Intellectual Property and Access to Medicines: A Comparative Study of Technology Transfer Laws, and Policy Options for Sub-Saharan African Countries

By

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Declaration

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Dedication

I dedicate this dissertation to my unborn son. Simply thinking about you and imagining what you will look like has given me a new purpose and drive in life. I cannot wait to finally meet you.

Acknowledgement

I would like to acknowledge and express my sincere gratitude to the following who contributed in several different ways to make this research a success:

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Abbreviations

African Charter	African Charter on Human and Peoples' Rights
APIs	Active Pharmaceutical Ingredients
ARVs	Anti-retrovirals
BTG	British Technology Group
CESCR	Covenant on Economic, Social and Cultural Rights
Committee on ESCR	UN Committee on Economic, Social and Cultural Rights
CSIR	Council of Scientific and Industrial Research
CSOs	Civil Society organisations
DHHS	Department of Health and Human Services
DNA	Deoxyribonucleic acid
DNDi	Drugs for Neglected Diseases Initiative
DST	Department of Science and Technology
FCST	Federal Council for Science and Technology
FDA	Food and Drug Administration
FRPAA	Federal Research Public Access Act
GAO	General Accounting Office
GMP	Good Manufacturing Practice
HEIF	British Higher Education Innovation Fund
HEW	Department of Health, Education and Welfare
IPA	Institutional Patent agreement
IPR	Intellectual Property Rights
KEMRI	Kenyan Medical Research Institute
NIH	National Institute of Health
NIPMO	National Intellectual Property Management Office
NKC	National Knowledge Commission
NPPC	National Patent Planning Commission
NRDC	National Research and Development Corporation
OECD	Organisation for Economic Co-operation and Development
PEPFAR	President's Emergency Plan for AIDS Relief
R&D	Research and Development
RCUK	Research Council United Kingdom
RECs	Regional Economic Communities

THRIP	Technology and Human Resources for Industry Programme
TRIPS	Trade Related Aspects of Intellectual Property Rights
TTO	Technology Transfer Office
UK	United Kingdom
UNAIDS	Joint United Nations Program on HIV/AIDS
United States	United States of America
WHO	World Health Organization
WTO	World Trade Organization

Keywords

Access to medicines

Biopharmaceutical technology

Innovation

Intellectual property

Patents

Public interest

Research and development

Research institutions

Sub-Saharan Africa

Technology transfer

Abstract

In the last decade, governments of different countries have promulgated or considered legislation aimed at promoting collaboration between research institutions and industries to ensure that research results fit into industries' needs. These laws require research institutions to transfer technologies they develop to industry for further development, translation into tangible products, and commercialisation. In Sub-Saharan Africa where most countries are net importers of finished products, this model could play a critical role in stimulating research and development (R&D), boosting local technological development and entrepreneurship.

This triple-helix model comprising: government which funds research; institutions which carryout research; and industry to which research of new technologies are transferred for further development and commercialisation, raises concerns like access to research results and products developed out of this collaboration as the stakeholders involved all pursue different goals. For instance, government in funding research institutions aims to boost research and consequently technological development. Research institutions aim to create and disseminate knowledge, and publish as soon as possible. Meanwhile, industries aim to keep inventions secret, and create monopolies through intellectual property protection to maximise profits.

This research provides an analysis of selected legislation aimed at promoting collaboration between research institutions and industries, and potential implications for access to pharmaceutical products developed out of intellectual property emanating from government-funded research. It also provides policy options for other African countries seeking to stimulate R&D at research institutions, technology transfer to industry partners, and local technological development in the biopharmaceutical technology industry while taking into account the differing goals of the parties involved.

CHAPTER 1

INTRODUCTION AND BACKGROUND TO THE STUDY

1.1 Introduction

At the centre of the debate on intellectual property and the public interest is the question of access to medicines. The relationship between intellectual property and access to medicines lies in the fact that intellectual property protection, in this case patents, in granting exclusive rights to innovators and inventors of pharmaceutical products (medicines), creates monopolies which result in high prices and impede economic access or affordability. Access to medicines, a core component of the right to health is fundamental and indispensable for the exercise of other human rights.[1] This right is recognised in all major international human rights treaties[2] and particularly in the International Covenant on Economic, Social and Cultural Rights (CESCR), which is regarded as the mother treaty of all socio-economic rights. The CESCR refers to 'the right to the highest attainable standard of physical and mental health.' In its General Comment 14, the UN Committee on Economic, Social and Cultural Rights (Committee on ESCR) in interpreting the right to health states that the right to health at all levels and in all its forms entails that healthcare services should be available, accessible, acceptable and of good quality.[3]

At the regional level, African states that have signed and ratified the CESCR have further committed to ensuring the full realisation of the right to health.[4] Under the African Charter on Human and Peoples' Rights (The African Charter), in addition to the triple duty to respect, protect and fulfil human rights, state parties have committed to promoting the human rights of their people.[5] The African Charter provides for the right to 'enjoy the best attainable state of physical and mental health' and calls on state parties to the Charter to take all necessary measures to protect

[1] General Comment 14 Committee on ESCR.
[2] Art 12 of the CESCR; art 25 of the Universal Declaration on Human Rights. Art 12 of the Convention on the Elimination of all forms of Discrimination Against Women speaks to the right to health of women.
[3] General Comment 14 Committee on ESCR.
[4] Art 14 of the Protocol to the African Charter on the Rights of Women in Africa; art 14 of the African Charter on the Rights and Welfare of the Child; arts 16 and 18 of the African Charter on Human and Peoples' Rights.
[5] Arts 25, 30, 45 and the Preamble of the African Charter on Human and Peoples' Rights.

the health of their people, and to ensure that citizens receive medical attention when they are sick.[6] Moreover, at the national level, a few African countries have included the right to health in their constitutions.[7]

In spite of these commitments, tropical diseases continue to plague the sub-continent more than any other part of the world.[8] The August 2014 Ebola outbreak in West Africa speaks for itself.[9] In addition to tropical diseases, and according to the World Health Organization, communicable diseases like HIV are more prevalent in Sub-Saharan Africa than any other part of the world. Of the estimated 35 million people estimated to be living with HIV/AIDS in 2015, 71% live in Sub-Saharan Africa. Research also indicates that the prevalence of non-communicable diseases is growing at an alarming rate in Sub-Saharan Africa.[10] Cardiovascular diseases for example are the second most common cause of deaths in Africa after communicable diseases.[11] This reality only aggravates the persistent problem of high disease burden on the sub-continent and further strains already weak healthcare systems,[12] as the increasing prevalence of these different types of diseases is not accompanied by an improvement in healthcare.

Sadly, Sub-Saharan Africa bears the greatest burden of diseases and has some of the poorest healthcare systems, also most countries on the sub-continent remain net

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[6] Art 16 of the African Charter.
[7] Sec 27 of the Constitution of the Republic of South African, 1996 (as set out in sec 1(1) of the Citation of Constitutional Laws Act 5 of 2005; art 43 of the Constitution of Kenya, 2010; art 47 of the Constitution of the Republic Angola.
[8] PJ Hotez & A Kamath 'Neglected tropical disease in sub-Saharan Africa: Review of their prevalence, distribution, and diseases burden' (2009) 3 *PLOS Neglected Tropical Diseases* 1.
[9] The Ebola outbreak started in Guinea in March 2014 and spread to other West African countries like Liberia, Sierra Leon, Nigeria and Senegal in August-September 2014. About 28 639 cases of infection were recorded, of these, 11 316 died. MFC Gomes *et al* 'Assessing the international spreading risk associated with the 2014 West African Ebola outbreak' (2014) *PLOS* Currents Outbreaks doi: 10.1371/currents.outbreaks.cd818f63d40e24aef769dda7df9e0da5; see also WHO Ebola Situation Reports http://apps.who.int/ebola/ebola-situation-reports (accessed 04 February 2016); see also Hotez & Kamath (n 8 above).
[10] Sub-Saharan Africa consists of all forty eight countries that are fully or partially located south of the Sahara. Namely: Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo(Brazzaville), Democratic Republic of Congo, Cote d'Ivoire, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gabon, The Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, South Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia, Zimbabwe.
[11] MAB van der Sande 'Cardiovascular diseases in sub-Saharan Africa: a disaster waiting to happen' (2003) 61 *Netherlands Journal of Medicine* 32 - 33.
[12] A Mbewi & JC Mbanya 'Cardiovascular diseases' in DT Jamison *et al* (eds) *Diseases and mortality in sub-Saharan Africa* (2006) 2nd ed 305 - 306.

importers of the most basic pharmaceutical products as there is very limited, and in some cases no, pharmaceutical manufacturing capacity.[13] This renders the provision of basic healthcare services expensive for governments given the high foreign exchange rates and budget constraints faced by most African countries. Also important to note is the fact that most countries on the sub-continent invest very little or nothing at all on research and development (R&D) generally, and biomedical R&D in particular.[14] Hence, the biopharmaceutical manufacturing sector in most of these countries is also very underdeveloped.[15] The above realities have led to a situation where essential medicines are economically inaccessible and sometimes unavailable to most of the people who need them.[16]

In a bid to contribute towards finding a solution to this R&D gap and the lack of local pharmaceutical manufacturing capacity, this research focuses on laws and policies that simultaneously promote R&D, sustainable growth of local pharmaceutical manufacturing, and pharmaceutical innovation. This research also proposes policy options for African countries which may be interested in achieving the same, while at the same time promoting access.

