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Strangers in the Night: A Comparative Study on the Socio-Legal Difficulties of Importing America's Bayh-Dole legislation to South African Universities

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Abstract

In 2008, the South African parliament passed the Intellectual Property Rights (IPR) from Publicly Financed Research and Development Act, which came into effect on 2 August 2010. In doing so, South Africa sought to replicate the apparent success of the United States of America's Bayh-Dole legislation. One of the express objectives of the Bayh-Dole Act is the increase in university-industry collaborations (U-I). Whilst U-I has not been expressly stated as a primary aim of the IPR Act, the legislative history has demonstrated that issues relating to U-I have permeated the political landscape from the inception of the IPR Act. It is therefore relevant – although hitherto unexplored – to consider whether South Africa's IPR Act might have the same supposedly positive effect on U-I experienced by the Bayh-Dole Act. In answering this question, this paper chooses to focus on two factors that may be considered particularly pertinent in light of South Africa's recent socio-legal landscape, namely (a) the lack of substantive patent examinations, and (b) government investment in higher education. To this end, it will be argued that the IPR Act will only serve to have a negative effect on U-I, if any at all.

Keywords: America, Bayh-Dole, Intellectual Property Rights, Patents, Publicly Financed Research and Development Act, South Africa, Universities.

Introduction

In 2008, the South African parliament passed the Intellectual Property Rights (IPR) from Publicly Financed Research and Development Act 2008 (henceforth 'IPR Act'), which came into effect on 2 August 2010 and remains to be the subject of in-depth academic critique. In passing the IPR Act, South Africa sought to replicate the apparent success of the United States of America's Bayh-Dole legislation. One of the express objectives of the Bayh-Dole Act is the increase in university-industry collaborations (henceforth 'U-I'). Whilst this is not an explicit aim of the South African legislation, this paper will ask how the IPR Act may impact U-I and whether it is likely to achieve a similar level of success in this regard as its American counterpart. Assuming the Bayh-Dole Act has increased U-I and in turn the numbers of patents registered by American publicly financed institutions, this paper will argue that such a result is not possible to replicate in the current South African social and legal climate.

In doing so, the paper shall firstly provide background information on the IPR Act and its application to South African publicly funded research institutions, focusing (as the Act itself does) on publicly funded higher education institutions such as universities. Secondly, it will examine the apparent success of the Bayh-Dole Act regarding patenting among publicly financed universities.

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In assuming some degree of success, a sample of the many factors that have played a part therein of the Bayh-Dole Act shall be examined and held up against the South African environment. These will include both legal aspects, namely the differing patent registration frameworks, as well as socio-political considerations, namely the differing culture of higher education investment by government. In concluding, it shall be argued that the current South African socio-legal landscape does not at present provide a rich environment in which legislation like the Bayh-Dole Act can flourish with regards to increasing U-I to a similar degree.

University-industry collaboration

The aims of the Bayh-Dole Act and the IPR Act are generally considered to be the increased commercialisation of research outputs by publicly funded research institutions, with a particular (although by no means limited) focus on patents. That patents are at the heart of the IPR Act can be seen on page 8 of the Department of Science and Technology's IPR from Publicly Funded Research Framework (upon which the IPR Act is based), where express reference is made to America's Bayh-Dole Act and the need to create similar legislation with an aim to increasing patenting by publicly funded research institutions (such as universities):

"Globally many nations have established legislative and/or regulatory frameworks to ensure better practice and returns from IP. This process started with the United States in the mid 80's [...]. These changes are intended to provide a basis for higher levels of patenting to result from publicly financed research with the attendant potential for commercialisation or regulated public use. Such patents are used as a basis for licensing of the intellectual property, usually to businesses that use the IP to improve products and services, to create new businesses or to secure a basis to reduce costs of IP developed in other jurisdictions in strategic health research programmes for example."

Furthermore, in defining the scope for such a policy framework, the framework points out on page 9 and 10 that:

"The scope of this policy framework, and the intended legislation is focused on and limited to Intellectual Property, i.e. patents and intellectual property forms that are integrally linked to the patented invention, protecting inventions made through work financed by public research funding. It deals with issues of ownership, benefit-sharing from licensing and use of the patents and intellectual property forms that are integrally linked to the patented invention and accountabilities of different role-players in the system of innovation." [Not my emphasis]

This paper accepts that the main aims of both pieces of legislation are the increased commercialisation of research outputs by publicly funded research institutions and that this may take many forms (e.g. spin-offs, licensing agreements and so on). One way in which to achieve this aim maybe by encouraging U-I as a means of increasing patents granted solely or in part to publicly financed research institutions. Indeed, this has been an explicit objective of the Bayh-Dole Act, with Congress stating at the outset that the policy and objectives of the Act are to:

"[e]ncourage utilisation of research; to promote collaboration between commercial concerns and non-profit organizations including universities; to enhance the commercialisation and public availability of the inventions; to ensure that the Government obtains sufficient rights in federally supported inventions so as to meet the needs of the Government and protect the public against non-use or unreasonable use of inventions and to minimise the costs of administering policies in this area." [Emphasis added]

The IPR Act does not make any such express declaration regarding increasing U-I. According to section 2(1):

"*The object of this Act is to make provision that intellectual property emanating from publicly financed research and development is identified, protected, utilised and commercialised for the benefit of the people of the Republic, whether it be for a social, economic, military or any other benefit*."

