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The privatisation of publically funded research in South Africa: Lessons from the US Bayh-Dole Experience

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Contents

Acronyms

BABS	Regulation on Bio-Prospecting, Access and Benefit Sharing No138 of Government Gazette No. 30739 of 8 February 2008.
CBD	Convention on Biological Diversity
DST	Department of Science and Technology
Innovation Plan:	Innovation towards a knowledge based economy: ten year plan for South Africa 2008-2018
IPR	Intellectual Property Rights
Public Research Act	Intellectual Property Rights from Publicly Funded Research and Development Act 51 of 2008
NIPMO	National Intellectual Property Management Office
NEMBA	National Environmental Management: Biodiversity Act 10 of 2004
R&D	Research and Development
TTO	Technology Transfer Office
TRIPS	Trade Related Aspects of Intellectual Property Rights
US	United States of America
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

"Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980... More than anything, this single policy measure helped reverse America's precipitous slide into industrial irrelevance."

Economist Technology Quarterly, 14 December 2002

Introduction

"Higher education is changing profoundly, retreating from the ideals of liberal arts and the leading edge research it always has cherished. Instead it is behaving more like $250 billion dollar business it has become."[1]

The Bayh-Dole Act, named after Bayh and Dole, two US senators who sponsored the Bill, was enacted in the US on the 12th December 1980.[2] The Act was introduced to address the US losing its competitive edge in the marketplace across several industries, and the concomitant decrease in industrial output, capacity and job losses. The US was determined to put an end to countries such as Germany, Japan and Russia with enhanced industrial capacity from freely utilising US innovation to produce improved products in the steel, electronics and automobiles industries.[3] The aim of the Bayh-Dole Act was thus to encourage and facilitate the transfer of technology from public to private institutions by way of intellectual property right (IPR) protection.[4] The rationale was that strong IPR protection would serve as a strong incentive for innovation to be converted into tangible commercially viable products. In this way, the US would be able to regain its foothold in the industrial marketplace.[5]

The Bayh-Dole's primary role was therefore to facilitate the transfer of innovative research generated by publicly funded bodies, to the private sector. Once under the control of the private sector, it would be used to develop tangible commercial end-products destined for domestic and international markets. The Act was thus designed to facilitate such transfer of technology through the granting of IPR protection to public research institutions and researchers vis-a-vis research and creative ideas. Such patent rights would then be licensed to the private sector.

The Bayh-Dole Act has thus dramatically changed the nature of publically financed institutions in the US from those conducting pure research to quasi commercial entities withholding information in a quest for patent protection.[6]

The Act constitutes a serious barrier to the sharing of and collaboration in research and innovation across Universities.[7] It also fosters patent protectionism in that universities become embroiled in costly patent lawsuits in a bid to protect their innovations and research tools.[8] This is a far cry from the very purpose for which public research institutions have been established, namely, to disseminate public research in the public domain for the benefit of the public and to foster academic progress and excellence.

Proponents of the Bayh-Dole Act measure the Act's success by pointing to increased patent applications, licensing revenue, commercial products and so forth.[9] [10] Indeed, during the 1980s, approximately 500 patents were granted in the US with this figure rising steeply and steadily over time. By 2007, 3622 patents were granted, with a staggering 13280 patent applications being filed between 1991 and 2003.[11] [12] [13] Since 1980, 4500 university linked start-up companies were established in the US.[14] Some of the products resulting from patent protected innovation from research institutions include various cancer therapies, vaccines, water purification technologies, human growth hormones and so forth.[15] [16]

This assumed success hides the fact that patented products made possible through public funding are more costly, thereby placing the burden on the public for such costs while the products remain outside of the reach of the poor.[17]

Numerous developing countries have opted to emulate the Bayh-Dole Act. These include Brazil, Columbia, China, India and South Africa.[18] [19] [20] At the time of writing, we were not able to ascertain to what extent Bayh-Dole type legislation had been part of the discourse in the rest of Africa. Indeed, countries in Africa are still struggling to bring their respective intellectual property laws in line with the requirements of the World Trade Organisation (WTO).

South Africa's adoption of the Bayh-Dole legislation through the Public Research Act and its associated regulations came into effect on 1 June 2009. In this paper, we present an overview of this legislation and draw on the experience of the Bayh-Dole legislation in the US to show the shortcomings of this approach and its dire consequences for R&D in South Africa and for the public.

