



May 7, 2009

Department of Science and Technology
Attention: Tsitso Daniel Rasenyalo
Building 53, CSIR Campus
627 Meiring Naude Road
Brummeria
Pretoria, 0184

VIA FACSIMILE and ELECTRONIC MAIL

Re: Draft Intellectual Property Rights from Publicly Financed Research and Development Regulations

Dear Sir:

We have followed the Intellectual Property Rights from Publicly Financed Research and Development Act (“the Act”), and its corresponding regulations (“the Regulations”), with great interest and gratefully take this opportunity to share our position on the current draft regulations and the Act. The Act is in many ways similar to a piece of American legislation called the Bayh-Dole Act of 1980,¹ which we have examined along with other models for commercializing the fruits of university research. Our organization, Universities Allied for Essential Medicines (UAEM), is a coalition of students at over 40 of the top research institutions in the United States, Canada, Germany, Uganda, and the United Kingdom. Our mission is to promote access to medicines for people in developing countries by changing norms and practices around university patenting and licensing in order to ensure that university medical research meets the needs of the majority of the world’s population, and by empowering students to respond to the access and innovation of medicines crisis.

We write today to share our strong concerns regarding the South African Act and Regulations. Below is a brief analysis of the legislation and the Regulations.

The United States Bayh-Dole Act is at the center of much of our work and we are concerned that the current South African Act will build upon the failures of the U.S. legislation and harm access to medicines.

Due to these concerns, we strongly urge the members of the South African government to consider the input of public and civil society organizations when enacting the Regulations for this Act.

The Bayh-Dole Act in the United States

While the Bayh-Dole Act of 1980 is commonly praised for dramatically increasing the patenting and licensing of publicly-funded research in the U.S., there is little evidence that

¹ Bayh-Dole University and Small Business Patent Procedures Act of 1980, 35 U.S.C. § 200 (2006).

the legislation was necessary for or successful in accomplishing the goals which inspired its drafting. The practice of licensing at universities in the U.S. has raised serious concerns regarding the application of similar legislation in South Africa.

- **The Bayh-Dole Act too narrowly focuses on patenting and licensing**, ignoring the fact that public sector research institutions contribute to the economy in multiple ways, through journal publication, collaboration with other scientists, consultations with industry, and education. As patenting increases, it has the potential to reduce the contribution made by these economic inputs by reducing free access to knowledge. Recent WHO negotiations, in which South Africa was a participant, developed a Global Strategy and Plan of Action to address the dual challenges of access and innovation. The final Global Strategy, building off of findings of a report issued by the WHO Commission on Intellectual Property Rights, Innovation and Public Health, recommended a number of agreed-upon strategies for improving access and innovation that do not rely solely on the patent system and which rely heavily on open sharing of resources.
- **The Bayh-Dole Act has failed to generate consistent revenues.** While a few universities have profited from “blockbuster” discoveries, overall, technology transfer offices at universities often barely break even, and most operate at a net loss.
- **The exclusive use of the patent model, without appropriate public health safeguards, threatens access to life-saving drugs.** The Act encourages research institutions to obtain patents on publicly-funded research to the exclusion of other methods that could in many situations be more beneficial to access and encouraging future innovation. Such rights allow the institutions and their licensees to charge monopoly prices that, in the case of South Africa, may place life-saving medicines out of reach of South Africa’s poorest consumers, denying them the opportunity to benefit from publicly-funded research. While we applaud the South African government’s preference for non-exclusive licensing and mentioned ability in regulations to the use of open-source methods, we urge that the strictures for recipients to use open licensing and non-patenting be more flexible to facilitate broader access to medicines.
- **The Bayh-Dole act contains only weak access safeguards.** Critics of the original American Bayh-Dole Act point out that the safeguards the act contained to allow for public access in case a publicly-funded innovation was not made available on reasonable terms have never been successfully used. We are concerned by language in the South African legislation that indicates the use of the similarly weak safeguard and urge the South African government to consider enacting more effective alternative safeguards. This would ensure taxpayers have access to publicly funded medicines on reasonable terms.
- **The patenting model is a bad fit for many forms of publicly-funded research.** Much of the research done at universities is upstream and basic research, often related to research tools that are critical for developing further innovations and are not appropriate for the consumer market. Patenting is not only unnecessary for these basic tools, but it can inhibit further downstream research and development by placing a costly “tax” on tools for innovation.

