

6 THE IMPACT OF INTELLECTUAL PROPERTY RIGHTS PROTECTION BY PUBLICLY-FINANCED RESEARCH INSTITUTIONS ON CLINICAL RESEARCH: LESSONS FROM SOUTH AFRICA

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ABSTRACT

South Africa's newly enacted Intellectual Property Rights from Publicly Financed Research and Development Act (hereinafter IPR Act)¹ came into force on 2 August 2010. It aims to ensure that the intellectual property right outcomes of publicly-financed research and development (*R & D*) are protected and commercialized for the benefit of the people of South Africa. Benefits envisaged in the Act include social, economic, and military or some other benefit. The Act, which has used Bayh-Dole-style legislation², has far-reaching effects on health research, particularly on data sharing, which is considered essential for expedited translation of clinical research results into knowledge, products, and procedures to improve human health. This notwithstanding, researchers often face difficulties in obtaining their colleagues' permission in sharing data. This paper highlights concerns about intellectual property (IP) protection by Publicly-Financed Research Institutions (PFRIs) and how South Africa's IPR Act has dealt with these concerns.

Keywords: *clinical research, data sharing, health research, intellectual property, publicly-financed research institutions*

I. INTRODUCTION

Stakeholders in the clinical research industry, particularly in developing African countries, must contend with complex issues relating to data sharing. These complexities may arise from diverse institutional policies. Furthermore, dealing with multiple patent holders can result in difficult, protracted and costly negotiations.³ A recent report established that there is a general lack of awareness and sufficiently deep understanding of intellectual property rights on the part of investigators, which can stifle the vital dissemination of science.⁴ According to the report, 'IPR is often cited as a reason why results cannot be disseminated, resulting in a potential conflict between the principle of sharing data and a system that supports wealth-creation by protecting intellectual property.'⁵ The usual expectation that the initial investigators may benefit from first and continuing use, but not from prolonged exclusive use, may not

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¹ Act No. 51, 2008.

² The Policy Framework document, on which the legislation is based, specifically mentions the need to base the legislation on best global practice and refers to the Bayh-Dole Act. See Department of Science and Technology, *Intellectual Property Rights (IPR) from Publicly Financed Research Policy Document*, (July 2006), page 9.

³ The European Science Foundation, *Forward Look – Investigator-Driven Clinical Trials*, (2009). Available online at http://www.esf.org/fileadmin/links/EMRC/FL_IDCT.pdf accessed on 23 September 2011.

⁴ *ibid.*

⁵ *ibid.*, page 10

always be met, particularly at the breakthrough stage, when any outcomes must be kept confidential at least until patent applications are filed.⁶

The pharmaceutical sector is widely noted to be knowledge intensive and sensitive to intellectual property rights. Equally, it has unusual prominence in the debate over IP policy, especially the relationship between intellectual property rights, *R & D* incentives, pricing and access to medicines.⁷ All these issues are directly affected by access to clinical research data, which eventually impacts product development.

The South African IPR Act provides a legal framework that aims to foster IP management. It has been correctly argued that legal frameworks governing technology transfer between publicly-funded biomedical research institutions and commercial entities play a significant role in shaping competition.⁸ It is against this background that this paper critically reviews the impact of the South African IPR Act. Since the Act is relatively new, this paper will aim to consider the extent to which it has dealt with relevant ongoing debates and, further, to isolate lessons that policymakers and researchers from other jurisdictions can learn from the South African experience.

II. CONCERNS ABOUT INTELLECTUAL PROPERTY PROTECTION BY PUBLICLY-FINANCED RESEARCH INSTITUTIONS

Publicly-financed research institutions (PFRIs) in South Africa consist largely of higher-education institutions and statutory science councils or research institutes. These PFRIs also form the largest concentration of skills and personnel in the area of science and technology in South Africa.⁹

It is important to note that South Africa is a severely skill-constrained society.¹⁰ Perhaps this explains the reason for the government's legislative intervention in this area. Another reason driving the intervention is that the South African National Research and Development Strategy identified the lack of a policy framework in relation to intellectual property arising from public funds allocated to research as a concern.¹¹ Kaplan observes that the strategy focussed more on publicly-financed research without focussing on the totality of the wider IP system or its economic and social impacts.¹² This limited focus is a real concern in view of the fact that research has established that most PFRIs lack the infrastructure to manage

⁶ Georges S Shemdoe, 'Introduction to Intellectual Property Rights for Investigators in Health Research and Institutional Intellectual Property Policy' (2009) 112S *ActaTropica* S80.

