



Submission to the Technology Transfer Advisory Committee**Global Access License Policy for Future UC Licenses****February 2009****Will the UC lose royalty revenue from a Global Access License (“GAL”)?**

Pharmaceutical sales, and therefore royalties, are unlikely to be impacted by a Global Access License, because the GAL is only relevant to Low and Middle-Income (LMI) countries where pharmaceutical companies sell nearly nothing. Consumers in the US, EU, and Japan comprise 93.2% of all pharmaceutical revenues.¹ While countries where a GAL would facilitate access have few consumers, they contain the world’s vast majority of patients; patients here are simply too impoverished to afford treatment. Mozambique, for instance, is home to at least 1,500,000 HIV positive persons², yet per capita GNI is \$320.³ Despite Poverty Reduction Strategies and Millennium Development Goal efforts and given the degree of their impoverishment, Mozambicans will clearly not become actual consumers in the near or medium term. Indeed it is doubtful whether poverty can be overcome without access to improved health care.⁴ The only royalty revenue that could come from treating these persons with pharmaceuticals will originate in multilateral funding agencies – the Global Fund, UNITAID, the Gates Foundation, etc – whose impact depends largely upon their ability to negotiate prices at or near cost.

Because there is no effective market in Mozambique, there exist no revenue streams for a GAL to potentially disrupt. As much was reiterated by Yale’s Dean of Public Health Michael Merson after Yale dropped its demand for stavudine royalties: “[t]his change was made at Yale without any negative consequences for the University – financial or otherwise.”⁵

Because of the economic crisis and endowment and budget declines, universities simply cannot prioritize global health.

Because revenue streams from licensing agreements would not be impacted by a GAL – US consumers spend twenty times more on pharmaceuticals than the United Republic of Tanzania’s entire gross domestic product – we reiterate that current financial challenges are unlikely to be impacted by the provision of a generic anti-retroviral in Honduras or Tanzania. While UAEM is aware that budgets are tighter than ever, the need and opportunity for our universities to improve access to treatment for the world’s poor has never been greater. Moreover, should incorporation of a GAL into all technology transfer agreements be postponed until California’s financial crises desist, we would argue that this is essentially a postponement ad infinitum.

Current financial challenges are, of course, not limited to universities. Especially in moments of economic contraction, a reduction in pharmaceutical expenses becomes even more important to patients dependent on donor and multilateral funders.

Will the University of California license fewer things?

The University of California is the country’s most successful licensor of technologies, precisely because it is a powerhouse of innovation. Nothing in the GAL affects this stellar record nor the likelihood of continued successes. The GAL, rather, is crucial for the UC because the UC will continue to license earth-moving technologies, and bringing the UC’s best to the world is unlikely without a GAL. We also note that universities carry out more than half of the basic research in the US, and more than 1/6 total R&D

¹ “The Pharm. Industry in Figures.” Euro Fed of Pharm. Ind. and Assoc. 2008 edition. p. 5.

² UNAIDS 2008.

³ World Bank 2008.

⁴ Sachs, J, and Palaney, P. “The Economic and Social Costs of Malaria.” *Nature*. Vol. 415. 7 February 2002. pp 680-85; and, Report of the Commission for Macroeconomics and Health, World Health Organization. Geneva: 2001.

⁵ Kapczynski et al. “Addressing Global Health Inequities.” 20 *Berk. Tech. L. J* 1031, 1089 (2005).



domestically.⁶ “At least a third of drugs marketed by the major drug companies are now licensed from universities or small biotech companies, and these tend to be the most innovative.”⁷ Looking farther back, 15 of the “most important” drugs sold between 1965 and 1992 “were developed using knowledge and techniques from federally funded research.”⁸

We are mindful, however, that technology transfer officers work in a buyer’s market, and that a GAL could be seen as a tax on all UC-licensed property. These concerns, however, are not supported by any biotech revenue data available to UAEM. Because >93% of revenues originate in countries ineligible for GAL-provision, and the essential pharmaceuticals in question overwhelmingly treat impoverished patients, GAL-imposed burdens are unlikely to materialize. We applaud the researchers whose tireless work produces essential medicines – it’s our common desire to see their innovations in universal action that motivates a GAL.