The above aim of the research is informed by the increasing number of developing countries that have in the past decade either passed or considered legislation aimed at boosting R&D at research institutions (including universities) and pharmaceutical manufacturing. The aim of these laws is to promote the practical application of technologies developed from government-funded research (also referred to as publicly funded research) through its translation into tangible products through

[13] African Development Bank Group 'Revitalizing Africa's pharmaceutical industry' 04 June 2014 http://www.afdb.org/en/news-and-events/article/revitalizing-africas-pharmaceutical-industry-13289/ (accessed 09 February 2015).
[14] United Nations Educational, Scientific and Cultural Organization 'Research and development: Africa is making great progress despite major challenges' 8 November 2010 http://www.unesco.org/new/en/media-services/single-view/news/research_and_development_africa_is_making_progress_despite_major_challenges/#.VNh7J_mUeSo (accessed 09 February 2015).
[15] B Nyasse 'Overview of current drug discovery activities in Africa and their links to international efforts to combat tropical infectious diseases' in K Chibale *et al* (eds) *Drug discovery in Africa: impacts of genomics*, *natural products, traditional medicines, insights into medicinal chemistry, and technology platforms in pursuit of new drugs* (2012) 9.
[16] Knowledge Ecology International 'EB134: Statement of South Africa on access to essential medicines (in the Wake of Pharmagate)' 23 January 2014 http://keionline.org/node/1913 (accessed 09 February 2015).

technology transfer.[17] Most of these laws and policies are inspired by the United States Patent and Trademark Law Amendments Act (Pub. L. 96-517, December 12 1980), generally referred to as the Bayh-Dole Act, and sometimes hailed as 'possibly the most inspired piece of legislation to be enacted in America'.[18] The Bayh-Dole Act grants universities the right to retain title over intellectual property created from government-funded research and to seek the commercialisation of this intellectual property through partnerships with industries.

Before the coming into force of the Bayh-Dole Act in the United States, a great deal of intellectual property emanating from government-funded research carried out by universities remained underexploited principally because ownership of intellectual property was vested in the federal government, hence available to everyone in the public on a non-exclusive basis.[19] The fact that this intellectual property was available to all industries to further develop and commercialise on a non-exclusive basis meant that any private industry that obtained a licence to exploit the intellectual property, developed and commercialised products therefrom, would not be able to prevent competitors from copying and commercialising similar products even before the original developer had recouped investment costs. This was a disincentive for industries. Therefore, the bulk of innovations emanating from publicly funded research remained unexploited until the Bayh-Dole Act was passed. Having obtained the right to retain ownership over intellectual property originating from publicly funded research, universities were able to grant exclusive and non-exclusive licences to industries for further development and commercialisation of these technologies through technology transfer. This has over the years led to the application of university developed technologies to the manufacture of tangible products for use, particularly in the area of biopharmaceuticals.

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[17] Technology transfer in this context refers to the process of transferring skills; knowledge; technologies; methods of manufacturing; samples of manufacturing; and manufacturing facilities from universities and other research institutions to private industry to ensure that scientific and technological developments are accessible to a wider range of users who can further develop and translate the technology into new products, processes, applications, materials or services. H Messer-Yaron 'Technology transfer in countries in transition: policy and recommendations' 21 August 2012 http://www.wipo.int/export/sites/www/dcea/en/pdf/Technology_Transfer_in_Countries_in_Transition_FINAL-21.08.2012.pdf (accessed 28 May 2013).

[18] 'Innovation's golden goose' *The Economist* 12 December 2002.

[19] PS Arno & MH Davis 'Why don't we enforce existing drug price controls? The unrecognized and unenforced reasonable pricing requirement imposed upon patent deriving in whole or in part from federally funded research' (2001) 75 *Tulane Law Review* 640.

1.2 Problem statement

Prior to 1995, when the World Trade Organization's (WTO) Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement came into force, individual countries were free to regulate intellectual property in a manner that best suited their individual national contexts, realities, social and economic development and welfare. The copying and reverse engineering of products developed in other countries was allowed. In India for instance, while process patents were granted to inventors and innovators, product patent protection on pharmaceuticals could not be obtained. Indian pharmaceutical industries could copy and produce pharmaceutical products using methods different from that of the originators. This boosted the Indian pharmaceutical industry enabling the industry to produce and commercialise generic versions of brand medicines at affordable prices, thus promoting access both in India and in Sub-Saharan African countries.[20]

When the TRIPS Agreement came into effect, countries were forced to radically change their national laws and policies on innovation and technological development. The TRIPS Agreement introduced uniform minimum standards for intellectual property protection granting patent protection on products and processes in all fields of technology, both to nationals and foreign individuals (including legal persons).[21] Copying and reverse engineering was no longer an option for countries seeking to boost their local manufacturing sector.

Another reality worth noting is the fact that leading pharmaceutical companies, most of which are United States based, conduct very limited R&D into tropical diseases because these diseases are only prevalent in developing and least developed countries which account for only a small fraction of their markets.[22]

As a result of the above realities, the need for developing and least developed countries particularly in Sub-Saharan Africa to invest in finding long-term local and

[20] K Choudhary & S Ritiraj 'India: The trickle-down effect of product patent in India and on the developing world' 12 September 2013 http://www.mondaq.com/india/x/262416/Patent/The+TrickleDown+Effect+Of+Product+Patent+In+India+And+On+The+Developing+World (accessed 10 February 2015).
[21] Art 27 (1).
[22] WL Kalima 'The 10/90 gap in sub-Saharan Africa: Resolving inequalities in health research' (2009) 112 *Acta Tropica* 8, R Lewis 'Fighting the10/90 Gap' 13 May 2002 http://www.the-scientist.com/?articles.view/articleNo/14016/title/Fighting-the-10-90-Gap/ (accessed 10 February 2015).

sustainable solutions to the health problems they face cannot be overemphasised. Promoting R&D at research institutions on the one hand and collaboration between these research institutions and industry for the translation of technology developed from publicly financed research on the other hand have been identified as the major ways through which technological innovation generally, and in this case biopharmaceutical technological innovation, can be more effectively achieved. This is particularly the case as research indicates that in countries like the United States where the biopharmaceutical industry is highly developed; most of the basic research into potential medicines is conducted at universities.[23]

1.3 Objective of the study

The objective of this study is to analyse different laws and policies aimed at promoting technology transfer and access to pharmaceutical products developed from publicly financed research; the merits and demerits of these laws and policies with respect to access to pharmaceutical products developed from publicly funded research; and to provide policy options for Sub-Saharan African countries which may be considering achieving similar goals in their respective countries while taking into account the experiences of countries where such legislation already exists.

1.4 Research questions

The main question that the research attempts to answer is: how can policy makers through laws and policies promote biomedical R&D to address diseases that disproportionately affect people living in developing and least developed countries and technology transfer to secure the translation of research output into products that can be accessible to most people?

Other questions which stem from this main question include:

1. To what extent has the Bayh-Dole Act promoted biopharmaceutical R&D, technology transfer and access to pharmaceutical products developed from publicly financed research in the United States?

[23] 'The pivotal role of government investment in basic research' Report by the USA Congress Joint Economic Committee May 2010 https://www.aau.edu/WorkArea/DownloadAsset.aspx?id=10828 (accessed 11 February 2015) 1 - 2.

2. Aside from the Bayh-Dole approach, how has publicly financed research been regulated in other countries?
3. To what extent can the transplant of the United States model address the critical problem of access to pharmaceutical product developed from publicly financed research in developing countries; ensure that further research is not blocked; and that the public's interest is prioritised?
4. What policy options must be taken into account by Sub–Saharan African countries seeking to regulate publicly financed research to promote R&D, technology transfer, boost local manufacturing capacity and access?

1.5 Research premise

This research proceeds from the premises that:

The internationalisation of intellectual property regulation through the introduction of minimum standards of intellectual property rights protection and its incorporation into binding international trade agreements is detrimental to developing and least developed countries, which are net importers of technologies. This is because technological development in these countries, particularly in Sub-Saharan Africa, is at an infant stage with the vast majority of patents being in the name of individuals and companies from developed and emerging countries. As a result, Sub-Saharan African countries have more to lose than to gain from intellectual property protection as patented products, especially pharmaceuticals, are unaffordable for many because exclusive rights ordinarily give rise to monopoly pricing.

Pharmaceutical companies like all other companies are out to make profit. Hence, they tend to focus more on diseases which are prevalent in developed countries where the purchasing power is high, ignoring R&D into diseases which are prevalent in developing and least developed countries. This is because the purchasing power in the latter countries are low, although there is greater need. Research indicates that of the 1393 new chemical entities marketed between 1975 and 1999, only 16 were for neglected diseases.[24] There is a 13-fold greater chance of a drug being brought onto the market for central nervous system disorders or cancer than for

[24] P Trouiller *et al* 'Drug development for neglected diseases: A deficient market and a public-health policy failure' (2002) 359 *The Lancet* 2188 - 2189.

neglected diseases such as malaria, Leishmaniasis, lymphatic filariasis, Chagas disease and schistosomiasis. As if to justify this reality, the pharmaceutical industry argues that R&D is too costly and risky to invest in low-return neglected diseases.[25] As a result, although great strides have been made in increasing the basic knowledge of some tropical diseases and processes of drug discovery and development, the above named diseases continue to cause significant morbidity and mortality in developing and least developed countries.[26]

Contrary to the argument by proponents of strong patent protection, that patent protection is an incentive for R&D for the benefit of society at large as it sustains present and future innovation, the reality is that in least developed and developing countries most people cannot afford the prices charged by pharmaceutical companies on patented medicines. Hence, the need for specific measures aimed at reducing prices of essential medicines. This implies that the overall effect of the current intellectual property regime under the WTO is context specific as the implications are not the same for all countries.[27]

The measure of the success of a research institution's technology transfer should not be limited to its financial returns but should include social and economic impacts that a research institution may have in the community. Examples of these impacts are: access to technologies and products developed by the research institution and its industry partners by people who need them.[28]

Although access to medicines has been greatly enhanced following the creation of the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria and other donor funded programmes for healthcare in Sub-Saharan Africa and developments like the Doha Declaration on TRIPS and Public Health that specifically targeted access to medicines in developing and least developed countries, a lot still needs to be done to secure continued access to life-saving treatment for the 7.6 million people already accessing antiretrovirals (ARVs) in Africa and the millions more, who still need to be

[25] As above.
[26] As above.
[27] WHO Report of the Commission on Intellectual Property Rights, Innovation and Public Health (2006) 22.
[28] http://www.arc.agric.za/Agricultural%20Sector%20News/Groundbreaking%20drought-tolerant%20maize%20hybrids%20launched.pdf (accessed 14 December 2014).

placed on treatment.[29] In addition, apart from HIV, non-communicable and tropical diseases are also serious health threats to people living in developing and least developed countries.