⁷ 'The Economics of Intellectual Property: Suggestions for Further Research in Developing Countries and Countries with Economies in Transition' (WIPO January 2009), page 169.

⁸ *ibid.*, page 150.

⁹ M Sibanda, 'Intellectual Property, Commercialization and Institutional Arrangements at South African Publicly Financed Research Institutions', in D. Kaplan (ed), *The Economics of Intellectual Property in South Africa* (WIPO 2009), pp. 113 to 114.

¹⁰ BS Javorcik, 'The Composition of Foreign Direct Investment and Protection of Intellectual Property Rights: Evidence from Transition Economies' (2002) 48 *European Economic Review* 39, cited in D Kaplan, *Intellectual Property Rights and Innovation in South Africa: A Framework* in D Kaplan (ed) (WIPO 2009), pp. 3 to 4.

¹¹ D Kaplan, 'Intellectual Property Rights and Innovation in South Africa: A Framework' in D Kaplan (ed) *The Economics of Intellectual Property in South Africa* (WIPO, 2009), page 13.

¹² *ibid.*

the process of invention disclosures, filing of patent applications, technology transfer and relevant policies for IP issues.¹³

The PFRIs are notably characterized by low patenting activity coupled with low conversions to licences and or products.¹⁴ As will be demonstrated in this paper, the IPR Act can be a catalyst for product development as it provides some policy guidelines for harnessing knowledge and fostering product development. This is because the IPR Act aims at ‘improved quality of patenting and higher conversion of patents to licences and/or products and services’¹⁵ The Act is a vast improvement compared to the Bill that was initially published for public comments. Visser, for instance, graphically described the Bill as paving the path to research hell with the best intentions!¹⁶ Visser’s well-founded arguments in support of his description of the Bill centred on the fact that its exclusive focus on patents and the inclusion of other types of intellectual property rights, only if they form an integral part of the invention, were rather obscure.¹⁷ Other critics also noted that the initial draft of the legislation was ‘extremely stringent and restrictive as it limited the right to publish any research results until the patent potential of the research had been established’.¹⁸

The relevant intellectual property rights that impact product development are copyright in supporting publications and material, trademark protection of brands and administrative mechanisms or *sui generis* provisions giving proprietary rights in clinical and manufacturing data used to support regulatory approval.¹⁹ These intellectual property rights show a clear link between clinical research data sharing and product development. For instance, conducting independent clinical trials while a patent is still in force may or may not be covered by research exemption and this certainly has an effect on the speed with which generics enter the market and the intensity of generic competition.²⁰ It has equally been noted that data exclusivity limits the ability of local generic manufacturers to enter the market as they are required to undertake their own clinical tests which can be time-consuming and costly.²¹ Current literature, however, shows that ‘many pharmaceutical and biotechnology companies acknowledge sublicensing to generic producers as a socially responsible and financially viable method to supply medicines to low-margin developing world markets.’²²

The two normative facets for the economic justification of patenting by universities are commercialization and public interest justification.²³ These raise a number of concerns:

¹³ Sibanda (note 9), page 129.

¹⁴ *ibid.*, page 140.

¹⁵ *ibid.*, page 141.

¹⁶ Coenraad Visser, ‘Intellectual Property Rights from Publicly Financed Research: the Way to Research Hell is Paved with Good Intentions’ (2007) 19(3) *SA Mercantile Law Journal* 363, page 371

¹⁷ *ibid.*, page 365.

¹⁸ Eve Gray, Position Paper 2: National Environmental Scan of South African Scholarly Publishing, The Centre of Educational Technology, University of Cape Town (April, 2009), page 21.

¹⁹ WIPO (note 7), page 152.

²⁰ *ibid.*, page 153.

²¹ *ibid.*, page 177.

²² CE Chen, et al., ‘The Silent Epidemic of Exclusive University Licensing Policies on Compounds for Neglected Diseases and Beyond’ (2010) 4(3) *PLoS Negl Trop Dis*.

²³ WIPO (note 7), page 182.

Researchers consider their data proprietary

Data is thus deemed to provide researchers ‘with a competitive advantage over other groups in terms of discovery and further acquisition of funds that would expand their research operations’ and failure to share may lead to duplication of efforts and high costs of research.²⁴ This concern is directly related to the item below.