A patent is a western concept and confers an exclusive monopoly right to an inventor to prevent all others from selling, producing, distributing, licensing or importing a specific invention. This right usually lasts for 20 years, and is enforceable in the country or region where the patent is granted.

Licensing in relation to patents is a contract between the patent holder (licensor) and the licensee whereby permission is given to the licensee to exploit the patent under certain conditions. The license could be exclusive or non-exclusive, and involve payment of royalty fees

White Paper on Science and Technology

During 1996, the national Department of Science and Technology (DST) published a *White Paper on Science and Technology*[21] articulating the government's intention of building a knowledge-based economy by *inter alia*, promoting and enhancing scientific and technological development and innovation. This was seen by the fledgling post apartheid government as key towards creating job opportunities for previously disadvantaged groups, economic development and giving South Africa a competitive edge in international trade.[22] [23] The White Paper identified a *lucana* or 'innovation chasm' between creative scientific and technological innovation and its application in the marketplace.[24] IPR protection for such innovation was thus earmarked as a means to close this chasm.[25] The White Paper stopped short of advocating for specific legislative changes to bring its vision to fruition in outlining policy guidelines to promote scientific and technological knowledge and innovation. In addition to financing, management and integration of innovation through promotion of science and technology, various sections of the White Paper specifically make mention of technology transfer within the IPR system. More specifically, section 6.1 of the White Paper identifies the need to align South Africa's IPR and other laws with international norms and standards in order to adequately protect its inventions and build a knowledge-based economy.

South Africa's National Research and Development Strategy

As a follow on, in 2002, the DST published South Africa's *National Research and Development Strategy* ("R&D Strategy"),[26] which clearly espouses the view that IPR protection is a key indicator of successful scientific and technological innovation.[27] The R&D Strategy went much further than the 1996 White Paper by explicitly recognising the need for effective IPR systems, including the application of such systems to publicly financed research.[28] Thus the R&D Strategy clearly expresses the government's interest in emulating the US style Bayh-Dole type legislation.[29]

The White Paper and the R&D Strategy hugely influenced the South African government's development of the *Intellectual Property Rights from Publicly Financed Research Policy Framework*, approved by Cabinet in May 2007. Consequently, the government set about crafting the *Intellectual Property Rights from Publicly Financed Research Policy Framework Bill*, which it published during May 2007, for public comment.[30] The ACB took the opportunity to submit its comments on the draft law on 18 July 2007.[31]

Intellectual Property Rights from Publicly Funded Research and Development Act 51 of 2009

The Intellectual Property Rights from Publicly Funded Research and Development Act 51 of 2008 (Public Research Act) was published on 22 December 2008. Secondary legislation to implement the Act, the Intellectual Property Rights from Publicly Financed Research and Development Regulations, 2009 (Public Research Regulation) was drafted and came into effect on 1 June 2009.[32] This legislation and the Regulation, like the Bayh-Dole, mandates public institutions to seek IPR protection over publicly funded research and to create a knowledge-based economy whereby such innovation will be licensed to and commercialised by private institutions. The South African legislation is dealt with in more detail below.

Other policy shifts towards commercialisation of knowledge and resources

The DST has also published a ten year plan titled "Innovation towards a knowledge based economy: ten year plan for South Africa 2008-2018" (Innovation Plan).[33] The Innovation Plan similarly expresses the government's aim of strongly supporting a knowledge-based economy through appropriate policies and plans.[34] One such plan is a "farmer to pharma" initiative, involving the commercialisation of biological resources and associated indigenous knowledge to enable South Africa to become one of the top 3 pharmaceutical manufacturers in the world.[35]

The National Environmental Management: Biodiversity Act 10 of 2004 (NEMBA) and its accompanying National Environmental Management: Biodiversity Act 10 of 2004: Regulation on Bio-Prospecting, Access and Benefit Sharing[36] (BABS), regulates bioprospecting of biological resources in South Africa.

Although the primary goal of this body of law is to regulate and manage the conservation of biodiversity to give a semblance of protection to indigenous knowledge, as required by the international Convention on Biological Diversity (CBD) to which South Africa is a Party, the legislation expressly supports the transfer of traditional knowledge to the private sector. This is done by encouraging bioprospecting, and commercialisation through IPR protection, of biodiversity involving indigenous knowledge.