The Act then proceeds to list additional express objects in section 2(2), such as ensuring that small enterprises and Broad-Based Black Economic Empowerment (BBBEE) entities, in particular, have preferential access to opportunities arising from the production of knowledge from publicly financed research and development and the attendant intellectual property. Although not one of

the express objectives of the IPR Act, the potential effect on U-I has clearly been a consideration in the legislative history of the IPR Act. As such, the question of what (if any) impact the IPR Act might have on U-I when compared with its American counterpart provides a solid and hitherto unexplored point of enquiry with regards to the wider implications of the IPR Act (and its potential limitations as applied to developing nations). In tracing said legislative history so as to evidence this common thread, one may go as far back as the original 1996 White Paper on Science and Technology, the objectives of which were stated as follows:

"*[This Paper] is based on a view of the future where all South Africans will enjoy an improved and sustainable quality of life, participate in a competitive economy by means of satisfying employment and share in a democratic culture.*"

It goes on to state that in order to obtain this vision, the following goal pertinent to the creative use and efficient management of innovation will have to be achieved:

"T*he establishment of an efficient, well co-ordinated and integrated system of technological and social innovation within which stakeholders can forge collaborative partnerships and interact creatively in order to benefit themselves and the nation at large.*"

To this end, the White Paper proposed the creation of an 'Innovation Fund' to take the lead among government agencies in encouraging and enabling innovation projects between U-I on a large scale. The proposed Innovation Fund was to have as one of its principal objectives – the promotion of 'increased networking and cross-sectoral collaboration within South Africa's national system of innovation'. This is because, as identified within the Paper:

"*Frameworks to promote linkages between universities, science, engineering and technology institutions (SETIs) and the private sector are needed with a view to sharing risks, resources and insights with respect to precompetitive research.*"

The Innovation Fund established by the White Paper laid the foundational framework for the 2008 IPR Act. This can be evidenced in a 2012 Ministerial Review on Science, Technology and Innovation, where the following is stated:

"*The operation of the Innovation Fund has been accompanied by its own innovations, such as institutional development involving staff capacity in intellectual property management, which laid the basis for the establishment of what is now the National Intellectual Property Management office (NIPMO), as well as the IPR capability of the new Technology Innovation Agency*."

This same Ministerial Review stressed that South Africa's aim to move to a knowledge-economy would require 'enhancing the interaction between business/industry and HEIs by strengthening and widening the incentive schemes operated by the DTI and TIA/DST' in order to increase the number of patents held by publicly financed research institutions. The Review moves on to state that, in order to 'move towards an economy driven by knowledge to a much greater extent than at present', it will require in respect of the business sector:

"*Much higher R&D expenditure by business/industry, probably as much as 50% more than at present. A greater degree of partnership between business/industry, and HEIs and science councils, representing the outsourcing rather than the performance of part or all of the R&D concerned*."

The 2008–2018 Innovation Plan - or 'Ten Year Plan' - created by the Department of Science and Technology proposed 'targeting R&D towards solutions to key development challenges, in order to mobilise and target resources and incite collaboration between researchers and other actors within the national innovation system'. The Innovation Plan also proposed the creation of a new agency, namely the Technology Innovation Agency (TIA). It was envisioned that the TIA would oversee the work of certain agencies, including the Innovation Fund, and establish a network of centres able to identify opportunities for collaboration between the private sector and public research entities (Brant, Sibanda, 2018: 1).

In 2006, the Department of Science and Technology published the IPR from Publicly Funded Research Framework, the framework within which the IPR Act was borne. That creating links and collaborative relationships with private industry was intended within this framework can be gathered by the listed benefits to public research organisations in the granting of rights generated from the use of public funds, which include the 'increased licensing and royalty revenues, more contract research and greater cross-fertilisation between entrepreneurial faculty and industry',

as well as 'the intangible benefits to an institution's reputation and to the quality of its research that closer interaction with the private sector can generate'. On these benefits, it is further stated within the framework:

"*In South Africa, within the National System of Innovation, businesses establish long-term partnerships with research councils and tertiary institutions. These positive and proactive relationships need to be incentivised and strengthened [...]. A key element of the capacity building will be the ongoing improvement in the quality of IP Management Offices at public research institutions. These IPMOs will perform essential functions in respect of the processing of invention disclosures, protecting patents, seeking commercial partners and monitoring the IP portfolios of their institutions and ensuring benefit sharing arrangements are in place and operational.*"

In conclusion, whilst U-I has not been expressly stated as a primary aim of the IPR Act (unlike with America's Bayh-Dole Act), the aforementioned legislative history has demonstrated that issues relating to U-I have permeated the political landscape from the inception of the IPR Act. It is therefore relevant and hitherto unexplored to consider whether South Africa's IPR Act might have the same supposedly positive effect on U-I as experienced by the Bayh-Dole Act. In answering said question, this paper will consider what the primary hurdles to achieving this may be. In doing so, there are multiple considerations that might be considered but which would be outside the potential scope for this particular article. As such, this paper chooses to focus on two factors that may be considered particularly pertinent in light of South Africa's recent socio-legal landscape, namely (a) the lack of substantive patent examinations, and (b) government investment in higher education.

