine. The report shall also include Licensee's proposed amendment to the Commercial Development Plan, Appendix XX, and the Benchmarks and Performance, Appendix YY, to address the needs for Licensed Products in Developing Countries. Licensee will diligently consider if it is possible from a commercial and technical point of view, to satisfy said potential Public Sector market either directly with Licensee's own resources and/or through joint ventures with third parties. Acceptance of this report and amendment is required by PHS in writing; such acceptance will not be unreasonably denied.

Framework 2: Require Developing Country Development and Specify Pricing Structure.

This approach requires developing country development and specifies the pricing structure to

be followed. Imperial Innovations Ltd. in the UK is experimenting with this approach. The fact that Imperial Innovations incorporates this into their licensing approach is particularly noteworthy because they are a publicly traded company on London's Alternative Investment Market stock exchange. The model adheres closely to the Bill and Melinda Gates Foundation's Global Access Strategy guidelines.

Implementation

• Include in Definitions:

"At-Cost" markets means those markets in Developing Countries where individual poverty and insufficient public funding prevent access to healthcare at developed country prices.

"Cost-Based Price" means, in respect of each Licensed Product, a price not exceeding that which fairly reflects the direct cost of manufacture of the Licensed Product plus a typical margin for a generic pharmaceutical product for the respective market.

"Developing Country Manufacturer" means a manufacturer of pharmaceutical products that is able efficiently to manufacture (either within or outside the Developing Country in which the At-Cost market exists), distribute and supply Licensed Product in an At-Cost market at a Cost-Based Price.

"Reasonable Developing Country License Terms" means terms that meet the requirements of Clause XXX and shall include terms based on the following principles:

i. The Licensee shall promptly transfer all required technology to the Developing Country Manufacturer to enable it to manufacture and supply the Licensed Product(s).

ii. The Developing Country License Terms shall not include any payments to be made to the Licensee in respect of the grant of the license in the At-Cost market other than a fee that shall not exceed the direct cost of transfer of technology to the Developing Country Manufacturer.

iii. If the Developing Country Manufacturer is granted any exclusive rights, the continued grant of those rights shall be conditional upon the Developing Country Manufacturer supplying At-Cost markets at a Cost-Based Price and meeting market demand in that market.

iv. The Licensee may impose reasonable conditions, including as to use of trademarks, trade dress, format and pack size, to differentiate the Licensed Product when sold in the At-Cost market from Licensed Products sold in other markets and to prohibit their export into other markets and territories, provided that such conditions or their implementation do not act as an unreasonable barrier to the prompt and efficient supply of Licensed Product in the At-Cost market.

• Include a Section "Supply to Developing Countries"

a. Supply by Licensee. The Licensee shall use Diligent and Reasonable Efforts to supply Licensed Products to customers in At-Cost markets at a Cost-Based Price and meet market demand.

b. Sub-licensing in Developing Country markets. In respect of each Licensed Product and At-Cost market, if the Licensee is unable to supply the Licensed Product at a Cost-Based Price to that At-Cost market and meet market demand, it shall use diligent and reasonable efforts to license one or more Developing Country Manufacturers on Reasonable Developing Country License Terms to manufacture, distribute and sell the Licensed Product at a Cost-Based Price to that At-Cost Market.

c. Pass on terms to sub-licensees. The Licensee shall ensure that the provisions of this Clause XXX form part of any sub-license agreement(s) with any sub-licensee (direct or indirect) of the Licensee.

Framework 3: Specifying Desired Outcomes And Including A "March In" Right As An Enforcement Mechanism To Achieve Competition If The Specified Outcomes Do Not Occur.

This approach sets the institution's expectations for global socially responsible access and reserves the right of the institution to grant additional licenses ("March In") if they are not met. The University of British Columbia and the Massachusetts General Hospital are experimenting with this approach.

Implementation:

• Include in Definitions:

"Global Access Policy" means the commercialization of the Technology, Improvements and any Products in a manner that enables availability and accessibility at reasonable cost to the people in the Developing World.