Protection of upstream research makes follow-on research costly

This point is debatable since studies have shown no strong evidence of anti-commons trends or significant foreclosure of public science in research fields where university patenting is significant.²⁵

The available evidence is currently more focussed on developed countries’ experience. The issue is relevant, however, in the context of countries such as South Africa where, as noted earlier, the *R & D* strategy has not focussed on the totality of the wider IP system or its economic and social impacts. There are unique concerns in Africa, which were highlighted during the first African Data Curation Conference.²⁶ Three concerns most relevant to this paper are worth mentioning here²⁷:

- Lack of information sharing and guarding of publicly-funded data from the general public;
- over-restrictive intellectual property regulations and laws that disregarded the potential benefits of data use and reuse among the public; and
- poor management practices and infrastructure and/or the deliberate attempt to conceal or destroy data for various reasons.

Experience from the University of Cape Town’s computational biology group, for instance, shows that researchers tend to share data only with collaborators since patient data is private.²⁸ The International Council for Science, Regional Office for Africa also noted that the key problems facing scientific data in Africa are restricted funding for research, which leads to a limited scale of data collection, protected knowledge and information, as well as data ownership and protection – all intellectual property right issues.²⁹ South Africa is not immune to these problems, insofar as it faces ‘challenges of accessibility to research data, and ... lack of funding

²⁴ EC Ad Carvalho, et al., 'Application Description and Policy Model in Collaborative Environment for Sharing of Information on Epidemiological and Clinical Research Data Sets' (2010) 5(2) *PLoS ONE*.

²⁵ WIPO (note 7), page 194.

²⁶ First African Digital Management and Curation Conference and Workshop, Pretoria, 12-13 February 2008, available online at: <http://stardata.nrf.ac.za/nadicc/programme.html> accessed 26 September 2011.

²⁷ Academy of Science of South Africa, 'First African Digital Curation Conference: A Resounding Success', (2008) 1(1) *Science for Society* 13 (Pretoria), page 14.

²⁸ Nicky Mulder, 'Data curation and management activities within the UCT [University of Cape Town] Computational Biology Group', First African Digital Management and Curation Conference and Workshop, Pretoria, 12-13 February 2008.

²⁹ Achuo Enow, 'State of Scientific Data in Africa', First African Digital Management and Curation Conference and Workshop, Pretoria, 12-13 February 2008.

criteria and agreements.³⁰ The strategy South Africa chooses to manage intellectual property rights from PFRIs must thus address these problems.

The *R & D* expenditure trends in South Africa could equally make the experience with Bayh-Dole-style legislation (based on the US Bayh-Dole Act, 1980) different. For instance, in 2001/2002, *R & D* expenditure by business enterprise amounted to approximately R 4 billion, while the government's approximate expenditure amounted to R 1.5 billion. The relevant figures for 2008/2009 were R 12 billion by business enterprises and R 4 billion by the government.³¹ This is in stark contrast to the situation in the United States, where in 2002 federal research funding was 61 per cent, while industry contribution was 9 per cent.³² The trend in the United States in 2009 was 62 per cent federal contribution and 7 per cent industry contribution.³³ In comparing the funding trends between the two countries based on 2002 surveys, Heher correctly argues that such a 'funding pattern has implications for IP generation and ownership, as well, and is an example of the differences that need to be considered when making projections based on international benchmarks.'³⁴ South Africa's *R & D* strategy should have considered the proportion between government and industry expenditure on *R & D* for the purpose of ensuring that the new legislation leads to more commercialization of research from PFRIs.

*Countries that have used Bayh-Dole-style legislation have weak provisions for safeguarding public access to publicly supported medicines*³⁵

Reviewers of the Bayh-Dole Act have noted that it 'has been much less successful at producing public goods for health.'³⁶ So, et al. have, for instance, pointed out that 'claims favouring Bayh-Dole-type initiatives overstate the Act's contributions to growth in US innovation.'³⁷

³⁰ Mosibudi Mangena, Minister of Science and Technology, South Africa, 'The Implications of the OECD Declaration on Open Access to Scientific Data for African and Specifically South African Policy on Research Data and Information Management and Curation', First African Digital Management and Curation Conference and Workshop, Pretoria, 12-13 February 2008.

³¹ South African Science and Technology Indicators 2010, produced by the National Advisory Council on Innovation Indicators Reference Group, page 26, available online at: <http://www.nacinnovation.biz/wp-content/uploads/South-African-Science-and-Technology-Indicators-2010.pdf> accessed 29 September 2011.