The creation of the South African IPR from Publicly Financed Research and Development Act 51 of 2008 and its application to publicly financed higher education institutions

The IPR Act was borne of the 2002 National Research and Development Strategy which found that 'given the poor state of intellectual property protection', a need for the creation of new policy exists in order to 'reduce the financial barriers experienced by institutions when they secure intellectual property from publicly financed research'. According to the Innovation Fund's 2007 Special Report on the State of Patenting in South Africa, between the period of 1991 and 2005 South African publicly funded institutions accounted for a mere 4.37 percent of all patent applications. The Report concluded that there needs to be a drive towards establishing a 'culture of patenting' and the commercialisation of patents, particularly among publicly financed higher education institutions. In the IPR and Publicly Financed Research Policy Document from 2006, it is stated that '[p]atenting when established reflects a nation's research and development and industrial specialisation'. As such, the IPR Act was borne.

The IPR Act is applicable to intellectual property developed after the Act's commencement date (2nd August 2010) and created with the use of publicly financed research and development. The IPR Act defines intellectual property broadly as:

"*[A]ny creation of the mind that is capable of being protected by law from use by any other person, whether in terms of South African law or foreign intellectual property law, and includes any rights in such creation, but excludes copyrighted works such as a thesis, thesis, article, handbook or any other publication which, in the ordinary course of business, is associated with conventional academic work.*"

It should be noted that, whilst copyright works such as a thesis will be exempt from the Act, an invention that is the subject of the said thesis may still fall within the scope of the Act. The main focus of the IPR Act is on patents that have resulted from – as the title would suggest – public funds, and therefore its application is particularly pertinent with regards to publicly funded universities. These shall be the sole consideration of this paper, although it is not the sole research institution to be the recipient of public funds and thus effected by the IPR Act.

The IPR Act makes it compulsory for recipient institutions such as publicly funded universities to identify research outputs that could potentially be protected (primarily by way of patent registration), manage such research by way of applying for protection, and put in place mechanisms for the commercialisation of the intellectual property emanating from publicly financed research capable of being protected (sections 5–7). Per section 5(1)(b), this is to be done

before such research is made public (e.g. published in academic journals). Where an institution has failed to commercialise any intellectual property, it must report to the National Intellectual Property Management Office (NIPMO), with full reasons as to why this failure has occurred [section 5(1)(i)]. In such an event, the NIPMO will have the option of taking ownership of and registering a patent in its own name over said research [section 4(3)].

Delays experienced in bringing the Act into effect, creating the infrastructure for said Act (such as the NIPMO), the setting up of technology transfer offices in universities and so on has meant that, to date, there is a noted scarcity of information as to the IPR Act save for papers detailing its coming into effect and outlining the content of the Act. Literature as to the effect – if any – it is having within the higher education environment seems to be distinctly lacking, both from an academic perspective as well as from a political perspective. This means that the issue is still very much open for consideration as the Act remains to be 'tested', as it were. However, in April of 2017 the South African National Survey of Intellectual Property and Technology Transfer at Publicly Funded Research Institutions was produced by the Department of Science and Technology (DST), the Southern African Research and Innovation Management Association (SARIMA), the National Intellectual Property Management Office (NIPMO) and the Centre for Science, Technology and Innovation Indicators (CeSTII). This preliminary report is based on a survey sent out to all 'institutions' as defined in the IPR from Publicly Financed Research and Development Act (IPR Act), which are the 23 Higher Education Institutions (HEIs) and the 10 Schedule 1 institutions or Science Councils (SCs). Of the 24 institutions that responded, 23 indicated that they have either established a dedicated office of technology transfer (OTT), have dedicated TT individuals or are members of a regional office.

America's Bayh-Dole Act and its relative success

As the South African IPR Act has been based on the Bayh-Dole Act, it is pertinent to deal briefly with said legislation. Prior to 1980, American federal agencies maintained inconsistent policies as to whether recipients of research grants (such as publicly funded higher education institutions) could take title to inventions that sprung from federally funded projects (Hemel, Ouellette, 2017: 286). This uncertainty, as well as increases in the costs of bringing pharmaceuticals in particular to market, led Congress to pass the Bayh–Dole Act of 1980. As with the South African legislation, the Bayh-Dole Act placed an obligation on public higher education institutions to obtain a patent on inventions derived from state funding (for example, see: Balut, Moschini, 2009: 123; Eisenberg, 1996: 1684-95; Jaffe, Lerner, 2011: 1 - 24). Unlike the case of South Africa's IPR Act, the Bayh-Dole Act has generally been justified in terms of the so-called 'commercialisation theory' (for example, see: Moore, 2006: 155; *In re Roche Molecular Sys., Inc.*, 516 F.3d 1003 (Fed. Cir. 2008)*; *Board of Trustees of the Leland Stanford Junior University, Petitioner v Roche Molecular Systems, Inc., et al* 131 S. Ct. 2188 (SC); Sampat, Lichtenberg, 2011: 333), although there have recently been contending views. For example, Hemel and Ouellette (2017: 286) argue that the Bayh-Dole Act can be more convincingly justified in terms of what they call 'the internalisation theory'. Under this theory, foreign consumers benefit from the inventions generated by federally funded research at US universities and when foreign consumers pay for these patented inventions much of this money flows back to the United States.