1.6 Research method

The research is principally limited to desktop and analytical research. Existing laws on technology transfer and publicly funded research have been critically analysed to identify applicable lessons for Sub-Saharan African countries. Both primary and secondary sources have been explored. Primary sources include: international treaties and agreements; and national laws and policies on technology transfer, publicly funded research and intellectual property; discussions, Skype interviews, and email exchanges with renowned researchers and policy makers involved in drafting and advising government policies on intellectual property, technology transfer and access to medicines. Secondary sources such as text books, journal articles and other articles have also been exploited.

The first chapter of this research provides a background into the problem of access to medicines faced by people living in developing and least developed countries, particularly in Africa, and the need for African countries to find lasting solutions to these healthcare problems themselves. The second chapter analyses an approach devised by the United States to address healthcare and other problems faced immediately after the Second World War as a possible option for countries considering addressing pressing healthcare problems, namely; encouraging research institutions and universities which receive gov't funding for research to seek partnerships with industries to ensure the translating of research outputs into products. The third chapter focuses on other approaches to regulate publicly funded research currently being implemented in other countries. The fourth chapter focuses on the regulation of publicly financed research in selected emerging countries. Countries analysed in this chapter are: India, South Africa and Brazil. The chapter provides a critical analysis of these laws and examines the potential access to medicines challenges that these laws present. The fifth chapter focuses on policy

[29] UNAIDS 'Cooperation for the local manufacturing of pharmaceuticals in Africa intensifies' 29 March 2014 http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2014/march/20140329ecapharmaceuticals/ (accessed 01 August 2014).

options for regulating technology transfer and the practical application of intellectual property emanating from publicly funded research for Sub-Saharan African countries, taking into account the realities in these countries. The sixth chapter concludes the study and makes recommendations for policy makers to consider as they implement measures aimed at overcoming the problem of access to reasonably priced medicines by majority of people in developing and least developed countries.

1.7 Limitations of study

This research is limited to providing policy options on the regulation of intellectual property emanating from publicly funded research in a manner that ensures that pharmaceutical products developed from or incorporating this research, are affordable for those who need them. This research does not consider access to other non-pharmaceutical products that may be developed and protected by intellectual property.

CHAPTER II

THE REGULATION OF GOVERNMENT-FUNDED RESEARCH IN THE UNITED STATES OF AMERICA

2.1 Introduction

The year 1980 will always be remembered in the United States biopharmaceutical technology sector and in universities involved in biomedical research. This year marked the passing of legislation described as having '… marked a sea change in U.S. government policy toward intellectual property rights in the results of government sponsored research.'[30] The P.L. 96-517 Patent and Trademark Amendments Act 1980, otherwise known as the Bayh-Dole University and Small Business Patent Procedures Act 1980 (the Bayh-Dole Act) was passed this year. The aim of this law was to harmonise federal law relating to ownership of inventions arising from government-funded research.[31] Through this law, universities and other non-profit institutions involved in government-funded research were allowed to retain ownership of intellectual property, (mainly patents), arising from their research.[32] More specifically, these research institutions now had the right to patent these inventions in their own names and grant exclusive or non-exclusive licences thereon to private companies. The goal was to promote further R&D on or with these university inventions that would possibly lead to their commercialisation, as most universities cannot develop early-stage inventions into finished products.[33]

Following the passage of the Bayh-Dole Act in 1980, there was a sharp increase in the number of patents granted to universities and a corresponding increase in licences granted by these universities to industry.[34] Through further R&D, these industries have optimised and proven the safety and efficacy of several different

[30] RS Eisenberg 'Public research and private development: Patents and technology transfer in government-sponsored research' (1996) 82 *Virginal Law Review* 1663.
[31] Eisenberg (n 30 above) 1665.
[32] 35 USC § 202 (a) (2002).
[33] USA Congressional Record proceedings and debates on the 96th second session 126 part 2 1980 1381.
[34] HW Bremer 'University Technology Transfer: Evolution and Revolution on the 50th Anniversary of the Council On Governmental Relations' in EC Kulakowski & LU Chronister (eds) *Research administration and management* (2006) 636.

products (particularly medicines) that address varying health problems, resulting in increased public welfare. A good number of blockbuster medicines used today were invented from basic research conducted by universities with government funds and licenced to industry.[35] The United States federal government has therefore contributed immensely in subsidising the biopharmaceutical technology industry in the United States.

While some scholars are of the view that without the Bayh-Dole Act the United States biopharmaceutical technology industry would never have grown to be what it is today,[36] others argue that the Bayh-Dole Act is just one of several other factors which led to the industry's growth.[37] The bottom line, however, is that the Bayh-Dole Act played a role resulting in both positive and negative effects. The aim of this chapter is to provide a background of the Bayh-Dole Act and to examine its provisions, paying particular attention to its merits and demerits with respect to access to technologies developed from government-funded research in the United States.

2.2 The history of technology transfer in the United States

Intellectual property protection in the United States dates back to 1789 when the constitution was adopted. The relevant provision in the United States Constitution reads as follows:[38]

> Congress shall have the Power … To Promote the progress of Science and useful arts, by securing for Limited times to Authors and Inventors the exclusive Rights to their respective Writings and Discoveries.

[35] WH Schacht 'Federal R&D, drug discovery, and pricing: Insights from the NIH-university-industry relationship' (2011) *Congressional Research Service Report for Congress* 17 - 19. Some of these include: Remicade for the treatment of certain types of arthritis; Lyrica for the treatment of pain caused by nerve damage due to diabetes, control seizures; Taxol® an anticancer medicine; and Zerit® against HIV.
[36] CE Gulbrandsen 'Address Bayh-Dole: Wisconsin roots and inspired public policy' (2007) 1149 *Wisconsin Law Review* 1150 - 1151.
[37] DC Mowery & MN Sampat 'The US Bayh-Dole Act of 1980 and university-industry technology transfer: A model for other OECD governments?' (2005) 30 *Journal of Technology Transfer* 116; DC Mowery 'Universities in national innovation systems' nd http://webcache.googleusercontent.com/search?q=cache:Qed6NIQZ5XIJ:https://smartech.gatech.edu/bitstream/handle/1853/43390/L2_presentation.pps+&cd=5&hl=en&ct=clnk&gl=za (accessed 05 January 2014).
[38] US Cons art 1 § 8.

In the same vein, President Abraham Lincoln, who himself held a patent over a device to lift boats over shoals,[39] in a speech noted that in the absence of patents,[40]

> … any man might instantly use what another had invented; so that the inventor had no special advantage from his own invention. The patent system changed this; secured to the inventor, for a limited time, the exclusive use of his invention; and thereby added the fuel of interest to the fire of genius, in the discovery and production of new and useful things.

According to President Lincoln therefore, patents grant special advantages to inventors for their ingenuity and encourage investment of time, money and labour in inventions. In the absence of these special advantages, inventors will not reap the fruits of their labour and will lose the incentive to innovate as anyone will be free to copy and commercialise their inventions.

Compared to other countries, the United States devotes an extremely large part of its finances (taxpayers' money) to funding research in biomedicine and biopharmaceutical technology in universities and other public research institutions.[41] Through technology transfer from universities and other research institutions to private enterprise, optimum use is made of government-funded research to avoid wastage of research and government funds by ensuring that this research is put to practical use. Ensuring proper technology transfer from these institutions to private industries for further development and commercialisation is therefore crucial. Given that progress in university research tends to affect industrial innovation in the biomedical sector (particularly biopharmaceutical technology) more than any other,[42] such products shall therefore be the focus of this research.

Before 1980 when the Bayh-Dole Act was enacted in the United States, there existed no single uniform mechanism to ensure that research carried out by universities and other research institutions could be put to practical use. As a result, different agencies that funded research had different procedures and requirements

[39] http://www.abrahamlincolnonline.org/lincoln/education/patent.htm (accessed 02 March 2013).
[40] http://quod.lib.umich.edu/l/lincoln/lincoln3/1:87?rgn=div1;view=fulltext (accessed 02 March 2013).
[41] The NIH invests over $30.9 billion annually in medical research for the American people. This is very high when compared to other developed countries. In the UK, the National Institute for Medical Research spends £25 million (about $41.6 million) annually on biomedical research http://www.nih.gov/about/budget.htm (accessed 07 January 2014); http://www.nimr.mrc.ac.uk/about/funding/ (accessed 07 January 2014); JR Burgdorf 'Health and medical research in Japan: Health research observatory' prepared as part of the Rans Europe's Health Research Observatory (2008) 4.
[42] Mowery & Sampat (n 37 above).

for managing intellectual property emanating from such research.[43] In principle, the federal government retained title over most of the patents resulting from the research it funded.[44] Nonetheless, a few universities managed to engage in technology transfer, but, because the process was both complex and confusing, these universities could only do so on a limited scale.[45] In addition, universities could only grant non-exclusive licences as they did not own the intellectual property emanating from government-funded research.[46] The fact that title to the intellectual property was vested in the federal government meant that it was in the public domain, and free for anyone to exploit. Wanting exclusive rights as an incentive, private industries to which these non-exclusive licences were issued were reluctant to invest in further development of these intellectual property into tangible products for commercialisation for fear that once this was done, competitors would almost immediately 'steal their markets by getting similar licences from the government'.[47] Hence, most government funded inventions languished on the drawing board.[48]

This state of affairs was not welcomed by lawmakers as it ran contrary to United States policy which (through the federal and state government) had always sought to ensure that the benefits of higher education and university research were applied to meet real-life problems. Universities in the United States were viewed not only as academic institutions, but also as centres of research and innovations geared towards meeting specific targeted public welfare goals.[49] While individual states