³² Association of University Technology Managers (AUTUM), US Licensing Activity Survey Highlights: FY 2002, cited in AD. Heher, 'Benchmarking of Technology Transfer Offices and What It Means for Developing Countries' in A. Krattiger, et al. (eds) *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (MIHR: Oxford, United Kingdom, and PIPRA: Davis, United States, 2007).

³³ AUTUM, US Licensing Activity Survey Highlights: FY 2009, available online at: <http://www.autm.net/AM/Template.cfm?Section=Documents&Template=/CM/ContentDisplay.cfm&ContentID=5880> accessed 27 September 2011.

³⁴ Heher (note 32), page 215.

³⁵ Chen CE, et al., note 22.

³⁶ RA Nugent and GT Keusch, 'Global Health: Lessons from Bayh-Dole', in A. Krattiger, et al. (eds.), *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (MIHR: Oxford UK and PIPRA: Davis, US, 2007), page 153.

³⁷ AD So, et al., 'Is Bayh-Dole Good for Developing Countries? Lessons From the US Experience' (2008) *PLoS Bio* 16 (10).

It can be argued that the South African Act has attempted to incorporate provisions that can be used to safeguard public interests in health research specifically through the inclusion of government walk-in rights, which are discussed in this paper. This style of safeguarding public interests is a lesson that other jurisdictions can learn from South Africa.

Patenting could penalize institutions with weaker bargaining power

Patenting is becoming important for its bargaining power in facilitating the exchange and sharing of protected tools and materials.³⁸ This is true insofar as the IPR regime is viewed as 'increasingly high-protectionist' such that legislative remedies 'cannot resolve the major obstacles to the open availability and exchange of scientific data heretofore in the public domain'.³⁹ In this regard, Reichman and Uhlir have contended that the scientific community 'can and should assert greater control over the management of its own data supplies'.⁴⁰ Consequently, the appropriate strategies for asserting control over the data supplies need to be explored and scientists need guidance on best practices for IP management.

Patenting has potential harmful effects

Patenting can lead to prohibitive costs of access to databases, materials and research tools. Other technology transfer mechanisms, such as publications, conferences, informal interaction with researchers and consulting may also suffer. The underlying argument here is that university patenting may become an important currency in the global scientific college but the currency may be expensive for individuals and institutions that traditionally hold a weak bargaining position.⁴¹

Possibility of low-quality patents being granted

There is a need to ensure that low-quality patents are not granted, since this could assist in alleviating the possible negative impacts of patenting public research.⁴² This concern is particularly relevant to the South African situation because its patent registration system has drawbacks that can discourage innovators and, most importantly, the former Companies and Intellectual Property Registration Office (CIPRO) and even the newly established CIPC⁴³ do not function as examining offices.⁴⁴ The mandate of the CIPC seems to emphasize delivering against the new Companies Act, which came into effect in April 2011. The IPR Act was not mentioned in the media release announcing the establishment of the CIPC.⁴⁵

³⁸ WIPO (note 7), page 194.

³⁹ JH Reichman and Paul F Uhlir, 'A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment' (2003) 66 *L Contemp Prob* 315, page 324.

⁴⁰ *ibid.*

⁴¹ WIPO (note 7), page 200.

⁴² *ibid.*, page 201.

⁴³ CIPRO merged with Office of Companies and Intellectual Property Enforcement (OCIPE) to form the newly established Companies and Intellectual Property Commission (CIPC), with effect from 1 May 2011.

⁴⁴ D Kaplan (ed.) *The Economics of Intellectual Property in South Africa* (WIPO 2009), page 3.

⁴⁵ CIPRO and OCIPE to transform into the Companies and Intellectual Property Commission (February 2011), available online at: http://www.cipc.co.za/Publications_files/MediaReleases/Commission.pdf accessed 23 September 2011.