Similarly, Ayre and Ouellette (2017: 271) argue that if commercialisation theory is the justification for Bayh–Dole patents, then universities ought to be required to license patents to the party willing to commit to commercialisation for the shortest period of exclusivity so as to minimise the welfare loss from higher prices. Eisenberg (1996: 1669) explains that the commercialisation theory focuses not on the initial costs of making an invention but rather 'the subsequent costs of developing an existing invention into a commercial product', based on the assumption that 'even after an invention has been made, further investment is necessary to refine it, test it, build the necessary facilities for production on a commercial scale, and find or create a market for it'. As such, the Bayh–Dole framework was intended to facilitate co-operation between university researchers and the private-sector firms capable of bringing the products of university

* *In re Roche Molecular Sys., Inc.*, 516 F.3d 1003 (Fed. Cir. 2008); *Board of Trustees of the Leland Stanford Junior University, Petitioner v Roche Molecular Systems, Inc., et al* 131 S. Ct. 2188 (SC).

research to market (Hemel, Ouellette, 2017: 286). To this end, the Bayh-Dole Act has seemingly been a success. In 1980 there were only 25 technology transfer offices, whereas in 2000 'virtually every U.S university had such an office' (Balut, Moschini, 2009: 125; Nelson, 2001: 13; Poyago-Theotoky et al., 2002: 10). There has been an overall increase in the number of public higher education institutions taking out patents, with the number rising from 30 universities in 1965 to 150 in 1992; a 15-fold increase in patenting and 5-fold increase in the number of universities granted patents between the years of 965 and 1992 (Balut, Moschini, 2009: 125; Henderson et al., 1998: 120). This has made the Bayh-Dole Act and its subsequent impact the subject of much economic debate (Balut, Moschini, 2009: 125; Henderson et al., 1998: 119; Jaffe, 2000: 531; Link et al., 2003: 1217; Mazzoleni, 2005: 499; Mazzoleni, Sampat, 2002: 234; Mowery et al., 2001: 99; Nelson, 2001: 13).

Whilst it would appear that the Bayh-Dole Act has been successful in that it has increased the amount of patenting taking place in publicly funded institutions such as universities, there has been a list of criticisms levelled against it. These include the effect on upstream technological development and the corresponding effect on downstream technological development (McManis, Yagi, 2014: 1050). By upstream innovation, what is meant is innovation that provides a basic-science research tool. In other words, as it is assumed that science and technological advancement is cumulative in nature (i.e. each new discovery relies on a body of discoveries that come before it), upstream innovation is a primary step towards the creation of further, downstream, patents (Bansi, Reddy, 2015: 185). Some of the other problems levelled at the Bayh-Dole Act have been that its policy is counterintuitive as it requires the public to pay twice for the same invention, namely once through the taxes used to fund such research, and again in the higher sales price and limited supply of the invention once it is sold to the public (Eisenberg, 1996: 1666; Mazzoloni, Sampat, 2002: 234). There is also the argument - arguably first put forth in the visionary 1945 article of Vannevar Bush - that public researchers are not incentivised to research for the sake of a profit motive, and therefore the traditional role of patenting (which is seen as a social cost endured in order to incentivise individuals to create) is absent (Bush, 1945: 1). This theory has since been the subject of much dispute (for example, see: Mazzoleni, Sampat, 2002: 246 – 247; Nelson, 2004: 455). Then there is the argument that whilst the number of university patents have risen since the introduction of the Bayh-Dole Act, the overall quality of such patents has drastically decreased. In other words, the aim of the Bayh-Dole Act is flawed in that it assumes all patents are created equally (Griliches, 1990: 1661; Henderson et al., 1998: 120; Jaffe, Lerner, 2011: 1 - 24; Link et al., 2003: 1223 - 1225; Sampat et al., 2003: 1371).

Whilst the above exhibits the fact that the Bayh-Dole Act's success is highly contentious within the American context, this paper will assume that the benefits outweigh the pitfalls, substantial or otherwise. The reason for doing this is two-fold. Firstly, it is to avoid dealing with the question of desirability regarding implanting foreign legislation, particularly from an economy as different as South Africa. Secondly, it is to provide as fair a comparison as possible between the two jurisdictions and ensure that said comparison is limited to a critique not of the legislation itself, but of the applicability therein. In other words, even if the Bayh-Dole Act was a Herculean piece of legislation, it would not – in the form of the IPR Act - yield similar results in terms of U-I in South Africa as it did in the United States because of the differing legal and political environments within which the Act would need to function. No law is free-standing; it must operate within a specific context. Where this context differs, so too will the applicability of said law.

South Africa's Patenting System

As a member of the World Intellectual Property Organisation (henceforth 'WIPO'), South Africa is required to uphold minimum standards of Intellectual Property protection as defined by the International Agreement on Trade-Related Aspects of IPR (henceforth 'TRIPS Agreement'). Under the TRIPS Agreement, South Africa is required to 'make patents [...] available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application' [Article 27(1)]. According to Article 29(1):

"*Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention*

known to the inventor at the filing date or, where priority is claimed, at the priority date of the application." [Emphasis added]

This is encapsulated in the 1978 South African Patent Act 57 of 1978 where, at section 25(1), it is stated that:

A patent may, subject to the provisions of this section, be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture. Regarding a substantive analysis of said patent, sections 25(5) and (6) combined state the following:

"*An invention shall be deemed to be new if it does not form part of the state of the art immediately before the priority date of that invention. The state of the art shall comprise all matter (whether a product, a process, information about either, or anything else) which has been made available to the public (whether in the Republic or elsewhere) by written or oral description, by use or in any other way*."