[43] A Johnson 'The End of Pure Science: Science Policy from Bayh-Dole to the NNI' in D Baird, A Nordmann & J Schummer (eds) *Discovering the nanoscale* (2004) 220.
[44] USA Congressional Record proceedings and debates on the 96th second session 126 part 2 1980 1380.
[45] LR de Larena 'The price of progress: Are universities adding to the cost?' (2007) 43 *Houston Law Review* 1437.
[46] G Pulsinelli 'Share and share alike: Increasing access to government-funded inventions under the Bayh-Dole Act' (2006) 7 *Minnesota Journal of Law, Science & Technology* 401.
[47] Pulsinelli (n 46 above) 398.
[48] Eisenberg (n 30 above) 1680.
[49] For instance, in the 19th century, Congress provided 30 000 acres of land to states through the Land Grant Act to be sold to provide an endowment for at least one college where the leading objective would be to: "… without excluding other scientific and classical studies, and including military tactics, to teach such branches of learning as are related to agriculture and the mechanical arts, in such manner as the legislatures of the States shall respectively prescribe, in order to promote the liberal and practical education of the industrial classes in the several pursuits and professions in life." The first universities to be created under this act include: Cornell University, Iowa State University, Kansas State University, the University of Kentucky, Michigan State University, the University of Minnesota, the University of Missouri, Pennsylvania State University, Rutgers University, the University of Vermont and the University of Wisconsin. Pennsylvania State University News 'Land-grant universities celebrate Morrill Act sesquicentennial'

were responsible for funding research in their respective universities, for many states, promoting industrial innovation and commercialisation was also a priority.[50] Therefore, funding decisions were based on the particular regional economic needs of states.[51] Public universities and private universities that emerged during this era developed curricula that placed more emphasis on practical subjects with immediate commercial applicability.[52] This targeted funding system also encouraged donors to make targeted contributions to research activities at universities.[53]

Between 1940 and 1980 the United States government began to seriously consider the idea of having a clearer and simpler intellectual property management policy with respect to the research and inventions it funded. To achieve this, the United States government assigned a number of commissions, individuals and consulting firms to conduct research and make recommendations to the federal government on the United States patent policy. The next part of this chapter focuses on the findings of some of these commissions and their recommendations to the United States government.

2.3 Towards the harmonisation of United States policy on government-funded research

2.3.1 The report of the National Patent Planning Commission

In 1940, President FD Roosevelt created the National Patent Planning Commission (NPPC). This commission was tasked with planning for the full utilisation of the country's expanded industrial capacity at the end of the Second World War.[54] In January 1945, this commission tabled a report titled 'Government-owned patents and inventions of government employees and contractors'. The key issue raised by this commission in its report was that government could protect its rights to freely use the inventions it funded through 'prompt publication'.[55] This commission further noted that commercial exploitation of inventions developed out of government

http://news.psu.edu/story/148276/2012/06/22/land-grant-universities-celebrate-morrill-act-sesquicentennial 22 June 2012 (accessed 02 March 2013); 7 USC § 304.

[50] BayhDole25 'The Bayh-Dole Act 25' 26 April 2006 http://www.bayhdole25.org/about (accessed 01 February 2013).

[51] As above.

[52] These areas of research included: engineering, applied science, business and finance. As above.

[53] As above.

[54] Eisenberg (n 30 above) 1671.

[55] United States National Patent Planning Commission 'Government-owned patents and inventions of government employees and contractors' (1945) 27 *Journal of the Patent Office Society* 79 - 82.

funding should be open to everyone, and it might in some instances be necessary to grant exclusive rights to private companies as an incentive for commercialisation.[56]

The commission therefore recommended that a law should be passed to authorise government agencies to issue exclusive licences where it seemed evident that the invention in question would not be put to practical use.[57] According to the commission, such a law was necessary because full government ownership of patents on inventions made by government contractors (research institutions including universities) would conflict with national interest.[58] This commission's research was followed by an investigation into government patent practices and policies by the Attorney General.

2.3.2 The report of the Attorney General

In 1947, the Attorney General finalised an investigation on government patent practices and policies. In contrast to the earlier report produced by the NPPC, the Attorney General's report recommended the adoption of a uniform federal policy in which title to inventions made by government employees and contractors (universities) is vested in the federal government.[59] The report identified two exceptions where title could be held by the contractor, namely in emergency situations and where the contractor had made a substantial contribution to the invention before the government contract.[60] While acknowledging that non-exclusive licences will not attract private investment and commercialisation, the Attorney General's report suggested that government should fund these investments rather than granting exclusive licences to the private sector.[61]

These different approaches to the management and regulation of government-sponsored research clearly portray the differing positions that prevailed at the time and even today. As clearly articulated by Eisenberg:[62]

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[56] As above.
[57] As above.
[58] As above.
[59] United States of America *Investigation of government patent practices and policies,* report and recommendations of the Attorney General to the President (1947) 3 - 4.
[60] As above.
[61] As above.
[62] Eisenberg (n 30 above) 1674.

> Advocates of a title policy [those who support retention of title by the government] generally feared that patents in the hands of government contractors would lead to concentration of economic powers in the hands of large businesses to the detriment of their smaller competitors.

On the other hand: [63]

> Advocates of a license policy [those who wanted research institutions to retain title] sang the praises of the patent system as a stimulus to innovation, new products, and new jobs and believed that without a promise of title to patents, the best firm would not bid on government contracts, would not bother to disclose the inventions they made with federal funds, and would not invest further in the development of discoveries owned by the government.

Another major event, which contributed in shaping the United States patent policy at the time, was the Second World War.

2.3.3 The role of the Second World War

One of the major events that drove the United States government to fully understand the importance of government-funded research and its application to real-life problems was the important role that science played in United States's success during the Second World War.[64] To meet the emerging needs of the United States military during the war, the government invested enormously in scientific research.[65]

The Office of Scientific Research and Development was created in 1941 under the directorship of Vannevar Bush to co-ordinate scientific research for military purposes during the war. To meet the high demands of the war, this research institute invented military weapons that were of utmost importance in securing victory for the United States and Allies. Some of these inventions included: the highly secretive Manhattan project that resulted in the invention of the first atomic bomb;[66] new adaptations of the radar and early-warning systems; lighter and more accurate hand weapons and penicillin.[67] The atomic bomb was used to bomb Hiroshima and Nagasaki in Japan on August 6 and 9 of 1945 to hasten the end of the war;[68] Penicillin was used to heal the wounds of United States soldiers,[69] again making them fit for the war; and the

[63] As above.
[64] EC Walterscheid 'The need for uniform government patent policy: The D.O.E. example' (1990) 3 *Harvard Journal of Law & Technology* 103 - 104.
[65] https://ipo.llnl.gov/data/assets/docs/TechTransfer.pdf (accessed 10 August 2012).
[66] http://www.doug-long.com/bush.htm (accessed 13 August 2012).
[67] JR Dean 'FDA at war: Securing the food that secured victory' (1998) 53 *Food & Drug Law Journal* 493 - 495.
[68] ET May *Homeward bound: American families in the Cold War* (1988) 25.
[69] Dean (n 67 above).

new adaptation of the radar were used to detect and attack distant objects like enemy ships and aircraft.[70]

As a result of the positive impact of scientific research on the United States' success in the war, the then United States President, Franklin Roosevelt, wrote a letter to Vannevar Bush in 1944 in which he commended the research efforts of the Office of Scientific Research and Development. He noted that information, techniques and research experience developed by this Office and the thousands of scientists in universities and private industry to support the war should be used after the war to improve national health, to create new enterprises and new jobs and to improve the national standard of living. The President further requested Vannevar Bush to make recommendations to the government on three key points, namely:[71]

1. What could be done to continue with biomedical and related scientific research that had been carried out during the war to meet the health challenges that were faced at the time?
2. How could government support public and private research institutions?
3. What an effective program for identifying and developing scientific talent in youths would be?

In response to the President's request, Vannevar Bush produced a report titled '*Science: the endless frontier'* in 1945 in which he explained to what extent scientific research could be helpful in meeting general public welfare even in times of peace. Vannevar Bush also made recommendations on how scientific research could be managed for government to make optimum use thereof. In this report, Vannevar Bush proposed the following key possible solutions among several others:[72]

1. Medical schools and universities are responsible for basic research in medicine and underlying sciences essential to progress in the war against disease, and government must extend financial support to basic medical research in these institutions.

[70] http://www.century-of-flight.net/Aviation%20history/WW2/radar%20in%20world%20war%20two.htm (accessed 13 November 2012).
[71] V Bush 'Science: the endless frontier' 25 July 1945 http://www.nsf.gov/od/lpa/nsf50/vbush1945.htm (accessed 10 August 2012).
[72] Bush (n 71 above).

2. Steps must be taken to modify procedures for recruiting, classifying and compensating scientific personnel to improve the quality of scientific research.
3. Suitable incentives for conducting research should be provided to industry, which should include among other options, strengthening the patent system to eliminate uncertainties, and ensuring the transfer of research results to industry.
4. To meet these recommendations, a new agency composed of individuals of broad interest and experience, and having an understanding of the peculiarities of scientific research and scientific education should be established with stable funds that will enable it undertake long-term programs.

According to Roger Pielke Jr, this report marked the beginning of modern science policy in the United States.[73]

2.3.4 The 1963 Presidential Memorandum and Policy Statement

In 1963, President John Kennedy in an attempt to achieve a greater degree of uniformity in government patent policy, issued a Presidential Memorandum and Policy Statement.[74] This policy statement was a hybrid of a licence policy and a title policy as it attempted to balance the need for private incentives to attract further development and commercialisation against the need to promote competition in industry.[75] It acknowledged the tension between having exclusivity as an incentive to drive incremental innovation and commercialisation and the goal of sharing government sponsored knowledge to encourage robust competition in the public's interest.

The policy identified a number of circumstances that would warrant the government holding title to inventions of public research institutions. Some of these circumstances included:[76]

1. Where the principal goal of the contract was to create products or processes intended for commercial use by the general public.