One cause for encouragement is the funding experience of the University of British Columbia in the year following the formal adoption of its Global Access Principles⁹ in September 2007. Funding for Sponsored Research from all sources, including government, non-profit, *as well as industry*, was stable or increased from the period 2006-2007 to 2007-2008¹⁰.

Does the University have the bargaining power to do this? Won't pharmaceutical companies just avoid the UC?

The University of California is world's second-most-prolific innovator. It is America's most prolific innovator.¹¹ Second only to the Japan Science and Technology Agency in aggregate patents issued, the University of California ranks first in biotech patents issued. The report “echoes the 2006 study from the Milken Institute, an independent think tank, which also found that the University of California system averaged the highest level of licensing income annually from its research discoveries in biotechnology.”¹² In addition, the combined University of California receives almost 10% of all NIH medical funding – multiples more than the next most awarded institution (Johns Hopkins).

Were a firm to avoid UC innovations, that company would abandon the most successful licensor of technologies in the country. As UCSF's media relations office acknowledges, the UC is the country's most successful technology transfer organization, generating over \$100,000,000 yearly for all technologies (*ibid*). Because the GAL does not affect the markets constituting over 93% of the pharmaceutical industry’s revenue sources, (for example, while there is a patient population in Mali, they do not constitute a market with an ability to pay), the prospects of pharmaceutical recrimination are vanishingly few. Moreover, there is abundant interest within industry to pursue some level of these policies: Gilead has already signed generic licenses for its enormously popularly – and lucrative – ARV tenofovir (Viread)¹³, and Gilead, Johnson & Johnson and Tibotec are all participating in patent pool discussions with UAEM and UNITAID.

⁶ Nat'l. Sci. Bd. Sci. and Eng. Indicators 2004, at 5-5, 5-8; Mowery et al. “Growth of Patenting and Licensing by US Univ.” 30 *Res. Policy* 99, 101 (2001)

⁷ Angel, Marcia. “The Truth About the Drug Companies. *NY Review of Books*. Vol. 51. No. 12, p. 4, citing *An Industry in Evolution*, 3rd ed., Mary Jo Lamberti, ed. CenterWatch, 2001. p. 22.

⁸ Congressional Joint Economic Committee [Senator Connie Mack, chair]. “The benefits of medical research and the role of the NIH.” May 2000. available online at http://opa.faseb.org/pdf/2008/nih_research_benefits.pdf.

⁹ In which UBC commits to implement Global Access Licensing whenever possible: www.uilo.ubc.ca/global.asp

¹⁰ UBC University-Industry Liaison Office 2007/08 Annual Report (p.4): www.uilo.ubc.ca/pdf/UILO_AR_2008.pdf

¹¹ “Biotechnology Report 2007.” Marks and Clerk. 2007. London.

¹² “Universities, not Companies, Drive Biotech Advancement.”

<http://pub.ucsf.edu/today/cache/news/200705084.html>

¹³ “Gilead Announces Licensing Agreements.” Sept 22, 2006. http://www.gilead.com/pr_908393



Isn't this a problem for Congress?

UAEM continues to work lobby the Congress to revise the Bayh-Dole Act¹⁴. Revising Bayh-Dole, though important, will not revise local technology transfer policies. Our policies are not federally mandated – they are our own. The methods with which the University of California shares its advancements with Californians, Americans, and the rest of the world are our responsibility. These are our labs. These are our PIs. These are our creations, and we are proud of them. The University of California is an entirely unique institution, the effects of which are felt globally. Moreover, the UC has been ahead of the curve since its creation – we don't need Washington to lead us.