South Africa imitates the Bayh-Dole Act: The Public Research Act and Regulations

The South African Public Research Act is based on the US Bayh-Dole Act and encourages licensing and commercialisation of innovation derived from publically funded research. Public research institutions regulated by this Act include higher education entities such as Universities, technical universities and Colleges. It also includes the Human Research Council, Water Research Commission, Council for Scientific and Industrial Research, Council for Mineral Technology, Agricultural Research Council, South African Medical Research Council, South African Bureau of Standards, Council for Geoscience, National Research Foundation, South African Nuclear Energy Corporation Limited, and any other body which the Minister may deem to fall under this Act in terms of a notice in the Government Gazette.[37] These institutions all utilise public funds to conduct research on diverse subject matters of interest and disseminate findings directly into the public domain.

The Public Research Act mandates public institutions to identify innovation of commercial value derived from publicly funded research, and to protect such research through IPRs.[38] The Public Research Act does not prescribe the form of IPR protection yet it implicitly favours patent protection. The private sector is encouraged to license and commercially exploit innovation and pay over royalty fees to the public institution. In this regard, inventors are to receive a minimum of 20% royalty fee from the profits on the licensed innovation, where the net profit is below R1million. If the profits exceed R1million, the royalty must be more than 30% of the net profit.[39] Where no IPR protection is sought by the research entity, the State can itself seek the IPR protection.[40]

The Public Research Act requires the inventor to disclose their innovation and intention to seek IPR protection prior to publication of their research findings.[41] Each institution is required to establish a technology transfer office (TTO) to whom such disclosure is to be made.[42] Where the TTO is of the opinion that the innovation warrants commercialisation, it is required to communicate its decision and intention to seek IPR to the National Intellectual Property Management Office (NIPMO).[43] NIPMO is established in terms of the Public Research Act and its functions include assisting in the establishment of TTOs and managing IPRs and so forth.[44]

A TTO is required to be staffed by qualified and experienced personnel within each public research institution, or alternatively two or three institutions may register one TTO regionally between the collaborating institutions.[45] A TTO's function is to receive disclosure of patentable research by researchers in public institutions, analyse the necessity of IPR protection, file and manage IPR, and so forth. [46] The institution is also under an obligation to report through the TTO to NIPMO on the progress of R&D for the public benefit, the reasons for non-commercialisation or commercialisation of an innovation, as well as on progress of the IPR protection and management.[47]

The establishment of a TTO within each public institution involves the incurring of high operating costs.[48] The DST has established a Patent Support Fund to subsidise patent application costs.[49] During 2003-2005, the Patent Support Fund subsidised R10million out of the overall R25million spent on patent applications by public institutions.[50]

Once IPR protection has been secured, the IPR is then licensed out to the private sector. Licensing to the South African private sector as opposed to foreign entities is preferred. Going further, the Act requires that preference be given to broad-based black economic empowerment entities (BBBEE) and small enterprises[51] in the hope that this would in turn create local jobs and contribute to national economic development.[52] However, where these BBBEE and small enterprises lack the capacity for commercialisation, the license may be outsourced to foreign entities. [53]

In instances where IPR is underutilised or undisclosed, or where the government deems it to be in the public interest for health, security or emergency purposes, it may step in and exercise "march-in" rights by reassigning the IPRs.[54] The government can, for example, invoke march-in rights in instances where the licensee charges exorbitant prices for the commercialised product. The Bayh-Dole also provides for march-in rights, however, these have never been effectively utilised in the US. Abott Laboratories in the US hiked the price of an AIDS drug Norvir, derived from public research, by a staggering 400%. The National Institute of Health invoked march-in rights in order to control the pricing on the grounds that such pricing was contrary to the public's interest. However, Senator Bayh testified as to the original intention of the Bayh-Dole legislation, which he said was not to control drug prices. It was therefore decided that march-in rights cannot be used to control drug prices.[55] It remains to be seen if at all, the South African government will invoke the march-in rights in the public interest.