• Include in Grant:

The Licensee agrees to commercialize the Technology and any Products in a manner consistent with the Global Access Policy. Without limiting the generality of the foregoing, the Licensee

agrees to require all sublicensees and other parties involved in any aspect of the commercialization of the Technology and any Products to execute agreements that bind such sublicensees or other parties (to the extent that they by agreement or operation of law obtain any rights in or to the Technology and any Products) to comply with the Global Access Policy.

The Licensee acknowledges and agrees that: the rights granted to the Licensee under this Agreement shall at all times be subject to a reservation by University of a transferable, irrevocable, perpetual, non-exclusive, royalty-free right to use and sublicense the Technology and to manufacture, have made, distribute, and sell the Products for the benefit of the Developing World. Exercise of this right will be at University's sole discretion, which University does not intend to exercise unless University determines that the Licensee is taking inadequate steps toward making the Technology or any Products available to the Developing World in a manner consistent with the Global Access Policy.

The University of California Davis is also experimenting with this approach and goes further by requiring the primary licensee to give away or sell the product at their cost of production. They would also require any licensee granted a "march-in" license not to sell products in developed countries.

Implementation:

• Include in "Definitions" section:

"Humanitarian Purposes" means (a) the use of Licensed Products covered under Compound Patent Rights ("Compound Products") for research and development purposes by any organization or other third party, anywhere in the world, that has the express purpose of developing the Compound Products for use in an Economically Disadvantaged Country, and (b) the use of the Compound Products by any organization or other third party for Commercial Purposes in an Economically Disadvantaged Country.

"Commercial Purposes" means to make, have made, use, have used, import, or export a product, good, method, or service for the purpose of selling or offering to sell such product, good, method, or service.

• Include in "Grant" section:

In any license to the Licensee, Licensee's commercial use of the Compound Patent Rights to make, use, sell, offer for sale and import Compound Products in EDCs will be royalty free and the Licensee will be required to give away the Compound Products for free or at cost.

Notwithstanding other provision of rights granted under this Agreement, the University hereby reserves the right to license the Compound Patent Rights to any third parties solely for Humanitarian Purposes. Such licenses for Humanitarian Purposes will expressly exclude the right of the third party licensee to export or sell the Compound Products from an EDC into a market outside of the EDC where Licensee has introduced or will introduce a Compound Product and where Patent Rights exist. In any such license, the third party licensee's commercial use of the Compound Patent Rights to make, use, sell, offer for sale and import Compound Products in EDCs will be royalty-free and the third party licensee will be required to give away the Compound Products at no charge or at cost. For avoidance of doubt, the third party licensee may be permitted to export Compound Products from the EDC of origin to other EDCs and all other countries mutually agreed to by the University and Licensee.

Framework 4: Create Competitive Sources in Developing Countries

Approach 4.1: Separate Licenses

This approach excludes developing countries from the license, allowing the University to license the technology non-exclusively in Developing Countries. The National Institutes of Health is using this approach.[22]

Implementation

• Include in Definitions:

Territory shall exclude Developing Countries.

Approach 4.2: Grant only Non-Exclusive Rights in Developing Countries

This approach reserves a non-exclusive right in the invention for use to develop products for developing countries, allowing the University to issue additional licenses in those countries. Public Intellectual Property Resource for Agriculture (PIPRA) is experimenting with this approach in licensing agricultural inventions and germplasm.

Implementation:

• Include in "Definitions" section:

"Humanitarian Purposes" means (a) the use of Invention/Germplasm for research and development purposes by any not-for-profit organization

22. Mark Rohrbaugh, Personal communication.

anywhere in the World that has the express purpose of developing plant materials and varieties for use in a Developing Country, and (b) the use of Invention/Germplasm for Commercial Purposes, including the use and production of Germplasm, seed, propagation materials and crops for human or animal consumption, in a Developing Country.

"Commercial Purposes" means to make, have made, propagate, have propagated, use, have used, import, or export a product, good or service for the purpose of selling or offering to sell such product, good or service.