[73] R Pielke Jr 'In retrospect science - The endless frontier' 19 August 2010 http://sciencepolicy.colorado.edu/admin/publication_files/2010.24.pdf (accessed 27 January 2013).
[74] Walterscheid (n 64 above) 118-119; IR Dubowy 'Subsidies code, TRIPS Agreement and technological development: some considerations for developing countries' (2003) 8 *Journal of Technology Law and Policy* 55 - 56.
[75] Walterscheid (n 64 above).
[76] R Nash & L Rawicz *Patents and technical data* (1983) 93 & 106.

2. Where the research directly concerned public health or public welfare.
3. Where the government had been the principal developer in the field, and the acquisition of exclusive rights might confer on the contractor a dominant position in the field.
4. Where the contractor was operating a government-owned facility or was co-ordinating and directing some other work.

In addition, this policy provided that, whenever it was necessary to grant exclusive rights as an incentive to call forth private risk capital and expenses to bring an invention to the point of practical application, the head of agencies and departments may grant such rights.[77] In such a case, contractors were required to provide a report to the government on how they had commercialised the inventions, and government was to retain 'march-in' rights.[78] Through march-in rights, government could terminate the exclusive rights granted to a contractor if within three years, the contractor failed to take effective steps to bring the invention to practical application.[79]

This policy also called on the Federal Council for Science and Technology (FCST), in collaboration with the Department of Justice, to prepare annual reports on the effectiveness of the policy, and to make recommendations for its revision.[80] While the 1963 Presidential Memorandum did not bring about direct uniformity among agencies, it generated further study on the question of how best to regulate publicly funded research and ensure its transfer to industry, thereby creating a favourable atmosphere for legal reform.[81] In 1965 the FCST established a Committee on Government Patent Policy to acquire and analyse information on the operation of the policy, and commissioned the Harbridge House to again conduct an extensive study of federal patent policy.[82]

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[77] BN Sampat 'Patenting and US academic research in the 2oth century: The world before and after Bayh-Dole' (2006) 35 *Research Policy* 778.
[78] A march-in right is a safeguard measure available to the government whenever an exclusive licensee or an assignee of intellectual property emanating from government-funded research fails to develop or commercialise the intellectual property, or does so in a manner that does not meet the public's need.
[79] Eisenberg (n 30 above) 1677 - 1679.
[80] As above.
[81] As above.
[82] Sampat (n 77 above).

2.3.5 The Harbridge House study

Harbridge House was specifically tasked with studying and investigating the impact of patent policy and exclusive rights on industry participation in government R&D programmes, commercial utilisation of government-sponsored inventions, and business competitions in commercial markets.[83]

Harbridge House conducted empirical research and produced a report that carefully addressed each of these questions. As noted by Eisenberg, the most important finding of Harbridge House was that no matter who held title, commercial utilisation of government-sponsored inventions was very low.[84] For instance, for inventions patented between 1957 and 1962, only 12.4% of a sample of government-funded inventions had actually been put to use. Of these, only 2.7% played a critical role in the commercial products in which they were incorporated. In the case of contractors who had prior experience in the field of inventions concerned, Harbridge House found that the rate of utilisation of government-funded research was 23.8 % when the contractor held title to the invention, and 13.3% when he did not.[85]

Based on these findings, Harbridge House concluded that available evidence did not indicate that either a title or a licence policy alone is the best way to promote utilisation of intellectual property emanating from government-funded research.[86] The House found that there were areas of technology where title was required for utilisation, areas where title inhibited utilisation and also areas where neither a title nor a licence policy promoted utilisation.[87]

[83] Harbridge House *Government patent policy study, final report for the FCST committee on government patent policy* (1968) VIII.
[84] As above.
[85] R Mazzoleni 'Patents and University-Industry Interactions in Pharmaceutical Research before 1962: An Investigation of the Historical Justification for Bayh-Dole' (2010) 10 *Journal of High Technology Law* 173.
[86] Dubowy (n 74 above) 56.
[87] Eisenberg (n 30 above) 1680.

2.3.6 The National Institute of Health's medicinal chemistry programme

The impact of the National Institute of Health's (NIH) patent policy in 1960 provided a greater understanding of the situation. Prior to 1962, under the medicinal chemistry programme, pharmaceutical firms regularly screened compounds developed by NIH-funded research for bioactivity at no cost. These firms did this without signing any agreement either with the NIH or with the researchers on rights arising from the screening. In 1962, the Department of Health, Education and Welfare (HEW) notified universities that firms screening compounds in their research laboratories must sign formal patent agreements preventing the firms from obtaining patents on technologies resulting from NIH funding.[88] Under these patent agreements, the NIH:[89]

1. Restricted the ability of these firms to disclose the results of these tests.
2. Compelled them to promptly report all results to the researchers for use by the Public Health Service.
3. Restricted the firms' rights to obtain patents on any new uses of the compounds.
4. Gave the government a non-exclusive royalty-free licence under the firms' patents with the right to sub-licence for government purposes.

Following these new restrictions, pharmaceutical firms almost unanimously rejected the agreement on grounds that it would amount to loss of proprietary rights and control over their testing and reporting results. These firms stopped screening NIH-sponsored compounds and sharing information.[90] In 1968 following an investigation by the Comptroller General of the United States, the situation was resolved through a revision of the terms of the patent agreement. The HEW used a revised standard Institutional Patent Agreement (IPA) in which patent rights were granted to universities with approved patent policies and the universities were able to transfer rights in new compounds to pharmaceutical firms for commercial development.[91]

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[88] Sampat (n 77 above); US General Accounting Office (1968) 10.
[89] Sampat (n 77 above); Eisenberg (n 30 above) 1682 - 1684.
[90] DC Mowery 'The Bayh-Dole Act of 1980 and university-industry technology transfer: A policy model for other governments nd https://projects.merid.org/SITECORE_DOCS/David%20Mowery%20Paper.pdf (accessed 17 April 2015 5-6; USA General Accounting Office (1968) 10.
[91] Mazzoleni (n 85 above) 178 - 180.

2.3.7 The report of the Committee on Government Patent Policy

In 1968, the Committee on Government Patent Policy produced a report on the results of the Harbridge House study. The Committee concluded that the study results provided no pragmatic basis for changing the basic principles of the 1963 Presidential Memorandum and Policy Statement.[92] The Harbridge House study had supported the view that whenever the purpose of a contract was public oriented, the government should hold title.[93] However, considering the reaction of the pharmaceutical firms to the NIH's patent position in the medicinal chemistry programme discussed above, it was clear that allowing government to retain title when the research was public oriented would not secure the participation of private industries that was needed.[94] Nonetheless, this Committee believed that the question of who should own title to government-funded inventions for public welfare could be dealt with as exceptions under the Policy. The Committee therefore recommended a modification of the 1963 Presidential Momentum and Policy Statement to allow contractors to retain title, or to allow government to grant exclusive licences, in appropriate cases.[95]

2.3.8 The amended Presidential Memorandum and Policy

In 1971, President Nixon implemented the recommendations of the Committee on Government Patent Policy in a revised Presidential Memorandum and Policy Statement on Government Patent and Policy.[96] Under this revision, private firms were granted greater than non-exclusive rights as an incentive for these industries to invest in the development of inventions for practical application or to recognise the relative equities of the contractor and the agency, even in cases where the invention was the primary objective of the research contract.[97]

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[92] Eisenberg (n 30 above) 1683 - 1684.
[93] As above.
[94] HW Bremer 'Patent policies for government-supported research (U.S.A.)' in A Gerstenfeld (ed) *Science policy perspectives: USA-Japan* (1982) 296.
[95] Eisenberg (n 30 above) 1683 - 1684.
[96] R Nixon: 'Memorandum about government patent policy' 23 August 1971 http://www.presidency.ucsb.edu/ws/?pid=3130 (accessed 16 April 2015).
[97] Eisenberg (n 30 above) 1684 - 1685.

In addition, government retained the right to exercise march-in rights;[98] agencies retained the right to revoke non-exclusive licences held by contractors in order to grant exclusive licences where necessary to encourage commercialisation of the invention; and the government was also authorised to grant exclusive licences on government-owned patents.[99]

2.3.9 The Commission on Government Procurement

The United States Congress established the Commission on Government Procurement in November 1969 to study and recommend measures to boost the economy, promote efficiency and effectiveness of procurement by the Executive Branch of the Federal Government.[100] The Commission recommended, among others, that it was necessary to enhance mechanisms for private appropriation of the results of government-funded research.[101] The Commission drafted an alternative approach to government patent policy, which consisted of a repeal of all existing statutes governing the allocation of patents in government-funded research in order to enact a uniform law.[102] As a general rule, the proposed uniform law granted title to the research institution subject to a strong system of government march-in rights.[103] Under this new draft law, exclusive rights were not to be granted in the following instances: where the government intended to fund the development of the invention to the point of commercial application; and where the contractor was an educational institute or a non-profit organisation and utilisation would not be fostered by granting title to such a contractor unless it is determined that the invention likely to flow from the contract will be promoted in a manner that is consistent with the objectives of, and maintenance of competition.[104]

In 1973, the Administrator of General Services passed new regulations to implement the 1971 Presidential Memorandum.[105] While these new regulations were still pending, the Justice Department questioned the constitutionality of this move given that under the United States Constitution Congress alone has the authority to

[98] As above.
[99] As above.
[100] Pub. L. 91-129, § 2, Nov. 1969.
[101] Eisenberg (n 30 above) 1685 - 1689.
[102] As above.
[103] As above.
[104] As above.
[105] As above.

dispose of United States property.[106] Public Citizen also filed lawsuits challenging the provisions of this regulations.[107] Although the lawsuits were dismissed for lack of standing on the part of the plaintiffs, they raised serious questions on the constitutionality of achieving the desired transformation in patent policy through administrative regulations rather than a new law.

In response to these concerns, the Committee on Government Patent Policy of the Federal Council for Science and Technology prepared a draft bill that would establish a uniform federal patent policy by statute.[108] Under this new policy, government contractors were allowed to retain a number of rights, namely, the rights to:[109]

1. Acquire patent rights on inventions made in the course of government-funded research.
2. Obtain exclusive licences on government funded research.
3. Assign title to inventions made by government employees in the course of their employment.