Particularly to UC – we've been leading HIV research and therapy since 1981, when a UCLA physician identified six men with AIDS, since UCSF pioneered care for HIV persons, since the entire system outpaced the Reagan Administration to fund HIV-AIDS research in the 1980s. It's in part this innovation and initiative that has resulted in over 25% of anti-retrovirals originating on university campuses.¹⁵

What about parallel importation?

Parallel importation involves low-priced generics finding their way into the black market in developed countries. New regulatory barriers and customs regulations have minimized this threat. In addition, this concern finds little empirical support, and can be addressed in the same manner that the WTO has elected to treat the issue: requiring the use of different packaging, pill color, and shape in different countries to facilitate identification of illegal (re)importations.¹⁶ Chris Viehbacher, Glaxo president of pharmaceuticals for Europe, said Glaxo "is seriously concerned" about the illegal shipments, "but is this going to shake our commitment to the program? Not at this time. The human need is too big."¹⁷

Diversion from poor countries is rarely observed. Generic drugs have been produced in India for decades without resulting in the infiltration of or undermining of Western markets.¹⁸ Likewise, "there is no empirical evidence of any substantial flows of medicines from LMI to rich countries."¹⁹ Insofar as diversion is a concern, it can be addressed in the same manner that the WTO has—by requiring use of different packaging, pill color, and pill shape in different countries to facilitate the identification of illegal imports.²⁰

Why not let our licensees determine global policies?

Two reasons: economics and history.

Bulk essential pharmaceuticals are most cheaply produced by generic manufactures in India. If you've taken acyclovir, your wallet knows this. Moreover, they are best administered and distributed by groups like Doctors Without Borders, the WHO, Gates Foundation, and similar international providers that specialize in therapy provisions in resource-constricted settings. The pharmaceutical firms that license university-IP are also talented – but in an entirely different niche. The production, marketing, and distribution of novel therapies in highly-developed countries have been perfected by the US pharmaceutical industry. But they are

¹⁴ 35 USC §200-12 (2000).

¹⁵ Sampat, Bhaven. "Academic Patents and Access to Medicines in Developing Countries." *American Journal of Public Health*. January 2009, Vol. 99, No. 1. p. 15.

¹⁶ "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", World Trade Organization 2003."

¹⁷ *Washington Post*, 10-03-02.

¹⁸ Presentation at the Earth Institute, Columbia University, by Andrew Farlow, Oxford University: 'Costs of Monopoly Pricing Under Patent Protection. December 4, 2003.

¹⁹ Kapczynski et al, p. 1078. See also Outterson, Kevin. "Pharm. Arbitrage: Balancing Access and Innovation in Int'l Prescription Drug Markets." *Yale Journal of Health Policy, Law, and Ethics*. Vol 5. Issue 1. January 2005.

²⁰ "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health." World Trade Organization 2003.



not design, and nor are they equipped, to provide the quantities of essential medicines at generic rates, the foundation of effective therapy scale-ups.

Bristol-Myers Squibb's history in Thailand explains the second answer – the company licensed a compound (didanosine) from the Department of Health and Human Services, added an antacid to improve effectiveness, and applied for exclusive rights of sale across the globe. When the company became dissatisfied with its original filing in Thailand, it sought to expand its patent, and prevent generic competitors from pursuing the businesses Bristol had itself declined to pursue, as per its patent prosecution. Nearly a decade of litigation later, Bristol returned the patent to Thailand – which was unable to produce didanosine for years because of the pending litigation. Bristol still refuses any differential pricing policies for its pediatric formulation,²¹ and refuses pricing differentials for Bolivia, El Salvador, and other countries whose patients it does not consider poor enough. This, we add, is with a compound developed at the National Cancer Institute with taxpayer dollars, and still it remains unavailable in countries where per capita incomes barely crest \$1/day. With domestic patents already expired for didanosine, BMS continues to seek rents for the NCI's innovation (in LMI countries) – with appalling consequences.