Sectors such as food and health are delicate and consequently require special attention in developing countries

Governments in developing countries should ensure that research results are widely used and correctly exploited in these crucial sectors.⁴⁶ The argument that it is irrational to invest so much in collecting data and yet so little in ensuring that we make the best use of it should serve as a wake-up call to such countries.⁴⁷ This concern is extremely relevant for South Africa, insofar as patenting in its institutions is concentrated in the areas of technology linked to life sciences/biotechnology and ICT research.⁴⁸

III. OPTIONS CURRENTLY UNDER DEBATE FOR IP PROTECTION AND PROTECTION OF SOCIAL AND ECONOMIC WELFARE

The options that are discussed below have been put forth by funding agencies as well as research institutions and researchers and are based mostly on their experiences in attempting to deal with the concerns mentioned in the preceding part of this paper. What is common in all the options is the attempt to be in conformity with the global strategy, giving effect to Article 7 of the TRIPS agreement. Article 7 states that:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.⁴⁹

Since the South African IPR Act is intended to manage intellectual property rights, the options that are selected for discussion are relevant for this purpose. Taubman's article, which explores policy dilemmas and apparent conflicts in IP management mechanisms, provides a useful insight for the purposes of this discussion. A fundamental question that the article raises is, for instance, 'how the *exclusive* rights established under IP law are, can be, or should be, deployed to achieve the *inclusive* goal of universal access to necessary health care.'⁵⁰ An equally relevant consideration explored in the article, from a South African perspective, is the fact that 'programmes of public sector knowledge management that entail obtaining and asserting IP rights can be construed as a form of privatization of public knowledge, or idealized as a means to maintain collective public-interest control over how public knowledge is developed and applied.'⁵¹

A commendable approach in the South African legislation, which is discussed in the next part of this paper, is that preference should be given to non-exclusive licensing. This approach incorporates the recommended public sector-management model, which, to be

⁴⁶ WIPO (note 7), page 203.

⁴⁷ E Pisani, et al., 'Time for Fair Trade in Research Data' (2010) 375 *Lancet* 703-5.

⁴⁸ Sibanda (note 9), page 121.

⁴⁹ For a more detailed discussion, see Sixty-First World Health Assembly, 'Global Strategy on Public Health, Innovation and Intellectual Property', available online at: http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf accessed on 23 September 2011.

⁵⁰ A Taubman, 'A Typology of Intellectual Property Management for Public Health Innovation and Access: Design Considerations for Policymakers' (2010) 4 *Open AIDS Journal*, 4-24, page 7.

⁵¹ *ibid.*, page 10.

workable should not 'entail an exclusive reliance on release into the public domain nor on wholly exclusive licensing.'⁵²

Emphasis on teamwork, value of data management and not just publications and citations

This option is used in the Wellcome Trust/National Institutes of Health (NIH) model. Both research-funding agencies have invested in the infrastructure needed for sharing data.⁵³ With effect from 1 October 2003, investigators submitting an NIH application seeking US\$500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why data sharing is not possible.⁵⁴ NIH defines 'the timely release and sharing' to be no later than the acceptance for publication of the main findings from the final data set. In this regard, NIH expects that the initial investigators may benefit from first and continuing use but not from prolonged exclusive use.

The Wellcome Trust on the other hand, states that 'should any Trust-funded IP arise from the Grant, then the Trust requires the Institution to consider whether the protection, management and exploitation of such Trust-funded IP is an appropriate means of achieving the public benefit.'⁵⁵

A useful proposal that researchers have put forward in order to foster team work in data management is the need to involve all collaborators, particularly developing country colleagues in drafting consortium or data sharing agreements.⁵⁶ South Africa's IPR Act certainly provides collaborating researchers with a reference point if public funding is involved.

Metadata sharing

Metadata sharing has been proposed as a solution to the concern that researchers consider their data proprietary. Metadata 'allows a precise and standardized way of describing content [of the data] in discrete packages called metadata records'.⁵⁷ This requires the establishment of an institutional process that is conducive to both patenting and publishing.⁵⁸

The above approach may not, however, suffice for the bureaucratic requirements that regulatory approvals usually entail. For instance, the South African Medicines Control Council

⁵² A Taubman and R Ghafele, 'Public Sector IP Management in the Life Sciences: Reconciling Practice and Policy - Perspectives from WIPO' in A Krattiger, et al. (eds.) *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (MIHR: Oxford, United Kingdom and PIPRA: Davis, United States, 2007), page 230.

⁵³ E Pisani and C Abou Zahr, 'Sharing Health Data: Good Intentions Are Not Enough' (2010) 88 *Bulletin of the World Health Organization* pp. 462 to 466.

⁵⁴ National Institutes of Health (NIH), Notice: Final NIH Statement on Sharing Research Data, NOT-OD-03-032 (26 February 2003).

⁵⁵ 'The Approach of the Wellcome Trust in Managing Intellectual Property to Maximize Public Health Benefit', available online at: <http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTX037150.htm> accessed 23 September 2011.