Read together, it is clear that both Article 27 and Article 29 of TRIPS could be taken to indicate that there ought to be in place a process by which the country in which the patent is being applied for can carry out an examination of the prior state of the art, as well as carry out the invention in order to test its applicability to industry and the nature of the disclosure made by the patentee. Without a patent examination, it is at least arguable that the standards set by Articles 27 and 29 cannot be said to have been met, albeit not to the degree of rendering said country non-TRIPS compliant. On paper, South Africa abides by these standards through the wording of its patent legislation much the same as the United States of America. That said, the similarities begin to end when the paper moves into practice.

In South Africa, unlike the United States of America, the process of filing a patent is purely procedural as the depository system for filing patents is utilised. In other words, the person or organisation filing the patent simply needs to fill in the correct forms and pay the said fees in order to receive a patent; there is no examination as to whether or not the product or process for which the application is being lodged in actual fact does meet the patentability criteria in terms of the TRIPS Agreement and in turn the South African Patent Act. Therefore, due to the lack of consideration to the substantive aspects of the patent application, it has been suggested that the majority of patents granted in South Africa fail to meet South Africa's patentability standards per section 25 (Pouris, Pouris, 2011: 1). As the TRIPS Agreement provides minimum standards for all signatories, failure to abide by its standards puts a country at a sub-standard level regarding patent protection, operating a patenting system that is below the standards of comparative economies.

In addition to the above, this lack of patent examination means there is no reliable way in which the substantive value of the patents being registered can be garnered. If registering a patent is a simple procedural step with no substantive enquiry or examination, this means that every completed application will be granted, therefore the quality of the patents being registered is dubious. Indeed, studies done as to the sheer quantity of patents granted in South Africa compared to other jurisdictions would seem to indicate this. For example, one study found that in Argentina 951 pharmaceutical patents were granted in 2000-2007; in Brazil, 278 patents were granted in 2003–2008; in Colombia 439 patents were granted in 2004–2008; in India 2347 patents were granted in 2005–2008; and in South Africa, 2442 patents were registered in 2008 (Correa, 2011: 1; Iskander, 2013: 95; Yale Global Health Justice Partnership, 2018: 1). While the time periods which are compared vary, the fact that South Africa granted more than double in a single year what any of the others did over a number of years speaks volumes. That this was down to the lack of a substantive examination procedure is supported by the fact that, between 2000 and 2002, South Africa granted 66 % more pharmaceutical patents than the United States of America and the European Union on identical patent applications (Tomlinson et al., 2015: 741). In 2014, the most South Africa granted two-thirds of the patent applications it received, with a grant rate seven times that of Brazil, almost five times that of India, and nearly triple that of China during the same period (Yale Global Health Justice Partnership 2018: 1). Of course, this does not mean that each and every patent granted does not meet international standards. It does, however, mean that, unless challenged in court, the quality of a patent remains uncertain and therefore there is a higher likelihood of more 'unworthy' patents within the system than if substantive patent examinations were to be put into place.

One of the criticisms levelled against the Bayh-Dole Act is that it has led to an increase in the volume of patents but a decrease in the quality of patents being registered (Griliches, 1990: 1661; Henderson et al., 1998; Jaffe, Lerner 2011: 11–12; Link et al., 2003: 1223–1225; Sampat et al., 2003: 1371). With this in mind, such criticism would seem to be particularly pertinent to South Africa as the quality of patents registered is compromised by the lack of a substantive examination process. Of course, that is not to say that there are no issues regarding the quality of patents granted in areas where there is a substantive examination therein. For example, a recent report made intellectual property news when, during a visit of the new Chair of the EPO Administrative Board to the Max Planck Institute for Innovation and Entrepreneurship Research in Munich, a group of patent attorneys lambasted what they believed to be 'the deteriorating quality of patent examination at the European Patent Office as a result of the overworking of patent examiners' (Schestowitz, 2017: 1). However, there can be no doubt that not having any examination procedure necessarily compromises the quality of all patent applications that have not had their voracity tested by the judiciary. This can be seen in the case of Bristol-Myers Squibb (BMS), who are the original manufacturers of entecavir, a drug used to cure Hepatitis B. Whilst the initial patent on entecavir expired in 2011, South Africa proceeded to grant three additional patents on entecavir that only expire between 2022 and 2026, while the third patent covers the process by which entecavir is manufactured (Fix The Patent Laws, 2014: 1). BMS had attempted to similarly evergreen its drug in the United States by filing for an identical patent to the one in South Africa pertaining to the process by which the drug is manufactured. However, this patent was subsequently overturned, with the decision on invalidity confirmed by the United States Court of Appeal in *Bristol-Myers Squibb Company v Teva Pharmaceuticals USA* No 13-1306 (United States Court of Appeals for the Federal Circuit, 2014) due to the obvious nature or lack of inventive step of said patent. The content of this patent has not been contested within South Africa, and as such BMS shall maintain its monopoly until such time as this is challenged in a court of law, should such a time ever come.