Highly relevant is the fact that the DHHS' initial license to BMS required a “reasonable relationship between licensee’s pricing of licensed product and the health and safety needs of the public and that this relationship be supported by evidence.”²² The need for revisions to existing licensing arrangements is made clear when highly profitable pharmaceutical firms take major steps to prevent severely impoverished nations from importing reduced-cost ARVs, as GlaxoSmithKline attempted to do in Uganda and Ghana.²³ We strongly believe that a GAL is the most practical and effective means to bring about a solution to the global access to medicines crisis, and that it must be initiated at the university level where many medical innovations begin.

Don't donation programs satisfy these needs?

Existing donation programs also regularly fail to meet demand, and include discarded pharmaceuticals. This represents an obscene reduction in the standard of care. In 1991, Pharmaciens Sans Frontieres found that it had to burn 80% of the donations it received.²⁴ Another analysis of pharmaceuticals donated to Bosnia and Herzegovina observed that up to 60% of all donated medical supplies were “inappropriate” and had to be burned at a cost of \$2,000 per metric ton (paid by aid organizations).²⁵

What about middle income countries, and developing markets?

Middle-income countries are usually characterized by extreme economic inequalities (e.g. Brazil and South Africa), wherein a few citizens are potential consumers for pharmaceuticals, while the vast majority remain severely impoverished. Here, we should acknowledge that it was South Africa, a middle-income country, home to more HIV-positive persons than any other country on earth, where the decisions of Bristol and Yale resulted in extensions of human lives. No doubt the needs for generic ARVs is greatest in countries lacking some of the infrastructure South Africa possesses, but nothing about relative wealth of a very small percentage of the country's population should prevent the delivery of essential medicines. Delays in delivery in one country – South Africa – resulted in over 330,000 preventable deaths.²⁶

Are there any examples of university action making a difference?

Yale and Bristol Meyers Squib reduced the price of stavudine (d4T) in South Africa by more than 95% by agreeing not to enforce the patent there. Though it required pressure from students, the researcher who

²¹ *Untangling the Web*. Doctors Without Borders. 2008. p. 15.

²² Ford et al. “The Role of Civil Society.” *The Lancet*. Vol 363. 14 February 2004.

²³ Shoofs. “Glaxo Enters Fight in Ghana on AIDS Drug.” *Wall St. J.* Dec. 1, 2000, at A3.

²⁴ Snell, Beverley. “Inappropriate drug donations: the need for reforms.” *The Lancet*. Vol 358. August 18, 2001. 578-80.

²⁵ Aplenc, R. et al. “Inappropriate Drug-Donation Practices in Bosnia and Herzegovina.” *N Engl J Med* 1998; 338; 1472-1474.

²⁶ Chugwedere et al. “Estimating the Lost Benefits of ARV Drug Use in South Africa.” *JAIDS*. December 1, 2008.



discovered the drug, and Doctors Without Borders, both Yale and BMS benefited from the positive publicity generated by their arrangement. These trailblazing efforts led the way for price reductions of many other drugs, which together enabled non-governmental organizations as well as governments to begin treating people infected with HIV in developing countries. Yale continues to have strong and healthy ties to the pharmaceutical industry, and Pfizer has recently built a new \$35 million dollar Clinical Research Unit in cooperation with Yale. Closer to home, UCSB donated patent rights to cardiovascular medicines for the treatment of schistosomiasis to the not-for-profit pharmaceutical company OneWorld Health in 2004 – this affirmative action offers great promise to the 200,000 patients who will die, every year, from the parasite. A GAL would multiply this singular event into broad policy. UC-Berkeley pursued royalty-free licenses for dengue diagnosis technology, and artemisinin, a malaria therapy. The University of British Columbia issues a royalty-free license for a novel, oral formulation of amphotericin B, the drug of choice for leishmaniasis, a neglected, often lethal parasitic infection affecting millions world-wide.

Will universities or pharmaceutical companies be liable for drugs produced generically under a GAL?

As there will be no direct relationships between pharmaceutical developers and generic manufacturers as part of the GAL, and the creation of the generic market is automatic and open, neither universities nor the pharmaceutical developer should be in any way legally liable for the actions of generic manufacturers. Implementing GAL does not necessitate any unique liability situations not currently seen in the pharmaceutical market.