Concerns with the Act and Draft Regulations

We have a number of concerns with the current act and draft regulations. These include:

- **The current legislation is overly broad in its scope.** The Act is designed to cover “any creation of the mind that is capable of being protected by law.”² By encouraging patenting across such a broad range, the Act offers no recognition of the difference between applied research that can benefit from licensing and upstream research that does not require licensing to encourage its use. As a result, it has the potential to discourage a broad range of productive research activity that has previously thrived under a system of free and open academic exchange.
- **There is a lack of a broad experimental-use exception.** A robust research exemption would do much to mitigate upstream patenting that has inhibited innovation and development in the United States. This exception should be applied, at a minimum, to all future publicly-funded research. Such an exception may also work to preserve the academic norms of free and open exchange, and collaboration by discouraging proprietary behavior within the research community. The current text only offers a research exemption for the recipient entity and intellectual property creators in certain circumstances.
- **There is a lack of effective provisions to safeguard access.** The United States example illustrates the need for an effective access provision. The Bayh-Dole Act recognized the need to ensure public access to publicly-funded inventions. While government march-in rights (like those found in the South African Draft Regulations³) have never been exercised to increase access in the United States⁴ and must therefore be considered a weak protection at best. The fact that the South African government has included provisions allowing NIPMO to acquire intellectual property rights from those recipients that are not being properly commercialized to benefit the people of the Republic indicates that access is important to the South African parliament. Further, the proposed regulations under section 8(8) appear to narrow the applicability of government rights under the Act, section 11(1)(e), by referring to “health, security and other emergency need” whereas the Act in 11(1)(e) refers to “health, security and emergency needs.” This important change means the regulations would only allow government rights to be used in the case of emergencies whereas the text of the original act would seem to allow action in a broader set of circumstances.

Acquiring intellectual property rights from recipients ex post facto would presumably create some level of protection, but it is merely a weak stop-gap measure rather than a proactive one, particularly if it can only be used in defined-period, emergency situations. South African lawmakers should consider access to be a priority up-front,

² Section 1, subsection (c) of the Intellectual Property Rights from Publicly Financed Research and Development Act, 2008.

³ Section 11 of the Intellectual Property Rights from Publicly Financed research and Development Regulations (draft).

⁴ Russell Korobkin, The Taxpayers’ Stake in Stem Cell Profits, in *Stem Cell Century* 130 (2007).

- particularly in cases involving publicly-funded research, rather than waiting for a problem to present itself.
- **Draft regulations unduly focus on commercialization of intellectual property.** NIPMO's review of recipients' progress is unduly dependent on the commercial success of their patents. The IP6 form which recipients complete in their periodic reports to NIPMO does not include measures of success outside of the commercial market – no questions about journal publications, collaboration with other researchers or donation of intellectual property to product development partnerships researching neglected diseases, to name a few examples, appear on the IP6 form.

Suggested Changes

We believe that the unrealistic expectations the Act and its corresponding Regulations will have on university revenues and a lack of consideration of the shortcomings of the original U.S. legislation has created flawed legislation. We recommend that the Department of Science and Technology reconsider its draft regulations in light of the concerns we have put forth and with the input of public and civil society. We also highly recommend the Department consider the recommendations of the Global Strategy and Plan of action adopted by the World Health Assembly in WHA61.21 (see Annex 1 for a non-exhaustive list of recommendations from the resolution).