Lessons for South Africa from the Bayh-Dole experience

The problems with patents on innovations

The concept of patents originated through granting exclusive monopoly or "privileges" to anyone who introduced a new technological invention.[56] Through granting such exclusive monopolies, the inventor is required to share the invention with the world through publication.[57]

The nature of patentable inventions, however, has broadened considerably over time. The United States Supreme Court case of *Diamond v Chakrabarty* set a precedent of allowing patents on life forms.[58] This concept of patents on life was eventually codified in the intellectual property regime of the Trade Related Aspect of Intellectual Property Rights (TRIPS) under the auspices of the World Trade Organisation (WTO). Article 27(3) of TRIPS allows the patenting of micro-organisms (e.g. fungi, viruses and planktons) and non-biological and microbiological processes. Thus all 153 members of WTO, including South Africa, are required to change their respective patent laws to incorporate this provision.[59]

The nature of patents globally therefore has changed to extend far beyond product inventions.[60] Patent protection can now be granted on the 'discovery' of a novel compound in nature, living organisms, services, administrative methods and research tools necessary in the furtherance of R&D.[61] This means that the scope of research over which patents are granted is extremely wide, which severely limits the amount of information being placed in the public domain.

Corrupting the free flow of information

It is common knowledge that patents can only be obtained for new inventions where there has been no prior publication of such invention. This means that research and innovation forming the subject matter of a patent application is withheld and remains unpublished until such time that a patent is filed. In the drug development sector, pharmaceutical industries claim that it typically takes between 15-20 years for a new medicine to come to the market.[62]

Trade secrets can also be used to suppress clinical researchl[63] since research data can be legally classified as confidential business information. This is contrary to the ethos of public institutions that should be about publishing research in a timely manner for the benefit of the public and other research institutions in the same sector.[64] Furthermore, it is morally justifiable that where public funds are used for research, there should be some public accountability and access to this information by the public. This closed and un-transparent approach to research dissemination is also not congruent with the open-source approach to research, favoured the world over. Equitable and fair diffusion of information and research is vital to address the crisis in health care and other humanitarian crises, particularly those occurring in developing countries.

Patent protection not necessary for technology transfer

As discussed earlier, patents have wide application in that they grant monopoly rights, not only over inventions, but also in respect of research tools and life forms. Integral to the rationale of the Bayh-Dole model is the assumption that patent IPR protection over publically generated research is necessary for technology transfer to take place.[65] This implies that the private sector is unable

to develop a product in the absence of exclusive licensing and that other forms of licenses are not attractive and thus would turn away possible investment. Yet research shows that several commercial products based on licensed innovations were quite capable of being developed without exclusive license and where research was disseminated in the public domain.[66] [67] [68]

Patent protection is not necessary for technology transfer to take place. Instead, it is the long term commitment to R&D by both the private and public sector that is the real catalyst for creating job opportunities, establishing small businesses and successful product development. South Africa's investment in R&D is merely 0.39% of its GDP and of this, only 65% is accessible by publically funded research institutions.[69] Indeed, publically inanced research institutions are constantly being asked to justify their research budgets, which the government views as money wasted.[70] [71] Under-funding is the real cause for the apparent lack of innovative products coming to the market. It is a spurious argument that privatisation of public research is the only answer to spearhead economic development and job creation in South Africa.

Myths of Profitable Licensing Revenue

The possibility of lucrative licensing revenue is alluring to poorly funded public institutions if they are able to obtain patents on their innovations. South African universities are keen to reap profits from their research as their US counterparts appear to be doing. For instance, in 2002, the gross licensing revenue accruing to Universities in the US amounted to $1.38billion.[72] Nevertheless, this revenue must be placed in context, as it is limited to very few blockbuster patents. Many universities in the US that go through the process of filing and maintaining patents find that they barely break even.[73] [74] This is also the experience in India, where during 2004-2005, the Council of Scientific and Industrial Research generated $1million in licensing fees from patents it obtained, having nevertheless spent over $2million in filing the patents.[75]

In South Africa, the costs of patent applications vary but are still an expensive affair. Currently the filing of a provisional patent application in South Africa could cost anything from R4500 (€361.51/ $589.14) - R20000 (€1763.45/$2618.38). A complete filing costs between R4100 (€396.78/$536.77) – R25000 (€2204.31/$3272.98) and the costs associated with an international patent application is between R12000 (€1058.07/$1571.03) – R50000 (€4408.61/$.6545.96).[76] [77]

South Africa's own R&D Strategy acknowledges that patent costs are high and staff costs for intellectual property offices in universities and research organisations are on the rise. It also appears to be alive to the fact that a good medium-sized intellectual property office in a US university would typically be staffed with around 15 people with skills in technology assessment, patenting and commercialisation.[78] The high costs involved in establishing TTO's in each institution, or regionally between two or three institutions, also needs to be taken into account before institutions are seduced by promises of lucrative royalty fees. The high costs associated with litigation for patent enforcement should also be factored into the equation.