Will this completely solve the problem of access?

No. Lowering thresholds for the provision of essential medicines does not erase global health disparities – but, importantly, it facilitates access. Obviously, existing funding mechanisms and NGOs that provide health care in developing countries are financially constrained – reducing their costs allows their efforts to reach more patients. Moreover, reducing the costs of some pharmaceuticals also allows new classes of drugs and therapies to reach patients. Though the “problem of access” is not solved by any silver bullet, a GAL is a crucial step in that direction. At least ten million patients die, every year, from lack of access to therapies – preventable deaths are legion. ARVs cut AIDS-related mortality by seventy percent in the US²⁷ – it is within our grasp and responsibility to make these therapies cheaper, and thus more available.

If many drugs are not patented in the world's poorest countries how is GAL relevant in these situations?

Even if there are no patents in a specific country other barriers may exist. Under a GAL, ideally regulatory barriers would be lifted through open licensing of any proprietary data held by the university or licensee. Importantly, since a country may not have the infrastructure to manufacture a drug within its own borders a GAL should take steps to lift manufacturing barriers. A GAL should provide for open licensing of the right to manufacture in any country for export to low and middle income countries. For example, India and Brazil are some of the largest manufacturers of generic medicines that are distributed throughout the developing world. The licensing barriers they face need to be lifted so they can supply those people who do not generate a sufficient financial incentive for the major branded pharmaceutical industry with low-cost medications.

If universities ultimately hold the patent for a given drug, why is it necessary to even negotiate with drug companies to allow for generic manufacture and distribution? Couldn't universities simply directly license their patents to third parties for generic distribution?

It is very rare that only one patent goes into making a new drug and that therefore the power is solely in the hands of a university. More often the case is that the university holds a patent for a very early stage component of a drug. In developing the drug the pharmaceutical company will take out several more patents for further developments along the way. In addition to those additional patents taken out in the initial

²⁷ Palella et al, 338 *NEJM* 853 (1998).



manufacturing of the drug, any subsequent improvements on the drug (such as an improved, once-per-day dosage or pediatric formulation) will also be separately patented. In a traditional licensing agreement the university has very little power over the pharmaceutical company's patents related to the drug.

What part of the market are we talking about, exactly?

Low and Middle Income (LMI) countries, which make up 88.3% of the world's population, account for only 5-7% of the overall pharmaceutical market.²⁸ This is overall bulk sales, however. Pharmaceutical companies make only a tiny part of their profits in these countries, either because of lower prices or because there is simply not enough demand in particular countries. These statistics represent the market failure that is causing many of the world's neediest populations to lack necessary medicines. The flip side of this point is that pharmaceutical companies still have a profit-incentive to develop drugs for only high-income countries, while allowing generic competition in the rest of the world. Drastic price cuts for ARVs in sub-Saharan Africa were estimated by one WHO official at no more than "three days' fluctuation of exchange rates."²⁹

If drug companies are already implementing some differential pricing schemes, what role can universities play?

Some pharmaceutical companies have enacted price differentials for selected drugs in the developing world and in some cases allow generic production of particular drugs. Yet the access gap persists. While the cost of a year's worth of anti-retroviral drugs in South Africa has been lowered to US\$99 in recent years, second-line therapy remains unattainable at US\$2,500 per year. Second-line therapies are essential components of treatment for HIV/AIDS, because patients acquire drug resistance. It is for this reason that patients in the US and EU can expect no fewer than four separate classes of therapies, with a range of lines therein. The WHO's 2007 ARV forecast, however, indicates that fewer than 4% of LMI patients are receiving second-line therapies; the 96% routinely receive therapies that are no longer recommended – even as alternative therapies – in the US/EU because of known toxicity and inferiority issues.³⁰

This is a pattern seen in most new drugs, which arrive in the developing world decades after they save lives in high-income countries. Today, fewer than 30% of Africans in need of treatment for HIV infection are receiving even basic care.³¹ Universities, which are at the forefront of creating new medical innovations, can change this outcome beginning at the first step in the drug pipeline. A GAL will ensure that any product that results from their innovations are made affordable via generic production.