⁵⁶ JA Singh and AS Daar, Intra-Consortium Data Sharing in Multi-National, Multi-Institutional Genomic Studies: Gaps and Guidance (2009) 3 *Hugo Journal* 11, page 12.

⁵⁷ M Moffat, S Chumbe, R MacLeod, "'Marketing with Metadata": Increasing Exposure and Visibility of Online Content with "Best Practice" Metadata' (2006) available online at: <http://www.icbl.hw.ac.uk/perx/advocacy/exposingmetadata.htm> accessed 6 June 2011.

⁵⁸ WIPO (note 7), page 194.

requires the submission for approval of clinical trials by investigators to include a report on clinical findings.⁵⁹ The use of metadata records may be problematic in such circumstances.

IPR management strategy that permits continued research

A recommendation that has been put forward in this regard is that licensing should be carried out in a manner that permits continued research and avoids logjams, undue royalty stacking and anti-commons problems.⁶⁰ One way of incorporating this strategy is to use the patent pools approach, which can address some issues of access to patented upstream technology and its possible applications to biomedical research.⁶¹

A more systematic approach, one that can ensure collaborative research and open dissemination of upstream research findings, has also been suggested. This approach entails promoting 'strategic partnerships with other public institutions, public-private partnerships, and open collaborative mechanisms.'⁶² The possibility of South Africa's legislation being capable of promoting such a systematic approach is not easy to assess at this embryonic stage of the Act's existence. It is simply a question of time, since the relevant provisions need to be tested in their ability to create/support such collaborative initiatives.

IV. THE APPROACH TO THE ISSUES IN THE SOUTH AFRICAN IPR ACT AND LESSONS FOR POLICYMAKERS AND RESEARCHERS

Although South Africa's IPR Act uses Bayh-Dole-style legislation, an attempt has been made to include a number of safeguards to avert the possible undesired consequences that have been experienced in the United States.⁶³ These safeguards and the strategic approach in the South African Act offer a number of lessons for other jurisdictions.

Inclusion of government walk-in rights

These rights are enshrined in Sections 2(g) and 11(1) of the Act. Section 2(g) provides that 'where necessary, the State may use the results of publicly financed research and development and the attendant intellectual property in the interest of the people of the Republic.' Section 11(1) contains a number of safeguards and provides very broad powers to the state. It provides that:

The recipient [of public funds] determines the nature and conditions of intellectual property transactions relating to any intellectual property held by it, but must take into account the following:

- (a) Preference must be given to non-exclusive licensing;

⁵⁹ The South African Medicines Control Council, Guidelines and Forms, available online at: http://www.mccza.com/dynamism/default_dynamic.asp?grpID=30&doc=dynamic_generated_page.asp&categID=177&groupID=30 accessed 19 September 2011.

⁶⁰ SA Merrill and A Mazza (eds.) *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* (National Academies Press 2006) page 8.

⁶¹ *ibid.*, page 15.

⁶² Taubman and Ghafele (note 52), page 237.

⁶³ For a discussion of these consequences, see BN Sampat, 'Lessons from Bayh-Dole' (December 2010) 468 *Nature* 755.

...

(c) Preference must be given to parties that seek to use the intellectual property in ways that provide optimal benefits to the economy and quality of life of the people of the Republic;

...

(e) Each intellectual property transaction must provide the State with an irrevocable and royalty free licence authorising the State to use or have the intellectual property used throughout the world for the health, security and emergency needs of the Republic;

...

The focus on health research in the above paragraphs of Section 11(1) is commendable. These provisions can be used to address the current concerns about clinical research data sharing and product development. They also represent a good way of linking IP protection with other sectors of the economy such as public health needs, fair trading and competition. As aforementioned, preference for non-exclusive licensing is notably helpful for complying with Article 7 of the TRIPS agreement.

A serious concern that has been raised is that the legislation appears ‘backward looking’ insofar as it does not take into consideration the current approach in a 21st century networked society that focusses more on open and collaborative innovation models.⁶⁴

Inclusion of benefit-sharing provisions

Section 10(1) and (2) specifies how benefits from intellectual property rights should be shared with the inventors and their heirs:

(1) Intellectual property creators at an institution and their heirs are granted a specific right to a portion of the revenues that accrue to the institution from their intellectual property in terms of this Act until such right expires.