Whilst the lack of an examination procedure is undoubtedly troubling, the reasons for utilising a depository rather than substantive examination procedure is understandable (and perhaps arguably justifiable). Few developing nations conduct any form of substantive patent examination, mainly due to a lack of capacities and resources (Commission on Intellectual Property Rights, 2002: 1). Indeed, patent applications may contain many pages of technical data covering a wide array of technology fields, and substantive examination involves both professional/technical competence as well as access to the international patent information computer databases. All of this requires resources, both in terms of humans with the required expertise in said fields, as well as technical such as reliable access to efficient technology. While these challenges faced by developing countries have been well documented in academic literature spanning many years, few have offered meaningful solutions to the immediate problems posed by the absence of an examination procedure (for example, see: Commission on Intellectual Property Rights, 2002: 1; Deere, 2008: 314 – 320; Free Market Foundation, 2017:1; Pager, 2007: 755; United States Agency for International Development, 2003: 1; Tvedt, 2010: 277).

It should be noted that there has been a push to drastically change South Africa's IP framework in general, including patents, which has yielded very recent and ongoing developments. On 24 May 2018, Cabinet released a statement approving the new Intellectual Property Policy Framework. The Intellectual Property Policy of the Republic of South Africa Phase I 2018 (henceforth 'IP Policy') in section 7.1 highlights the government's commitment to the rolling-out substantive examination of patent applications at a national level to replace its current depository system. The government itself acknowledges on page 17 that, without substantive examinations, patents as a measure of innovation are less than ideal:

"*The introduction of SSE will result in greater legal certainty for patent owners and ensure that the public interest is served by ensuring that the patent system truly promotes innovation. It is crucial to work toward the adoption of SSE. The underlying policy rationale of patents is to serve as an incentive to stimulate innovation, and SSE is a key tool to ensure this objective is met.*"

However, the commitment to incrementally introducing substantive examinations of patent applications appears to be limited from the outset. The government makes it clear that it does not intend for all patents to receive substantive examinations; much time in the IP Policy is spent

justifying the approach of only intending to introduce substantive examinations for patents in a few 'strategic sectors', and abating any concerns this will doubtlessly create among various stakeholders. This can be seen on page 18, where the following is stated:

"*[C]oncerns expressed by some stakeholders that patent applications in only one field of technology (namely pharmaceuticals) will be subject to full substantive examination are misplaced. The intention is to identify a range of strategic sectors for full SSE, including and beyond the health sphere, based on capacity within government, as well as development and public interest considerations […]. The SSE Guidelines, to be developed in due course, pursuant to extensive consultations, will detail the precise modalities*."

Also on page 18, the IP Policy seeks to justify the government's selective approach to substantive examinations of patents by arguing that:

"*[I]t has previously been determined in the WTO dispute settlement process that Article 27.1 of the TRIPS Agreement permits differentiation among fields of technology for legitimate reasons, which would naturally include assessing patent applications for different subject matter areas in a manner appropriate to those areas*."

The sole reference to support this argument put forward by the South African government in their IP Policy is to be found on page 18 in footnote 13 to the case of *Canada – Patent Protection for Pharmaceutical Products*, WT/DS114/R, which – as shall be discussed - is itself a weak source upon which to claim such an interpretation. This is a long and complicated case that covers a host of complex claims, but the IP Policy provides a pinpoint reference to paragraph 7.94 in its footnote, and therefore relates to one claim, in particular, namely the challenge lodged by the European Communities against section 55(2)(1) of the Canadian Patent Act. This section of the Canadian Act, known as the 'regulatory review exception', stated the following:

"*It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires*."

The European Communities alleged that this section of the Canadian Patent Act, by treating patent holders in the field of pharmaceutical inventions less favourably than inventions in all other fields of technology, violated its obligations under Article 27(1) of the TRIPS Agreement requiring patents to be available and patent rights enjoyable without discrimination as to the field of technology (para 7.94). The European Communities acknowledged that the words of the regulatory review exception of section 55(2)(1) did not limit its application to pharmaceutical products (para 7.95). However, they alleged that there was *de jure* discrimination against pharmaceuticals because these were the only products mentioned in Canada's 1991 legislative debates on the enactment of section 55(2)(1) (para 7.96). The Panel rejected this claim as it is trite that the legislative history does not confine the scope of the law itself once enacted, and there was nothing in the wording of the exception to justify such a limited interpretation (para 7.99). Furthermore, Canada had issued a formal declaration to the Panel that this exception was not intended to be limited to pharmaceutical inventions (para 7.99). In the alternative, the European Communities argued *de facto* discrimination in that the actual effects of section 55(2)(1) were limited to pharmaceutical producers (para 7.96). This was also rejected by the Panel as the European Communities could not provide any evidence as to the range of industries making use of section 55(2)(1), nor could it point to any practical considerations that would limit the scope of the section's application to the pharmaceutical industry (para 7.102). For these reasons, the Panel found there to be insufficient evidence provided by the European Communities to prove discrimination, either *de jure* or *de facto*, according to Article 27.

It is therefore submitted that instead of this case bolstering the claim that only providing substantive examinations of patents to a few choice areas would not conflict with Article 27(1) as it does not amount to discrimination, the case, in fact, leaves the door open for the alternative interpretation of Article 27. Had it been proven that Canada's regulatory review exception had either in interpretation or in effect been limited to pharmaceutical inventions, the Panel would surely have found there to be discrimination; whether or not they would have found said discrimination to be justified was never addressed as it was not necessary on the facts of the case. This alternative interpretation of the case is damning in light of its being the sole source upon which the IP Policy relies. For the areas that are not to be afforded substantive examinations in

South Africa, the above arguments relating to Article 27 will still hold true. For the areas that are granted substantive examinations, a comparator between South Africa and the United States will be limited in scope and many years into the future if one is to have enough reliable data from which to make any claims.