• Include in "Grant" section:

Reservation of rights. Notwithstanding any other provision of rights granted under this agreement, University hereby reserves an irrevocable, non-exclusive right in the Invention/Germplasm for Humanitarian Purposes. Such Humanitarian Purposes shall expressly exclude the right for the not-for-profit organization and/or the Developing Country, or any individual or organization therein, to export or sell the Germplasm, seed, propagation materials or crops from the Developing Country into a market outside of the Developing Country where a commercial licensee has introduced or will introduce a product embodying the Invention/Germplasm. For avoidance of doubt, not-for-profit organization and/or the Developing Country, or any individual or organization therein, may export the Germplasm, seed, propagation materials or crops from the Developing Country of origin to other Developing Countries and all other countries mutually agreed to by Licensor and Licensee.

Approach 4.3: Don't Allow Licensee to Patent in Developing Countries

This approach requires the Licensee not to patent in developing countries, therefore permitting generic manufacturers and not-for-profit organizations freedom to operate in those developing countries. We did not identify examples of this approach being used.

Implementation

• Include in Patent Rights

The University and Licensee on behalf of themselves and any successors-in-interest to the Intellectual Property covenant that they have not previously, are not currently and will not after the date of this agreement, obtain Patent Rights in Developing Countries.

Approach 4.4: Mandatory Sublicensing with Reservation of a March-In Right

This approach is being used by the University of California, Berkeley which first developed the approach in 1998 in response to the report of a working group on the licensing of research tools convened by Harold Varmus, the then Director of the National Institutes of Health, which encouraged universities generally to reduce their use of exclusive licensing. Berkeley adopted the following as a balance between their need to grant exclusivity to allow licensees to justify investing in developing early stage technologies and the need to ensure that technologies that were exclusively licensed are fully developed:[23]

"If REGENTS or a third party discovers that the INVENTION is useful for an application covered by the LICENSED FIELD OF USE but for which LICENSED PRODUCTS have not been developed or are not currently under development by LICENSEE, then the REGENTS, as represented by the Office of Technology Licensing, shall give written notice to the LICENSEE.

Within ninety (90) days following LICENSEE's receipt of REGENTS' notification LICENSEE shall give REGENTS written notice stating whether LICENSEE elects to develop LICENSED PRODUCTS for the application.

If LICENSEE elects to develop and commercialize the proposed LICENSED PRODUCTS for the new application, LICENSEE shall submit a progress report describing LICENSEE's commercialization efforts in developing the new application every six months to REGENTS pursuant to Article xx herein.

If LICENSEE elects not to develop and commercialize the proposed LICENSED PRODUCTS for use in the new application, REGENTS may seek (a) third party(ies) to develop and commercialize the proposed LICENSED PRODUCTS for the new application. If REGENTS identifies a third party, it shall refer such third party to LICENSEE. If the third party requests a sublicense under this Agreement, then the LICENSEE shall report the request to REGENTS within thirty (30) days from the date of such written request.

If the LICENSEE refuses to grant a sublicense to the third party, then within thirty (30) days after such refusal the LICENSEE shall submit to REGENTS a report specifying the license terms proposed by the third party and a written justification for the LICENSEE's refusal to grant the proposed

23. Carol Mimura, Personal communication.

sublicense. If REGENTS, at its sole discretion, determines that the terms of the sublicense proposed by the third party are reasonable under the totality of the circumstances, taking into account LICENSEE's LICENSED PRODUCTS in development, then REGENTS shall have the right to grant to the third party a license to make, have made, use, sell, offer for sale and import LICENSED PRODUCTS for use in the LICENSED FIELD-OF-USE at substantially the same terms last proposed to LICENSEE by the third party providing royalty rates are at least equal to those paid by LICENSEE.

This approach is included in the "Nine Points to Consider" document referenced above.