The Bayh-Dole model is outdated for today's innovation environment. We strongly encourage the Department of Science and Technology to bear in mind the following point as it continues to draft the Regulations:

- Strengthen public access protections for publicly-funded research. A number of recommendations are included in WHA 61.21.
- Ensure that NIPMO's operations and procedures, as well as those for its Dispute Tribunal, are transparent to the citizens of the Republic, as well as public and civil society.
- Include a broad experimental-use exemption, narrow the scope of the Act, and include other measures to preserve the norm of open exchange of ideas critical to academic advancement.
- Consider the dual issues of innovation and access holistically, rather than focusing exclusively on patenting and revenues as measures for success. Success based on patents and revenues can create perverse incentives for research and harm the free exchange of ideas that allow universities to thrive. Such perverse incentives ultimately harm the public-interest mission of academia and innovation.
- At a minimum, ensure that march-in rights reserved in the Act are defined and effective to protect taxpayer access to the fruits of publicly funded research and undo the narrowing of enactment of government march-in rights which in the regulations becomes possible only in emergency situations.

The Intellectual Property Rights from Publicly Financed Research and Development Act currently has flaws that must be addressed in an open and public setting to determine how the regulations enforcing it should be tailored. Given the track record of the Bayh-Dole Act in the United States, the Department of Science and Technology must seriously consider



what needs to be accomplished through such regulations, the suitability of its provisions for the needs of the Republic, and whether the draft regulations will accomplish the stated goals of the legislation while protecting the public interest. The draft regulations should not be enacted in their current condition.

We thank you for this opportunity to share our concerns and welcome any requests for clarification you might have.

Kind Regards,

A handwritten signature in black ink, appearing to read 'E. Guillen', is written over a light gray rectangular background.

Ethan Guillen
Executive Director
Universities Allied for Essential Medicines
ethan.guillen@essentialmedicine.org
www.essentialmedicine.org

Annex 1: Elements of WHA61.21 Global Strategy

Below is a non-exhaustive list recommendations of the Global Strategy developed by the World Health Organization Intergovernmental Working Group on Public Health, Innovation and Intellectual Property and adopted in WHA61.21 which are relevant to publicly funded research.

(2.2) promoting upstream research and product development in developing countries

(a) support discovery science, including where feasible and appropriate, voluntary open-source methods, in order to develop a sustainable portfolio of new products

(b) promote and improve accessibility to compound libraries through voluntary means, provide technical support to developing countries and promote access to drug leads identified through the screening of compound libraries

(2.4) Promoting greater access to knowledge and technology relevant to meet public health needs of developing countries

(a) promote the creation and development of accessible public health libraries in order to enhance availability and use of relevant publications by universities, institutes and technical centers, especially in developing countries

(b) promote public access to the results of government funded research, by strongly encouraging that all investigators funded by governments submit to an open access database an electronic version of their final, peer-reviewed manuscript

(c) support the creation of voluntary open databases and compound libraries including voluntary provision of access to drug leads identified through the screening of such compound libraries

(d) encourage the further development and dissemination of publicly or donor-funded medical inventions and know-how through appropriate licensing policies, including but not limited to open licensing, that enhance access to innovations for development of products of relevance to the public health needs of developing countries on reasonable, affordable and non-discriminatory terms

(e) consider, where appropriate, use of a “research exception” to address public health needs in developing countries consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights.

(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies

(a) examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices

(b) explore and, if feasible, develop possible new mechanisms to promote transfer of and access to key health-related technologies of relevance to public health needs of developing countries especially on Type II and III diseases and the specific R&D needs of developing countries in respect of Type I diseases, which are consistent with the provisions of the TRIPS agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health.

(5.1) supporting information sharing and capacity building in the application and management of intellectual property with respect to health related innovation and the promotion of public health in developing countries

(a) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the TRIPS Agreement and other WTO instruments related to that agreement and meets the specific R&D needs of developing countries