In examining the differing patent systems, various conclusions can be drawn. Firstly, because South Africa has and still does follow a depository system of patenting (and intends to continue doing so, at least for some industries), South Africa fails to meet the minimum standards used at an international level regarding the granting of patents. As stated above, it is arguable that as a result of patents being granted without any qualitative analysis, issues such as evergreening, duplicate patenting, patents being granted to various patentees and more have a higher likelihood to occur as well as go by unchecked until such a time as it is challenged in court (which itself gives rise to numerous access to justice issues beyond the scope of said paper). These limitations have been acknowledged by the government itself in its IP Policy. It, therefore, seems nonsensical to discuss patents as a marker for economic growth within this context in such a way as the IPR Act presupposes. Indeed, if the granting of a patent merely requires the filling in of paperwork and payment of a fee, then increasing the number of patents filed by higher education institutions would seem less an exercise in U-I and more an exercise in cutting administrative costs. Until South Africa adopts a substantive examination of patents filed prior to making a decision on whether or not to grant the application, there can be no meaningful dialogue about mechanisms for increasing the state of university research and resulting patents, and any such dialogue will at best be premature. Additionally, the conservative approach toward rolling in an examination procedure ought to be revisited in favour of a broader, more encompassing approach in light of the lack of evidence provided to support such a claim.

Government Investment in Higher Education Prior to Bayh-Dole legislation

The IPR Act seeks to regulate research that has been publicly funded. Whilst broad, the primary bodies effected by this legislation will be publicly funded universities within South Africa. This necessarily leads to the question of whether or not the IPR Act will encourage U-I in such a way that businesses will be enticed into investing resources in universities as an additional income stream. This was both a central aim of the American Bayh-Dole Act, as well as being an indirect rationale for the creation of the South African IPR Act.

Arguably, the Bayh-Dole Act has been successful in encouraging U-I. Whilst this is contentious, the majority of the literature would seem to favour such an interpretation of the legislation's effect. However, the legislation was created within a specific higher education environment which simply does not exist within South Africa. Looking at budget data available online from the United States Government Printing Office on government spending as a percentage of gross domestic product (GDP), it is clear that the United States had historically taken a much more 'investment-minded' approach to higher education in the post-war era. In 1950, spending was 0.37 percent of GDP on higher education, but this increased incrementally until, in the 1970s, higher education spending was 1.44 percent of GDP. In other words, during the three decades that preceded the creation of the Bayh-Dole Act, government spending as a percentage of GDP had just about quadrupled (US Government Spending: 1). The background had been laid in which legislation to the effect of Bayh-Dole, which sought to encourage businesses to invest in collaborative research projects with universities, could have the maximum chance of success as these higher education institutions had, for decades, been able to foster their own research culture through government funding with which to attract industry investment.

Compare the above with the situation in South Africa post-democracy (by which it is meant the creation of the Constitution of the Republic of South Africa 1996 – which marked the official end to apartheid – to the present day). According to statistics and numbers available from the Council on Higher Education and Training (2016: 1), government spending as a percentage of GDP has been declining over the years, from 0.95 percent of GDP in 2006/7 to 0.92 percent in 2008/9 and 0.76 percent in 2010/11. For 2012, spending on higher education was lower than other comparable countries such as Ghana, Chile, Senegal and India (Universities South Africa, 2016: 1). According to a 2006 Research Report for the Council on Higher Education, expenditure for 2001 on higher education as a percentage of GDP from the South African government was lower than the average value of 84 countries within the same year and the average value of 15 African states.

According to the Organisation for Economic Co-operation and Development's 2003 report, the average public spending on higher education as a percentage of GDP for 29 OECD countries in 2000 was 0.90 percent; South Africa fell well below this average, with a spend of 0.70 percent (OECD, 2003: 1). By contrast, the same source cites the United States as spending the highest percentage of GDP on higher education in the same period. This trend has continued to present day, with 0.7 percent of South Africa's GDP going to higher education in 2017 as opposed to an average of 1.3 percent in OECD countries and 1.1 percent in G20 countries (OECD, 2018: 1). Unlike in the United States, the South African government does not have a history of investing in higher education. As such, business investment in South Africa is and has been very low: if two-thirds of the unrestricted revenue comes from the government, and 30 to 40 percent comes from student fees, this leaves a paltry sum coming in from corporate investment (Universities South Africa, 2016:1).

The link between U-I and patents has been well-established, although it has not gone unchallenged. Most recently, the voracity of using such a link was questioned by Sterzi et al. (2019: 309). The authors undertook a longitudinal sample of Italian academic patents assigned either to universities or firms, and found that the lower value of university-owned patents versus firm-owned ones could be owing to lower technological importance of the inventions (i.e. the limited relevance or originality of the academic inventions that form part of universities' portfolios) and less effective exploitation of the related patents (i.e. the universities' lack of managerial and specialised skills in the managing and efficient use or commercialisation of patents within their portfolios). The authors argued that caution should be taken in pushing universities to expand their portfolio of patents and in using university-owned patents as indicators of wider technology-transfer activities.