Berkeley has included the provision in most of its exclusive licenses and option agreements starting in 1997, and has executed over 25 licenses containing it, including four with large companies (one negotiated directly, one due to a large company acquisition of a startup and assignment of the license to the acquirer, while another was due to a sublicense by a licensee to a large entity).[24] Berkeley's experience has been that companies find the provision acceptable, rather than being punitive, because it is tantamount to free market research, since they get first shot at fulfilling the newly identified opportunity. That said, the details frequently change during the course of negotiations. The provision has been invoked at least twice. The resolution in each case was that, rather than the licensee issuing a sublicense, they elected to renegotiate the license to a narrower field of use. In one of the two cases, Berkeley issued a new license to the second company, so clearly, the mechanism is both acceptable to licensees and effective.[25]

MIT has also used this approach, particularly in exclusive licenses to start-ups, for a number of years. MIT reports that licensees have found the measure acceptable because they get the first opportunity to develop the newly identified opportunity. Like Berkeley, MIT has had to implement the process on more than one occasion and the outcome has typically been a narrowing of the field of use.

Berkeley as well as MIT and the University of Vermont apply the approach to socially responsible licensing, defining a "Charitable Objective" as being the availability of the product in developing countries at low cost and requires the licensee to issue sublicenses to additional parties that request licenses for developing countries, with the University reserving the right to issue a license itself directly if the licensee does not respond to the request promptly.

Implementation:

- Include in "Definitions":

"Charitable Objective" shall mean the availability of the Licensed Products in developing countries at affordable prices.

- Include in "Grant" section:

If Licensee elects not to develop and commercialize the proposed Licensed Products for the Charitable Objective, University may seek one or more third parties to develop and commercialize the proposed Licensed Products for the Charitable Objective. If University identifies a third party, it shall refer such third party to Licensee. If the third party requests a sublicense under this Agreement, then the Licensee shall report the request to University within thirty (30) days from the date of such written request. If the request results in a sublicense, then Licensee shall report it to University.

If the Licensee refuses to grant a sublicense to the third party, then within thirty (30) days after such refusal the Licensee shall submit to University a report specifying the license terms proposed by the third party and a written justification for the Licensee's refusal to grant the proposed sublicense. If University, at its sole discretion, determines that the terms of the sublicense proposed by the third party are reasonable under the totality of the circumstances, taking into account Licensee's Licensed Products in development, then University shall have the right to grant to the third party a license to make, have made, use, sell, offer for sale and import Licensed Products for use in the Licensed Field-of-Use at substantially the same terms last proposed to Licensee by the third party providing royalty rates are at least equal to those paid by Licensee.

Approach 4.5: Non-Assert Approach

This approach requires the primary licensee to agree not to assert the licensed patents against third party manufacturers and sellers in developing countries. It therefore allows for generic competition in developing countries.

The approach protects against parallel imports by requiring a distinctive trade dress for products for which the non-assert is invoked, and it allows for commercial markets within developing countries by limiting the non-assert to sales to public agencies, broadly defined.

24. *ibid.*
25. *ibid.*

Boston University is experimenting with this approach.

Implementation:

- Include in "Grant" section:

Non-suit: University and Licensee on behalf of themselves and any successors-in-interest to the Intellectual Property covenant that they will not, before or after the date of this Agreement, assert any claim of patent infringement (including direct infringement, contributory infringement, and inducing infringement) under the Intellectual Property for manufacture, use, sale, offer for sale or importation of Product against any third party engaged in the manufacture, use, sale offer for sale, or importation of Licensed Product, in, or into, Non-Suit countries for sale to Public Sector Entities.

This non-suit provision shall only apply to Products which are in a physical form when offered for sale to end users in a Trade Dress that is different from Licensee's Trade Dress in every respect and which Products have gained regulatory approval from either the U.S. Food and Drug Administration (FDA), the European Agency for the Evaluation of Medicinal Products (EMEA) or have been pre-qualified by the World Health Organization pre-qualification scheme.

XII. The Pharmaceutical Industry is Starting to Move in this Direction by Itself

It is not the purpose of this article to document the humanitarian activities of the pharmaceutical industry. However, in proposing this model to universities, we are encouraged by signs that the pharmaceutical and biotechnology industries are already moving in this direction.