This draft bill was forwarded to the Office of Management and Budget and to the Director of the Office of Science and Technology Policy but was never forwarded to Congress.[110] However, this concrete proposal made it clear that a new law was needed.

2.3.10 President Jimmy Carter's industrial innovation programme and the Bayh-Dole Act

President Jimmy Carter initiated the Domestic Policy Review on Industrial Innovation in 1978.[111] In a bid to increase industrial productivity and innovation, this policy recognised the need to enact a law that would promote the private appropriation of intellectual property emanating from government-funded research in line with the amended Presidential Memorandum.[112] While addressing Congress in October

[106] As above.
[107] As above.
[108] Sampat (n 77 above) 779.
[109] Eisenberg (n 30 above) 1685 - 1689.
[110] As above.
[111] Dubowy (n 74 above) 56.
[112] Pulsinelli (n 46 above) 400.

1979, President Carter reiterated his support for a law that would harmonise government patent policy as a means to promote industrial innovation.[113]

In spite of the presidential support for such a law, one major question remained unanswered, namely, would such legislation not favour large companies to the detriment of smaller ones? In response to this concern, senators Birch Bayh and Robert Dole introduced a bill in the Senate called the Bayh-Dole Bill, which provided for the harmonisation of the patent policy in line with the amended Presidential Memorandum. It authorised small companies alone to retain rights to inventions arising from government-funded research,[114] while large companies had to continue with the old regime of agency-by-agency determination of title to inventions arising from government-funded research.[115] After a series of deliberations, this bill was passed into law, named after the drafters and titled the Bayh-Dole University and Small Business Patent Procedures Act 1980.

The very first provision of the Bayh-Dole Act succinctly and exhaustively sets out the main policy and objectives of the act. It reads:[116]

> It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

To facilitate the realisation of this ambitious provision, the Bayh-Dole Act allocates rights and obligations to research institutions and the government as an overseer. Under the Act universities and other non-profit organisations engaging in government-funded research have the right to elect to retain title to inventions

[113] Dubowy (n 74 above) 56.
[114] Sampat (n 75 above) 779.
[115] Pulsinelli (n 46 above) 403. It should however be noted that, today thanks to a Memorandum to the Heads of Executive Departments and Agencies signed by President Reagan in 1983, and 'quietly endorsed by Congress…' large business contractors enjoy the benefits Congress explicitly provided for small businesses and non-profit organisations under the terms of the Bayh-Dole Act. Eisenberg (n 30 above) 1694 - 1695.
[116] 35 USC § 200; D Keating (2008) 'The US experience with technology transfer' India-United States technology transfer roundtable Delhi, India.

emanating from the research and to grant exclusive or non-exclusive licences on these inventions to private industries for further R&D leading to commercialisation. As a public welfare safeguard, however, the Bayh-Dole Act contains a number of exceptions and monitoring mechanisms. Through the former and the latter the United States government retains the right to interfere with these licences in case of abuse or if their exploitation is detrimental to public welfare. However, a close examination of the implementation of the Bayh-Dole Act since 1980 when it was passed suggests that while there has indeed been a significant increase in collaboration between research institutions and industry in R&D and technological development leading to a massive growth in the biopharmaceutical technology industry, affordability of medicines remains a major challenge in the Unites States.

Alongside the Bayh-Dole Act, the United States Congress passed the Stevenson-Wydler Technology Innovation Act in 1980, which applies to research conducted by the government or government actors like scientists at the NIH.[117] Under this law, laboratory science and engineering professionals are responsible for technology transfer in the course of their work.[118] In 1986, the Technology Transfer Act was enacted to amend the Stevenson-Wydler Technology Innovation Act to allow government-operated laboratories enter into co-operative research and development agreements with industry and to agree to assign patent rights to industry in advance.[119] From the above, it is clear that the path towards enacting the Bayh-Dole Act was not a smooth or quick one. It seems that the length of time it took allowed those for and those against to raise their concerns before a way forward was adopted. It also took several different commissioned research papers to ascertain what kind of law would best balance public and private interests. When the Act was eventually passed and until date, some consider it to be one of the best laws ever passed in the history of the United States and regarded as the backbone of the biotechnology boom that followed shortly after 1980. However, the Bayh-Dole Act, probably like any other piece of legislation, has its limitations. The following section of this chapter focuses on some of the main provisions of the Bayh-Dole Act and their shortcomings.

[117] Pulsinelli (n 46 above) 409.
[118] 15 USC 3710(a)(2).
[119] Pulsinelli (n 46 above) 409; Eisenberg (n 30 above) 1705 - 1707.

2.4 Analysis of the main provisions of the Bayh-Dole Act

Having provided a background to the Bayh-Dole Act, this section analyses some of the main provisions of this law and how some of these provisions have been implemented over the years. The research questions to be answered here are: is there a balance of rights and interests between the tax paying public and private industries? Does the tax paying public get a fair share through access to products developed from government-funded research (in this case pharmaceuticals)? Does the tax paying public and researchers from other research institutions have access to research results generated from government-funded research?

2.4.1 Retention of title, patenting and licensing

Under the Bayh-Dole Act, each funding agreement with a small business firm or non-profit organisation (including universities) shall provide that:[120]

> … the contractor make a written election within two years after disclosure to the Federal agency … whether … [it] will retain title to a subject invention … the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within such times … [A] contractor electing rights in a subject invention agrees to file a patent application prior to any statutory bar date … [the federal agency shall] require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees …

With respect to the type of licence that can be issued to industries, the Act provides that:[121]

> A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention ... only if granting the license is a reasonable and necessary incentive to call forth the investment capital and expenditures needed to bring the invention to practical application; or otherwise promote the invention's utilization by the public.

One of the reasons why intellectual property emanating from government-funded research remained undeveloped prior to the Bayh-Dole Act was that title to the intellectual property reverted to government, rendering the inventions available to everyone in the public to exploit with little or no incentive. The above provisions give research institutions the option to seek the utilisation of inventions upon obtaining patent protection by licensing them to industry on an exclusive or partially exclusive basis. The aim is to provide some degree of exclusivity as an incentive to private industries when this is needed to ensure the commercialisation of an invention.

[120] 35 USC 202(c)(2) (5).
[121] 35 USC 209.

Also important to note is the fact that the Act does not make it mandatory for research institutions to retain ownership over the intellectual property they create, and gives them enough time (two years)[122] to decide on whether or not they wish to retain title to the inventions. This gives the institutions sufficient time to evaluate the pros and cons of retaining ownership over the intellectual property, the commercialisation potential and perhaps the public interest benefits of each commercialisation route. When the research institution decides not to retain ownership, ownership reverts to the United States federal government.

In addition the Bayh-Dole Act authorises the granting of both exclusive and partially exclusive licences only when this is necessary to promote the utilisation of the invention. This implies that where the granting of an exclusive or partially exclusive licence is not the only way through which an invention can be successfully commercialised, a non-exclusive licence should be preferred.

However, research indicates that universities at times grant exclusive licences to private companies with little or no consideration for whether the invention can also be developed and commercialised through a non-exclusive licence because private companies prefer exclusive licenses.[123] As a result, pharmaceutical products that could have been developed and commercialised under non-exclusive licences are developed and commercialised under the monopoly of exclusive licences leading to higher prices.[124]

[122] 35 USC 202(c)(2).
[123] MJ DeGeeter *Technology commercialization manual strategies, tactics and economics for business success* (2004) 47.
[124] Given that individual income tax in the United States has been the largest single source of federal revenue since 1950 (averaging 8% of GDP) it is unreasonable from a public interest perspective that the prices charged on these medicines are unaffordable to the average United States citizen who has already paid for this research through taxes which government used to subsidise the university research in the first place. ML Creech 'Make a run for the border: Why the United States Government is looking to the international market for affordable prescription drugs' (2001) 15 *Emory International Law Review* 1 - 5; http://www.taxpolicycenter.org/briefing-book/background/numbers/revenue.cfm (accessed 21 April 2013).

2.4.2 Manufacture substantially in the United States

Under the Bayh-Dole Act an exclusive licence shall be granted on inventions arising from government-sponsored research only if the licensee undertakes to manufacture products embodying or produced through the use of the invention substantially in the United States, where this is feasible. The relevant provision reads as follows:[125]

> Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

This is an important safeguard, probably aimed at creating and sustaining jobs in the United States. Substantial manufacture as used in the above provision could be interpreted to mean that the product must have over 50% of its components manufactured in the United States. This requirement would be met if the cost of the components mined, produced or manufactured in the United States exceed 50% of the cost of all components required by the licensee to make the product.[126]

However, as mentioned in the above provision a waiver may be obtained by the contractor from the funding agency where domestic manufacture is not commercially feasible, or where the research institution has tried unsuccessfully to find a licensee that would manufacture in the United States.

2.4.3 March-in right

March-in right is one of the main safeguard provisions of the Bayh-Dole Act. The relevant provision reads as follows:[127]

> … the Federal agency under whose funding agreement the subject invention was made shall have the right, … to require the contractor, an assignee or exclusive licensee … to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible

[125] 35 USC 204.
[126] United States Office of the Federal Register *Code of federal regulations*, *title 14: aeronautics and space revised as of January 1, 2013 442.*
[127] 35 USC 203.

> applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself.

For purposes of clarity and transparency, the Bayh-Dole Act further outlines circumstances under which a Federal agency may exercise this right. Some of these instances include:[128]

1. Where the contractor or assignee has not taken effective steps to ensure practical application of the invention and is not expected to do so within a reasonable time.

2. Where march-in rights is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, his assignee, or his licensee(s).

3. To meet the requirement for public use specified by Federal regulations not reasonably satisfied by the contractor, his assignee, or licensee(s).

The Bayh-Dole Act further provides that when the government exercises march-in rights, contractors adversely affected have the right to oppose within six days. Such an opposition will hold the march-in right in abeyance pending a court ruling, and exhaustion of appeals.[129] These restrictions are both aimed at eliminating abusive exploitation of exclusive licences obtained by private industries on inventions emanating from government-funded research while also preventing arbitrary interference with exploitation of these inventions by the government.