Are there anti-trust concerns about universities conspiring to set prices?

No. Federal Courts have heard cases concerning open-source and general public licenses, and challenges to them on the basis that companies "conspire" to eliminate competition. The precedent is *Wallace v. IBM, Inc.*,³² Wallace sued IBM and two prominent software manufacturers, Red Hat and Linux, for their use of a license devised by the Free Software Foundation, that allowed users to obtain the product free-of-charge, and for derivative products to be created for the same price. Judge Easterbrook of the Seventh Circuit Court of Appeals found, "[c]opyright and patent laws give authors a right to charge more, so that they can recover their fixed costs (and thus promote innovation), but they do not require authors to charge more. No more does antitrust law require higher prices."³³ Though the plaintiff sued because the license agreements would "eliminate competition in the operating system market by making Linux available at an unbeatable price"

²⁸ "Pathways to Biopharm Innov." PhRMA. 40 (2005).

²⁹ Gellman, Barton. "An Unequal Calculus of Life and Death." *Washington Post*. December 27, 2000. Page A01.

³⁰ World Health Organization, 2007 Antiretroviral Forecast. p. 17; Department of Health and Human Services ART Guidelines, November 2008.

³¹ UNAIDS 2008.

³² 467 F.3d 1104 (7th Cir 2006).

³³ *Id.* at 1107.



(free), the suit was rejected because the licensees in question “have nothing to fear from the antitrust laws” as “[e]mploying antitrust law to drive prices up would turn the Sherman Act on its head.”³⁴

A related case against the Free Software Foundation was also dismissed by US Federal Court Judge Daniel Wallace, who ordered the plaintiff to pay for defendant's fees (an indication of a baseless suit). Wallace wrote, “the GPL encourages, rather than discourages, free competition and the distribution of computer operating systems, the benefits of which directly pass to consumers. These benefits include lower prices, better access and more innovation.”³⁵

Patent pools for intellectual property have also been considered in light of existing anti-trust concerns. The Department of Justice’s analysis thereof, however, concludes that pools “can have procompetitive benefits, for example, by exploiting economies of scale and integrating complementary capabilities of the pool members.”³⁶

Could this impact NIH funding?

The GAL would not change any framework required by the NIH, and NIH funding is unrelated to university-specific technology transfer policies. Yale saw no change in its NIH funding after it dropped its patent rights for stavudine; UC Berkeley’s use of double-bottom line metrics has similarly not impacted its NIH funding. The NIH, itself, is also subject to Bayh-Dole, and its licensing is subject to government oversight and marching-in rights.³⁷ The NIH is actually moving its grant recipients to publish their research in open-access repositories, among other efforts to revisit existing exclusive arrangements.

GALs also have a history of attracting funding. UC Berkeley Vice Chancellor Carol Mimura described the Gates Foundation’s \$42.6 grant this way: “Gates would not fund until we could guarantee access,” requiring that the technology be sold to developing nations at the cost of production.³⁸

³⁴ Id. at 1108, 1007.

³⁵ unpublished Order of Dismissal in *Wallace v. Free Software Foundation*, S.D. Indiana, 2006, Case 1:05-cv-00618-JDT-TAB. (2006). available online at <http://www.groklaw.net/pdf/WallaceFSFGrantingDismiss.pdf>

³⁶ Antitrust Guidelines for the Licensing of Intellectual Property. US Department of Justice and the Federal Trade Commission. April 6, 1995. available online at <http://www.ftc.gov/bc/0558.pdf>.

³⁷ 35 U.S.C. § 202(c)(4)(2000).

³⁸ Ledford, Heidi. “IP: Ideas for Purchase?” *Berkeley Science Review*. Spring 2006. p. 38.