Glaxo has implemented a Voluntary Licensing program which enables local manufacturers to produce and sell generic versions of some of its products. Since October 2001, Glaxo has signed seven licensing agreements for antiretrovirals in Kenya and South Africa, the first of which was granted to Aspen Pharmacare in October 2001. Some cover just parts of Africa and others all of sub-Saharan Africa.[26]

Voluntary Licenses allow the holder to produce fixed dose combinations and to use the U.S. Food and Drug Administration's fast track approval process for anti-retrovirals to accelerate the availability of generic anti-retrovirals for PEPFAR (U.S. President's Emergency Plan for AIDS Relief) program.

Gilead, the world's second or third largest biotechnology company by market capitalization, has also voluntarily adopted this strategy. Gilead sells four HIV/AIDS drugs—Viread® as well as Emtriva®, together with Truvada® and Atripla® which are combinations of these drugs—and so has been on the front line of the debate over global access. In a talk at the Infectious Diseases Society of America meeting in October 2007 and an interview afterwards, Gilead's CEO, John Martin talked about Gilead's strategy in the developing world.[27] Martin said:

"Gilead's access programs provide HIV drugs free of charge to poor patients or those without insurance in the United States and have traditionally offered no-profit pricing in under-developed countries. It has done so at a loss.

It's not something we've debated. It just is something we had to do.

We are disappointed that dominant Gilead HIV products in the United States and Europe don't have greater market share in the no-profit market. So Gilead has tweaked its global access program over the past year, allowing several drug makers in India to produce generic versions of Gilead drugs and market them in 95 countries.

Those companies can charge more than Gilead was charging for the drugs, but the profit motive actually could drive greater access.

Gilead will receive a royalty on those drug sales."

Eli Lilly which, as part of a $70 million worldwide partnership to treat multi-drug resistant tuberculosis ("MDR-TB"), is transferring manufacturing technology and expertise for both of its antibiotics that are effective against MDR-TB:

- cycloserine and
- capreomycin

to four pharmaceutical companies in countries with the highest MDR-TB burdens:

- Aspen Pharmacare in South Africa,
- Hisun Pharmaceutical in China,
- Shasun Chemicals and Drugs in India, and
- SIA International in Russia.

The final example of dual markets in action we will cite was described by Bill Gates in his talk on "Creative Capitalism" at the 2008 Davos World Economic Forum:

26. *http://www.gsk.com/responsibility/cr_report_2005/access-to-medicines/dc-voluntary-licensing.htm.*

27. "Gilead taking a global view," *San Francisco Business Times*, Ron Leuty Friday, October 19, 2007.

> "In another case, a Dutch company, which holds the rights to a cholera vaccine, retains the rights in the developed world, but shares those rights with manufacturers in developing countries. The result is a cholera vaccine made in Vietnam that costs less than $1 a dose—and that includes delivery and the costs of an immunization campaign. There are a number of industries that can take advantage of this kind of tiered pricing to offer valuable medicine and technology to low-income people."

Gates was referencing the cholera vaccine Dukoral® developed at the University of Gothenberg by Professor Jan Holmgren. In Sweden, professors own their own inventions and Holmgren assigned the patents to the cholera toxin subunit B technology which underlies Dukoral® to Vitech AB,[28] a company he wholly owned. Vitec licensed the technology to a Swedish vaccine start-up called SBL Vaccin, which developed it for developed countries and sells it for around $10/dose. SBL was acquired by another Swedish company, Active Biotech, and was later acquired by Powderject and finally by Crucell in Holland in November 2006.

The University of Gothenberg licensed the technology to a Vietnamese company in the 1980's,[29,30] which developed a formulation suited to developing country needs. The cost of production was 20¢/dose. The International Vaccine Initiative has worked with Vietnam on quality control and on transferring the technology to other producers in India and Indonesia.

XIII. Universities Allied for Essential Medicines and the Equitable Access License

Universities Allied for Essential Medicines ("UAEM") is a student organization that evolved from the work of Amy Kapczynski at Yale.[31] It has chapters at an increasing number of institutions and tends to bridge law schools, medical schools and schools of public health.