With respect to the above provision that government shall exercise march-in rights where the contractor or his assignee has not taken effective steps to ensure practical application of the invention, the Act defines practical application to mean:[130]

> … to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

The implementation of this provision has proven to be challenging as there is a controversy as to whether the phrase *reasonable terms* as used above does or does not include pricing. Peter Arno & Michael Davis, argue that under United States law, the phrase *available to the public on reasonable terms* absent a clear legislative

[128] 35 USC 203(a)(1) (a)(4).
[129] 35 USC 203.
[130] 35 USC 203 § 201 (f).

history should be interpreted in line with United States law which has always held that, absent a clearly explicit statutory intent to the contrary, ordinary words must be interpreted in their ordinary meaning.[131] Citing the cases of *Byars v Bluff City News Co*[132] and *American Liberty Oil Co v Federal Power Commission,*[133] both scholars note that in similar contexts, this phrase has been interpreted under United States case law to include price.[134]

Former Senator Birch Bayh (one of the initial drafters of the Bayh-Dole Bill) during a 2004 march-in petition involving Abbott's patents on ritonavir claimed that the Bayh-Dole march-in provisions were not intended to address cases of unreasonable pricing of inventions.[135] This affirmation is contrary to Senator Bayh's earlier stance in a 1997 march-in petition involving CellPro, in which he and Lloyd Cutler requested the Department of Health and Human Services (DHHS) to interpret *reasonable terms,* considering the impact of licensing polices on the prices faced by consumers.[136]

Despite the theoretical availability of march-in rights in the Bayh-Dole Act, government has never exercised this right, even in cases of excessive pricing by pharmaceutical companies. Two of these cases, namely Novir® and Xalatan® are discussed below.

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[131] *Demarest v Manspeaker* 498 US 184, 190 (1991); *Chisom v Roemer* 501 US 380, 404 (1991) (Scalia J dissenting).
[132] *Byars v Bluff City News Co* (1979) 609 F 2d 843.
[133] *American Liberty Oil Co v Federal Power Commission* (1962) 301 F 2d 15.
[134] 'In the United States in similar contexts, the words "reasonable terms" have uniformly been interpreted to include price. In *Byars v Bluff City News Co*, the United States Court of Appeals for the Sixth Circuit, recognising that establishing "reasonable terms" is necessary to remedy a monopolistic market, noted that "[t]he difficulty of setting reasonable terms, *especially price*, should be a substantial factor" in how to proceed. Similarly, in *American Liberty Oil Co v Federal Power Commission*, the United States Court of Appeals for the Fifth Circuit, interpreting a statute that allows the Federal Power Commission to establish "reasonable terms and conditions," concluded that this meant that the 'price must be reasonable.' Arno & Davis (n 18 above) 662, 650 & 651.
[135] J Love 'Birch Bayh's competing interests and evolving views' 23 August 2012 http://keionline.org/node/1537 (accessed 10 March 2013).
[136] The position of both former senators seems to have changed following their involvement in one way or the other with pharmaceutical companies. While both are Beltway lobbyists, Bob Dole was a star in a Pfizer advertisement on Viagra in 1996 when he left the US Senate. As above.

The Novir® case

In this case, James Love and Sean Flynn on behalf of Essential Inventions[137] requested the DHHS to exercise march-in rights over ritonavir (an HIV treatment medication) manufactured and sold under the trade name Novir®. Ritonavir was invented by Abbott Laboratories from a grant from the National Institute for Allergy and Infectious Diseases,[138] a section of the NIH. By the end of 2001, just five years after Food and Drug Administration (FDA) approval, total sales for Novir® had reached $1 billion.[139] In spite of these profit margins, in 2003 when the medicine moved from being a primary treatment agent to one used in small doses to enhance the effects of other ARVs, Abbott increased the retail price in the United States by 400%.[140] When the march-in request was forwarded to the NIH, Elias Zerhouni, the then NIH director noted that Abbott had met the requirement of practical application by manufacturing Novir® and making it available for use by people living with HIV and that the NIH did not have information leading it to believe that the exercise of march-in rights was warranted.[141] The NIH director further noted that it is the responsibility of Congress alone, and not the NIH, to address medicine price control through legislation.[142]

[137] Essential Inventions is a non-governmental organisation that promotes the creation and distribution of essential inventions and other works that support public health, nutrition, learning and access to information and cultural life. http://essentialinventions.org/ (accessed 22 October 2013).
[138] Essential Inventions 'Petition to use authority under the Bayh-Dole Act to promote access to Ritonavir, supported by National Institute of Allergy and Infectious Diseases' 29 January 2004 http://www.essentialinventions.org/legal/norvir/norvir-29jan04petition.pdf (accessed 16 March 2013); Knowledge Ecology International 'Four NGOs ask NIH to grant open licenses to ritonavir patents under the Bayh-Dole march-in provisions' 25 October 2012 http://keionline.org/node/1573 (accessed 15 March 2013).
[139] As above.
[140] JH Raubitschek & NJ Latker 'Reasonable pricing – A new twist for march-in rights under the Bayh-Dole Act' (2005) 22 *Santa Clara Computer & High Technology Law Journal* 158.
[141] National Institute of Health Office of the Director 'In the case of Novir® manufactured by Abbott Labortories, Inc.' 25 May 2006 http://www.ott.nih.gov/policy/March-In-Norvir.pdf (accessed 16 March 2013); AA Rives 'Reorienting Bayh-Dole's march-in: Looking to purpose and objectives in the public's interest' (2013) 5 *American University Intellectual Property Brief* 89.
[142] National Institute of Health Office of the Director (n 141 above).

The second Novir® case

In October 2012, four civil society organisations (CSOs) representing the public interest,[143] for the second time requested the NIH to exercise march-in rights against Abbott over ritonavir.[144] The group's request in this case asked for two general rules to be applied to ritonavir and any medicine invented out of government funding, namely:

That there should be a ceiling on prices to United States residents, where:[145]

> The Secretary shall normally grant open licenses to third parties to use patented inventions that have benefited from federal funding, subject to the payment of a reasonable royalty and an appropriate field of use, if a product or products based upon those inventions are sold in the United States at prices higher than in other high income countries.

The group further requested that there should be permitted use of the invention for a dependent technology, and that the Secretary be granted the rights to grant licenses to third parties to use patented inventions that have benefitted from government funding, subject to the payment of a reasonable royalty for the product based on the patented inventions where:[146]

> (a) it is a drug, drug formulation, delivery mechanism, medical device, diagnostic or similar invention, and
> (b) it is used or is potentially useful to prevent, treat or diagnose medical conditions or diseases involving humans, and
> (c) it's a co-formulation, co-administration or concomitant use with a second product is necessary to effect significant health benefits from the second product, and
> (d) the patent holder has refused a reasonable offer for a license.

Were the above to be implemented, prices for medicines that government and employers have to pay under the Affordable Care Act would be reduced. However, like the first petition on the same product, the NIH declined to exercise march-in rights in this case on the grounds that the United States healthcare 'delivery system' differed from other wealthy countries, and price disparities between the United

[143] The American Medical Students Association (AMSA); Knowledge Ecology International (KEI); the United States Public Interest Research Group (US PIRG); and the Universities Allied for Essential Medicines (UAEM).
[144] KE Noonan (2013) 'NIH declines to exercise march-in rights over Abbott Laboratories' Novir®' 10 November 2013 http://www.patentdocs.org/2013/11/nih-declines-to-exercise-march-in-rights-over-abbott-laboratories-norvir.html (accessed 22 March 2014).
[145] Knowledge Ecology International (2012) '15 frequently asked questions about the 2012 - 1023 Ritonavir march-in petition' nd (accessed 22 March 2014).
[146] As above.

States and other countries did not trigger any of the Bayh-Dole march-in right criteria.[147]

The Xalatan® case

In 2004, Essential Inventions Inc. requested the NIH to exercise march-in rights on latanoprost, the world's bestselling glaucoma treatment[148] (also used to treat ocular hypertension) and sold under the trade name Xalatan®. Latanoprost was developed by Columbia University under a grant of over $4 million from the National Eye Institute and exclusively licensed to Pharmacia Corporation now owned by Pfizer.[149] According to the petition, the price of this medicine was two to five times higher in the United States than in Canada and Europe.[150] The response of the NIH director in this march-in petition was very similar to the response in the first Novir® case discussed above. Namely, that Pfizer had fulfilled the practical application of the invention by manufacturing and making the medicine available to the public, and that march-in right is not an appropriate remedy for price control, which should be addressed by Congress through legislation.[151] Other equally unsuccessful march-in requests already made to United States agencies to date are the Fabry Disease case[152] and the Myriad BRCA test.[153]

The above failed attempts to secure government march-in rights are an indication of the implementation challenges of the Bayh-Dole Act.

[147] C Pruitt 'NIH once again reject calls to exercise march-in rights' 19 December 2013 http://www.insidemedicaldevices.com/2013/12/19/nih-once-again-rejects-call-to-exercise-march-in-rights/ (accessed 22 March 2014).
[148] Essential Inventions 'Pressure mounts for U.S. to open competition on two Gov't funded medicines' 30 March 2004 http://www.essentialinventions.org/drug/ngos03302004.html (accessed 01 April 2013).
[149] Raubitschek & Latker (n 140 above) 158.
[150] Raubitschek & Latker (n 140 above) 160.
[151] As above.
[152] Rives (n 141 above); J Conley 'Government refuses to march-in under Bayh-Dole again' nd http://www.genomicslawreport.com/index.php/2011/01/18/government-refuses-to-march-in-under-bayh-dole-again/ (accessed 22 March 2014).
[153] D Zuhn 'Senator Leahy urges NIH to use march-in rights on Myriad BRCA test' 17 July 2013 http://www.patentdocs.org/2013/07/senator-leahy-urges-nih-to-use-march-in-rights-on-myriad-brca-test.html (accessed 22 March 2024).