(2) Intellectual property creators at an institution and their heirs are entitled to the following benefit-sharing:

(a) at least 20 per cent of the revenues accruing to the institution from such intellectual property for the first one million rand of revenues, or such higher amount as the Minister may prescribe; and

(b) thereafter, at least 30 per cent of the net revenues accruing to the institution from such intellectual property.

The benefit-sharing provision is in line with a policy that requires that ‘inventors working in public research institutions are, in all circumstances (public or private financing),

⁶⁴ Eve Gray, note 18, pp. 22 to 23.

entitled to benefit-sharing arrangements if their IP secured in patents provides economic benefits to their institution or to a client of the institution.⁶⁵

A glaring omission in the above provision is benefit sharing with the community where research leading to the invention was conducted. This essentially raises the issue of how social dividends can be delivered to poor South African communities in general and, more particularly, to those who may have participated in the research in question.

Section 10(5) does leave institutions free to distribute the balance of revenues generated by intellectual property as they deem fit, though it seems to oblige the institutions to apportion part of their funding to more *R & D*, the operations of the office of technology transfer, and statutory protection of intellectual property. It would have been more commendable if benefit sharing with the participating communities was expressly provided for under this section. Another alternative, proposed by Nugent and Keusch, which could work well in South Africa, is formulating provisions on social dividends into licensing agreements.⁶⁶ This alternative can only work if institutional technology transfer offices are conscientious in ensuring that it is used.

Indirect incorporation of foreign IP standards

The definition of intellectual property in Section 1 of the Act is so broad that it indirectly incorporates foreign IP standards into South African IP law. It provides that 'intellectual property' means any:

[C]reation 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, dissertation, article, handbook or any other publication which, in the ordinary course of business, is associated with conventional academic work; (emphasis added)

This approach is in stark contrast to the resistance that most countries, including South Africa, have displayed towards the harmonization of IP legislations.

Unintended introduction of a two-edged sword in regulating research

The IPR Act generally gives inventors some freedom to decide whether or not to protect their inventions. This is clear from the wording of Section 4 of the Act. Two subsections are, however, a cause for concern. Subsection 2 provides that:

A recipient that prefers not to retain ownership in its intellectual property or not to obtain statutory protection for the intellectual property must:

- (a) make the choice in accordance with the regulations and any guidelines published by [the National Intellectual Property Management Office] NIPMO by notice in the Gazette; and

⁶⁵ Department of Science and Technology, note 2, paragraph 8.13.

⁶⁶ Nugent and Keusch, note 33, page 161.

(b) within the period set out in section 5(1) (e), notify NIPMO of the decision and the reasons therefore.

This provision could conceivably be invoked in order to interfere with a properly negotiated consortium agreement on data sharing and protection of intellectual property rights that accrue from a project. This becomes evident when the subsection is read together with subsection 3, which provides that:

NIPMO may, within the prescribed period, after considering the reasons provided by the recipient in terms of subsection (2)(b), and any prejudice that may be suffered by the State if no statutory protection for the intellectual property is obtained, acquire ownership in the intellectual property and, where applicable, obtain statutory protection for the intellectual property.

The two subsections can be viewed to be a two-edged sword, facilitating research while at the same time contradicting and negating the current exception for experimental/non-commercial use protected under South African law. This essentially means that PFRIs will require licences for follow-on research.

V. CONCLUSIONS

The analysis of South Africa's legislative intervention on the management of intellectual property rights from PFRIs provides positive lessons to be learnt, while at the same time showcasing definite weaknesses that would benefit from improvement.

On a positive note, the preference for non-exclusive licensing and emphasis on licensing preference being given to parties who can provide optimal benefits to the economy and quality of life to the people is highly commendable. The manner in which South Africa has included government walk-in rights to safeguard public interest in health research can also be replicated in countries that are considering a similar framework.

The main weakness in the legislative intervention is the failure to provide an appropriate strategy for addressing some concerns, such as the position of institutions with weaker bargaining power in accessing data from PFRIs. In this regard, South Africa should have heeded the call by critics of the Bayh-Dole Act and avoided repeating the mistake of creating barriers to the development of products for the poor. This weakness is equally evident in the manner in which the Act has failed to provide for benefit sharing with the participating communities or groups. South Africa equally needs to reconsider its approach to its legislation with regard to the indirect incorporation of foreign IP standards and the unintended introduction of the need of PFRIs requiring licences for follow-on research, particularly if they choose to commercialize their research output.

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