UAEM is a highly effective organization. It is sufficiently well funded that two of its members take a year off from their studies to devote their full time efforts to the organization's objectives. UAEM organized a conference in November 2006 in Philadelphia to address global health issues and created a statement called the Philadelphia Consensus Statement[32] addressing the issue of universities and the contributions they can make to global health. A substantial number of distinguished academics, including a number of Nobel Prize winners have signed it.[33]

An independent working group based at Yale University convened by UAEM developed a form of license agreement, Equitable Access License ("EAL"),[34] as a mechanism to implement global health safeguards. The full text of the EAL forms Appendix 1 to this article.

The licensing paradigm for the EAL is a (a) a reservation of humanitarian rights in the intellectual property included in the license and (b) a mandatory grantback of all improvements made by the primary licensee to the academic institution, which can then license the complete package of intellectual property non-exclusively to third parties who wished to make and sell the products in developing countries. The university would charge a 2 percent royalty for sales in Low Income Countries or 5 percent for sales in Middle Income Countries (using the World Bank's definitions), which would be split with the primary licensee.

The major advantage of the EAL is that it explicitly addresses and solves the problem of follow-on Licensee-developed patents discussed in Section IX.A above.

The drawback of the EAL is that pharmaceutical companies with whom we have discussed this approach have told us they would not license academic inventions if the license agreement contained these provisions. This reaction is not surprising—it is a universal experience of academic licensing negotiations that licensees strongly resist grantbacks of the developments they make to the licensed intellectual property even for non-commercial research purposes, so they are even less likely to be receptive to it for commercial purposes. We have suggested an approach in Section IX.A above that may address this use in a more acceptable manner.

28. Press Release 06/29/98, "Active Biotech steps up efforts in ETEC and cholera vaccine through acquisition of VITEC," accessed through *www.rDNA.com* 2/24/08.

29. *http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6TD4-4M0S21X-2&_user=489277&_rdoc=1&_fmt=&_orig=search&_sort=d&view=c&_acct=C000022679&_version=1&_urlVersion=0&_userid=489277&md5=1a4edcab021bc8e68f8b805bf7f3d6cf,* accessed 2/24/08.

30. *http://www.ivi.org/program/tr_chovi_program.html* accessed 2/24/08.

31. *http://www.essentialmedicine.org/.*

32. *http://www.essentialmedicine.org/cs/?page_id=3.*

33. *http://www.essentialmedicine.org/cs/?page_id=4.*

34. *http://www.essentialmedicine.org/EAL.pdf.*

It is also extremely burdensome on academic licensing offices, who are not equipped to manage the flow of information that would result from the grantback provision.

UAEM has frequently reiterated that it is not wedded to the EAL as a mechanism for implementing generic competition,[35] but offers it as one model. In the absence of other models, such as we have presented herein, it is certainly the most widely disseminated approach.

XIV. The Risks of Inaction—Legislation

A. The Federal Level—S.4040

On September 29, 2006, the "Public Research in the Public Interest Act" (S.4040) was referred to the Senate Judiciary Committee by its Chairman, Senator Patrick Leahy (D., VT). The bill proposed that life-saving medications resulting from publicly-fund research be made available in certain developing countries at the lowest possible cost.

The bill would amount to a substantial amendment of Bayh-Dole. Additional obligations would be attached to "Subject Inventions," which are defined in the same way as in Bayh-Dole. The Bill includes, verbatim, the licensing construct of the Equitable Access License, so this construct would be imposed on academic institutions as a matter of law. As we noted above, this would make it harder, if not impossible, to license academic healthcare inventions in the first place, and so we believe would be counterproductive.

B. The State Level

On January 28, 2008, at the request of a University of Vermont Medical School student, Representative Ann Pugh, of S. Burlington, VT introduced a bill into the Vermont House of Representatives titled: "The Vermont Public Research in the Public Interest Act of 2008." The licensing paradigms and structure of the bill are very similar to those of S.4040, and our concerns are similar.