However, the link between the two has been largely supported by writers and data alike. For example, in Japan the Act on the Promotion of Technology Transfers from Universities to Private Industries 1998 has seen the number of joint research projects nearly double, as well as the number of patents registered by Japanese publicly-funded higher education institutions rising sharply from 918 in 2003 to 5033 in 2009 (Japanese Ministry of Education, Culture, Sports, Science and Technology, 2010: 1; Motohashi, Muramatsu, 2012: 149 - 162). A study conducted by the World Bank of Chile and Colombia showed that collaboration with universities substantially increased the propensity of firms to introduce new products and to patent, as well as finding that 'collaboration with universities could increase the probability of patent activity in the firm by 37 percent or the probability of introducing a new product by 29 percent' (Marotta et al., 2007: 1). A study done by Balconi and Laboranti used patent data (particularly, the number of EPO and USPTO patents assigned to firms and comprising a university professor of electronics among the inventors) as an indicator of collaboration, to measure the extent and intensity of the ties of academic with industrial researchers. It found that strong U-I connections are associated with high scientific performance evidenced by way of resulting patents (2006: 1616).

At both national and sub-national levels support for university-industry linkages is presented as a means to achieve two objectives simultaneously: (a) facilitate technology transfer and increase technological intensity at the firm level; (b) create incentives for university research to address relevant practical problems, generating market value. This includes increasing the number of patents where at least one inventor is listed as a university. Regarding the question of whether a lack of U-I is problematic in terms of commercialising IP by higher education institutions, the 2018 study by Frederick R. Bezuidenhout sheds light on the current barriers to commercialisation within South Africa. His study found that, through analysing the mean values of each factor (which included interviews with stakeholders, literature review, and questionnaires), the top four measured factors that hindered commercialisation of IP in the public sector were university red tape, funding barriers, entrepreneurial orientation, and U-I disconnect. Of the four themes, U-I measured the highest when the interview, questionnaire, and literature data were considered and was therefore identified as the greatest perceived barrier. Bezuidenhout himself states this finding is in direct contrast with similar studies done in America, which indicated that U.S. TTOs in 1980 achieved success stories in closing the gap between university and industry. This might be an indication that U-I relationships was a relevant topic in the 1980s and still remains to be relevant within the context of commercialisation today.

What the above summations seek to display is that the South Africa government's investment in higher education is below comparable international standards. South African universities are and historically have been reliant on state support and student fees as a means of financial revenue, with corporate investment playing at best a minor role. In order to change this, universities need to find ways of attracting private industry to invest in them, and this can only be done by promulgating a research culture within which industry can see the potential value. The data relating to low levels of GDP directed towards higher education highlights the underfunding of higher education institutions both before the creation (2008) and after the bringing into effect (2010) of the IPR Act serves to evidence why such a research culture is not financially viable, yet it is – as per the example of the United States – a foundational truth for such legislation to operate successfully in terms of fostering U-I. The correlation between the need for government spending on higher education for the creation of a higher education research culture within which private industry wish to invest in cannot be underestimated, nor can it be replaced with legislative initiatives such as the IPR Act. South Africa has been plagued by violent student protests about, among other things, the need for greater government investment in higher education. In response, various political interest groups have called for the corporate sector to make up the shortfall, either voluntarily or by a legislative intervention (see the following news reports: Biz News, 2015: 1; ENCA, 2015: 1; HTXT, 2016: 1; Politics Web, 2016: 1). Indeed, beyond an increase in patenting activity, increased investment by the government today might result in both a financial relief for the state coffers and an additional source of revenue for universities in the long-run (not to mention addressing issues of escalating student fees and such similar results of the current *status quo*). While South Africa does not and will never have the long history of investment in higher education that the United States does, this is no reason why the current government cannot create such a culture and therefore improve the educational - as well as economic - environment in the years to come.

Conclusion

It has been shown that, for both legal as well as policy reasons, the IPR Act is unable to replicate the (somewhat controversial) success it has seen in the American environment as the Bayh-Dole Act with regards to increasing U-I, at least for the immediate future. The long-standing pre-Act history of the United States investing heavily in higher education as a percentage of GDP means that the political landscape and university research culture within which the legislation was to operate was already one in which the Act could prove fruitful. In South Africa, the pre-Act and present-day investment by government in higher education institutions have not only been on an ever-declining level, but it has also dipped below comparative standards on an international scale. In addition to the political environment, patent legislation must operate within the said jurisdiction's legal framework. In the United States, it has been the long-standing position that substantive examination is required prior to the decision on whether or not to grant an application for a patent, which means that the value of said patents can be attested to, both inherently according to internationally recognised standards, and economically. In South Africa the depository system whereby every application will be granted if it is filled in correctly and fees are paid means that any discussion about the importance of patents as a measure for innovation or economic growth is at best premature by at least a decade or more, depending on when substantive examinations are to be introduced by the South African government and limited to whichever industries the government chooses to apply the procedure to. A patent within the current depository system is merely an empty vessel until the content therein is attested to by a substantive examination that can be held up to international standards, and even then there will many more years before comparable data can be accumulated in order to make such a comparison. For these reasons, until there is drastic reform within the South African environment that is proven to be both sustainable and positive, it will be impossible for the IPR Act to garner the same level of success with regards to U-I as its American counterpart.

Conflict of interest

This author declares no financial conflicts of interest.

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