Patent driven public research: the public loses out

The private sector is hardly likely to seek licenses for products for the social good and in respect of which there is little or no profit involved.[79] Globally, less than 10% of investment in health care research is devoted to 90% of the health problems globally,[80] most of which are prevalent in developing countries. A 2008 Global Health Forum Report shows that diseases of the poor are sorely neglected under the current global R&D framework. It also argues that the monopoly patent system is skewed in favour of drug treatment that merely alleviates systems of diseases,

rather than curing them. In this way, the pharmaceutical industry continues to profit from drugs over the span of a patient's lifetime – he or she never dies, but never gets well either.[81]

It is not only in the health sector that the research focus is skewed due to public-private partnerships, patents and licensing rights. Truly independent scientific research is severely under-funded or non-existent. For instance, despite the on-going raising of concerns about the biosafety risks posed by genetically modified organisms (GMOs), to human and animal health and the environment, there is a dearth of independent biosafety research.[82] Blame for this state of affairs can largely be attributed to Bayh-Dole model, which promotes corporatisation of public research, which lacks independence and credibility.[83]

The public pays twice

End products brought to the market as a result of patented innovations are usually prohibitively expensive and out of the reach of the poor in developing countries. The costs involved in product development, as well the high costs associated with patent applications, are invariably built into the cost of the merchandise.[84] The unaware public pays twice for the product: first through the public revenue that funds research institutions, and second, for the built-in patent costs when the end product is purchased. [85] This scenario also applies to the purchase of patented medicines by the poor. The moral and ethical repugnance of this situation has been condemned by many, including Ralph Nader, an attorney and former candidate for President of the United States. In a letter to the US secretary of health in March 2001, he pointed out that the US taxpayer forks out more than $20 billion annually for healthcare, which is spent on a plethora of patents and IPRs for HIV and other drugs of importance to developing countries particularly in Africa, and which are sold or licenced to these countries at exorbitant prices.[86]

The prohibitive costs of health products or technologies associated with sold or licensed patent rights derived from public research is aptly described in the case of Myriad Genetics.[87] In this case, a gene sequence associated with breast cancer was sold to Myriad Genetics by the University of Utah who first made the discovery. Myriad Genetics became the sole proprietor of the breast cancer testing and diagnosis tools, for which they charged $2300 per test. However, when other universities began to use the test on the public at a cheaper price or conduct further research, they were sued by Myriad Genetics. Myriad Genetics was asking the public to fork out prices demanded by it as sole owner, yet the public had already paid $4,6billion in the discovery phase of the research.

Conclusion

South Africa has obviously done its own cost-benefit analysis and opted in favour of the Bayh-Dole with its eyes wide open. It has sacrificed a great deal in doing so. The general public is probably unaware of the far reaching implications of this legislation and the extent to which their lives will be changed as result.

It is our view that South Africa should rather favour open-source research. South Africans and people world wide need more equitable, transparent and free access to information, research and technology. Various regional and international fora support such an approach, including the South African Regional Universities Association and the Global strategy and Plan of Action on Public Health Innovation and Intellectual Property of the World Health Organisation.[88] Ironically, the DST itself supports and financially contributes towards the Academy of Science of South Africa and the Committee for Scholarly Publishing that promote open-access publishing.[89] Various South African universities seem to prefer such open-access research dissemination as well.[90]

Significantly, South Africa also adopted a resolution passed on 22 May 2009 by the 61st World Health Assembly of the World Health Authority recognising a 'needs driven' approach to R&D to in the health sector in order to address the illnesses prevailing in developing countries. The implementation of the resolution would involve the use of open-licensing, open-source research and development, and open and equitable dissemination of research.[91]

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