While Vermont does not provide substantial funding for scientific research, states such as California, Massachusetts, New Jersey, New York and Texas have announced initiatives to invest almost $8 billion in life sciences research over the next ten years. It would have a significant impact if these license provisions were required to be attached to licenses to any resulting intellectual property.

XV. Will Incorporating Global Social Responsibility in License Agreements Diminish the Value of Academic Technologies?

The ultimate question that could slow adoption of global social responsibility safeguards in academic licenses is whether it will diminish their value.

We believe not, because the developing world will not be a significant market for newly developed drugs at Western prices; but only time can answer this question. However, a clue may be provided by looking at the experiences of Gilead

As we discuss in Section XII above, Gilead chose to do voluntarily what the licensing paradigms described in this paper will enable generally. During this time, Gilead's stock price continued to climb (see Figure 1), indicating that any loss of market share in the developing world didn't diminish the company's value.

We believe that academic institutions, which are charitable organizations with a public service mission, should give even less weight to hypothetical financial concerns than publicly traded companies

Figure 1: Gilead Five Year Stock Price History

35. See, for example, "Universities Have a Key Role in Global Access to Medicines," by Rajesh Panjabi, Rahul Rajkumar, and Jim Yong Kim, *Point Of View, Chronicle of Higher Education*, February 22, 2008, *http://chronicle.com/weekly/v54/i24/24a03201.htm.*

who have a fiduciary responsibility to maximize shareholder value.

XVI. Conclusion

We believe the conclusions are clear—Universities should act and should be seen to be acting to ensure that their innovations reach the developing world affordable and expeditiously before either the federal government or state legislatures act for them. We hope that this article has shown that it is straightforward contractually to do so, so that the issue will devolve to a business negotiation. Academic licensing officers have consistently shown ingenuity, resiliency and creativity in their business negotiations, and we are confident that academic institutions will increasingly not only incorporate one of these licensing approaches into their standard license agreements, but will make it a formal policy of their institution to use licensing to promote global social responsibility.

Appendix 1

Model Provisions For An "Equitable Access And Neglected Disease License"

1. *Definitions*

a. "Licensed Technology" means the rights licensed by the University to the Licensee pursuant to [Main Agreement].

b. "Associated Licensee Rights" means all rights in data, information, know-how, methods, procedures and processes, including patent and marketing rights, possessed by Licensee during the term of this Agreement that are necessary to make, use, sell, offer to sell, import or export an End Product or to perform Neglected Research, including but not limited to biological, chemical, biochemical, toxicological, pharmacological, metabolic, formulation, clinical, analytical and stability information and data.

c. "Associated Notifier Rights" means all rights in data, information, know-how, methods, procedures and processes, including patent and marketing rights, possessed by a Notifier during the term of the Open License granted to such Notifier that are necessary to make, use, sell, offer to sell, import or export an End Product or to perform Neglected Research, including but not limited to biological, chemical, biochemical, toxicological, pharmacological, metabolic, formulation, clinical, analytical and stability information and data.

d. "Eligible Country" means any country classified by the World Bank as "Low-income" or "Middle-income" at the time a Notification is made.

e. "End Product" means any product whose manufacture or use relies upon or is covered by the Licensed Technology.

f. "Fair Royalty" means:

i. For countries classified by the World Bank as "Low-income" at the time of the sales on which royalties are due, 2 percent of Notifier's Net Sales of End Products in the Notified Country of Net Sales;

ii. For countries classified by the World Bank as "Middle-income" at the time of the sales on which royalties are due, 5 percent of Notifier's the Net Sales of the End Products by the Notifier in the Notified Country in question.

g. "Licensed Technology" means the rights licensed by University to the Licensee pursuant to [Main Agreement].

h. "Neglected Disease" means any disease, condition, or affliction that, at the time Notification under Section 3.a. is made, either affects less than 200,000 persons in the United States or for which there is no reasonable expectation that the cost of developing and making available in the United States a treatment, prophylaxis, or device for such disease, condition, or affliction can be recovered from sales in the United States of such treatment, prophylaxis, or device.

i. "Neglected Research" means any use of the Licensed Technology or Associated Licensee Rights in an effort to develop treatments, prophylaxis, or devices for a Neglected Disease.

j. "Notification" means a writing that announces the intention of a party to receive an Open License.

k. "Notification Fee" means:

i. For Notification to receive an Open License to supply End Products to an Eligible Country that is classified by the World Bank as "Low-income" at the time of Notification, $5,000;

ii. For Notification to receive an Open License to supply End Products to an Eligible Country that is classified by the World Bank as "Middle-income" at the time of Notification, $50,000;

iii. For Notification to receive an Open License to perform Neglected Research, $500.

l. "Notified Country" means an Eligible Country indicated by a Notifier in a Notification.

m. "Notifier" means a party that has submitted a Notification to the University and Licensee[along with an appropriate Notification Fee]. [University or

Licensee acceptance of the Notification and Notification Fee are not required for a party to be a Notifier or for a Notifier to receive an Open License.]

n. "Open License" means a non-exclusive license to the Licensed Technology, Associated Licensee Rights, and Associated Notifier Rights granted by the University to a Notifier from University upon Notification. There are no limitations on the number of Open Licenses that may be received or the parties whom may receive an Open License.

2. *Licensee Grant*

Licensee hereby grants University a license to the Associated Licensee Rights for the sole purpose of granting Open Licenses either to Supply in accordance with Section 3.a. or for Neglected Research in accordance with Section 4.a.. [The licensee also agrees to include, in any patent application for a Licensee Improvement, a sentence reading: "This patent is subject to the provisions of the Equitable Access and Neglected Disease License."]

3. *Notification to Supply*

a. Grant of Open License to Supply: Upon providing to University and Licensee Notification to receive an Open License to supply End Products to an Eligible Country, a Notifier automatically receives an Open License from the University permitting the making, using, selling, offering to sell, importing, and exporting of End Products in the Notified Country and the making and exporting of End Products in any country other than the Notified Country for the sole purpose of supplying End Products to the Notified Country. If Notifier exercises its right to make and export an End Product in any country other than a Notified Country for the sole purpose of export to a Notified Country, then Notifier shall use reasonable efforts to visibly distinguish the End Product it manufactures from the End Product sold distributed by the Licensee in the country of manufacture, but such reasonable efforts do not require Notifier to expend significant expense.

b. Fair Royalties: The Open License to supply End Products received by Notifier shall be irrevocable and perpetual so long as Notifier submits to University and Licensee payment of a Fair Royalty on sales of End Products covered by the Licensed Technology or Associated Licensee Rights within 90 days of such sales, such Fair Royalty to be divided equally between University and Licensee. [Failure or refusal of University or Licensee to accept the Fair Royalty shall not terminate or affect in any way the Open License.]

c. Notifier Grant: In exchange for receipt of an Open License to Supply, Notifier grants University a license to its Associated Notifier Rights for the sole purpose of granting Open Licenses either to Supply in accordance with Section 3.a. or for Neglected Research in accordance with Section 4.a.

4. *Notification for Neglected Research*

a. Grant of Open License for Neglected Research: Upon providing to University and Licensee Notification to receive an Open License to perform Neglected Research, a Notifier automatically receives a worldwide, irrevocable, and perpetual Open License from the University to perform Neglected Research.

b. No Royalty: No royalty shall be payable to either the University or the Licensee for the Open License for Neglected Research.

c. Notifier Grant: In exchange for receipt of an Open License for Neglected Research, Notifier grants University a license to its Associated Notifier Rights for the sole purpose of granting Open Licenses either to Supply in accordance with Section 3.a. or for Neglected Research in accordance with Section 4.a.

5. *Assurance of Freedom to Operate*

No license or other transfer of the Licensed Technology or Associated Licensee Rights by the University or Licensee shall be valid unless the terms of this Equitable Access and Neglected Disease License are incorporated therein.

6. *Transparency*

Notwithstanding any other agreement or provision between the parties, either party may publicize the fact that the Licensed Technology and Associated Licensee Rights are subject to a license that includes this Equitable Access License. ■