2.4.4 Government-use right

A government-use right sometimes also referred to as a government licence right refers to the right of a funding agency to practice an invention arising from research it has funded, or to have it practiced by someone else on its behalf. This right is defined by the World Intellectual Property Organisation (WIPO) as a non-exclusive, non-transferable, irrevocable and royalty-free right retained by the government to practice, or have practiced, an invention arising from publicly funded research for health, security, national emergency, to promote technological innovation, transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge in a manner conducive for social and economic welfare, and for a balance of rights and obligations.[154] Under the Bayh-Dole Act:[155]

> … the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced … any subject invention throughout the world: provided, that the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States …

This provision acts as an important safeguard. A patent excludes third parties from making, using and selling a product or a process. Through the government licence exception, government retains the right to manufacture the patented products globally in spite of the patent. Government can also use the right to allow other research institutions involved in government-funded research to freely access and use research results and intellectual property it has funded for research, educational, experimental and other non-commercial purposes.

It may be interesting to note that research indicates that some scientists and researchers in the United States are stuck and unable to make progress in potentially promising biomedical research projects because they are required to pay huge licencing fees[156] to gain access to research tools[157] (equally arising from

[154] WIPO 'Exception and limitations to patent rights: private and/or non-commercial use' Standing Committee on the Law of Patents Geneva 27 - 31 January 2014 2.
[155] 35 USC 202 (c) (4).
[156] JP Walsh *et al* 'The patenting of research tools and biomedical innovations' prepared for the Science, Technology and Economic Policy Board of the National Academy of Sciences 09 October 2000 http://www.iatp.org/files/Patenting_of_Research_Tools_and_Biomedical_Inn.htm (accessed 17 March 2013).
[157] Research tools refer to research materials that are necessary to perform further research. Genes are an example of research tools.

government-funded research) that has been patented. A study commissioned by the NIH in 1998 revealed that:[158]

> There is a rising frustration among bench scientists about the ascendancy of "intellectual property issues" that impede their access to state-of-the-art research tools. … Virtually every firm that we spoke with believed that restricted access to research tools is impeding the rapid advance of research and that the problem is getting worse.

Another study conducted by a group of researchers in 2000 revealed that the majority of respondents reported that there are very few cases where valuable research projects were abandoned due to inaccessibility to research done by other contractors. This group noted that:[159]

> We find little evidence [not no evidence] of either routine breakdowns in negotiations over rights, or significant impediments to progress in biomedical research due to such negotiations. We do find that research tool patents can impose a range of social costs, and the potential for problems [i.e. research being blocked] exists.

Even though the second study insists that the problem arises in very few instances, the bottom line is that biomedical research progress is sometimes blocked or abandoned by researchers because they are not able to access or use research results owned by other entities involved in government-funded research. Given these hurdles to upstream research, it might be particularly important for the United States government to consider exercising its government licence rights with respect to these launch-pad inventions.

The case for government-use right to support ongoing innovation is particularly compelling in the case of government-funded follow-on research.[160] If properly utilised, government contractors working on biomedical research projects could gain access to research findings of other recipients (research institutions and universities)

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[158] Medical Research and Human Experimental Law 'Report of the National Institute of Health (NIH) Working Group on Research Tools presented to the Advisory Committee to the Director' 04 June 1998 http://biotech.law.lsu.edu/research/fed/NIH/researchtools/Report98.htm#compet (accessed 17 March 2013); MS Mireles 'An examination of patens, licensing, research tools, and the tragedy of the anticommons in biomedical innovation' (2005) 38 *University of Michigan Journal of Law Reform* 191 - 194.

[159] Walsh *et al* (n 156 above).

[160] The term follow-on research in this context as defined by WIPO refers to research and development innovations and technological advances that follow from or are incremental to prior technological advances or prior knowledge. WIPO 'Follow-on Innovation and Intellectual property' nd http://www.wipo.int/export/sites/www/policy/en/global_health/pdf/who_wipo.pdf (accessed 29 November 2015).

of government funds for follow-on research or for independent research through government licence rights without having to pay licensing fees.[161]

According to Lorelei de Larena, failure to exercise government-use rights stems from three main reasons, namely: the absence of a unified searchable database to notify appropriate officials of inventions that are subject to this provision; the fact that universities fail to report government-sponsored inventions; and the apparent unwillingness of agency officials to invoke this provision probably for fear of the disincentive of a revolving door with industry.[162]

Following a 2003 General Accounting Office (GAO) study, it was shown that the NIH spends close to $30 billion in research yearly,[163] yet in 2001 the Department of Veteran Affairs and Defence spent $120 million on only six medicines all developed from government-funded research. A suitable option would have been for the government to exercise its government-use right to have manufactured medicines on behalf of the United States government at more affordable prices.[164] When questioned on why government-use rights are not exercised, to access cheaper medicines, the relevant agencies advanced three reasons. Firstly, it was not easy to identify which products were eligible for government-use rights; secondly, they believed they had received favourable pricing; and thirdly, they were not required by law to do so.[165] This example clearly illustrates the United States government's reluctance to take any steps that would impinge on pharmaceutical companies' profits.

2.4.5 Disclosure and reporting of inventions

With respect to disclosure and reporting, the Bayh-Dole Act provides that:[166]

> Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions … that the contractor disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible

[161] De Larena (n 45 above) 1395.
[162] As above.
[163] United States General Accounting Office *Technology transfer: Agencies' rights to federally sponsored biomedical inventions* (2003) 6.
[164] De Larena (n 45 above) 1395.
[165] United States Government Accounting Office *Technology transfer reporting requirements for federally sponsored inventions needs amendment* (1999) 3; De Larena (n 45 above).
[166] 202 USC 202 (c).

> for the administration of patent matters, and that the Federal Government may receive title to any subject invention not disclosed to it within such time.

Research indicates that contractors greatly under-report inventions emanating from government-funded research. In 1998 Congress commissioned an investigation by the GAO on how well the Bayh-Dole Act was being implemented.[167] The GAO in its report noted with respect to reporting that it was not logically possible to establish whether research institutes like universities were conforming with the disclosure requirement or not. This is because no mechanism had been put in place to ensure this. Hence, funding agencies simply relied on self-reporting by the research institutions themselves.[168] The GAO research concluded that the reporting provision was abided with only in 6% of the times,[169] amounting essentially to massive wrongful possession of property belonging to the government by research institutions.[170]

In the case of biomedical research, failure to report has severe repercussions. Firstly, it means that research institutions are not accountable to taxpayers. Secondly, because the government is not aware of these inventions, it cannot exercise march-in rights or grant government-use rights should the need arise. Again, government-funded inventions upon which other researchers may rely for follow-on research are unknown to the NIH, other funding agencies and to fellow scientists and researchers.

The above discussed limitations of the Bayh-Dole Act have given rise to two main problems and the adoption of alternate approaches by research institutions to ensure broader access to technologies and products developed from government-sponsored research. The following paragraphs discuss some of these concerns and alternatives.

[167] De Larena (n 45 above) 1397.
[168] United States Government Accounting Office (n 165 above) 6.
[169] United States Government Accounting Office (n 165 above).
[170] Arno & Davis (n 19 above) 679.

2.5 Some concerns arising from the Bayh-Dole Act in the United States

2.5.1 Concerns over collaboration and openness of research

The idea of research institutions and industry working together has been a subject of debate for several years among law makers, academics, CSOs and other stakeholders in developed countries where technology transfer from academia to industry dates back several years. While proponents of research collaboration between universities and industry contend that research ought to be subjected to market forces, those against commercialisation 'decry the prostitution of what was once a noble ideal - that is, the purity of research and the pursuit of knowledge for its own sake.'[171] Among other reasons, the debate arises because the two institutions concerned, academia and industry, seek different goals. While public research institutions are generally driven by public welfare, namely: education, research and openness for the public benefit; industry is primarily driven by profit. This results in the fear that the public welfare inclination of research institutions may be subsumed into the profit maximisation agenda of industry as they become partners. This may take the form of refusals to share academic research findings with fellow colleagues on the part of universities; delays in publication; diversion of faculty research from basic to more applied or translational research; conflicts of interest in universities; and patenting and licensing of basic upstream genetic research tools which may in turn block research and give rise to patent thickets or the tragedy of the anti-commons.[172] In fact, research indicates that the Bayh-Dole Act interferes with open source research, research collaboration between universities and has resulted in research silos, secrecy and publication delays.

According to David Blumenthal *et al.*, a survey aimed at identifying the prevalence and determinants of data-withholding behaviours among academic life scientists,

[171] S Basheer & S Guha 'Outsourcing Bayh-Dole to India: Lost in Transplantation?' 23 *Columbian Journal of Asian Law* 271.

[172] The tragedy of the anti-commons arises when basic research discoveries necessary for subsequent work are owned, not by one entity, but by a number of different entities. AK Rai & RS Eisenberg 'Bayh-Dole reform and the progress of biomedicine' (2003) 66 *Law & Contemporary Problems* 295 - 298; CR McManis & S Noh 'The impact of the Bayh-Dole Act on genetic research and development: Evaluating the arguments and empirical evidence to date' 13 August 2006 https://www.google.co.za/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&ved=0CC0QFjAA&url=http%3A%2F%2Fwww.law.berkeley.edu%2Ffiles%2Fmcmanis(1).doc&ei=VvpsUu-hFoLBhAeT_oD4Aw&usg=AFQjCNHcAi1XazcC56FUEy_qoS-Z_HPK1g (accessed 20 October 2013) 19; D Blumenthal *et al* 'Withholding research results in academic life science' (1997) 277 *Journal of the American Medical Association* 1224 - 1225.

revealed that 19.8% of their research results had been delayed for publication by more than six months at least once in the last three years to allow for patent application, to protect their scientific lead, to slow the dissemination of undesired results, to allow time to negotiate a patent, and or to resolve disputes over the ownership of intellectual property.[173] In addition, 8.9% of respondents reported refusing to share research results with other university scientists in the last three years.[174] In multivariate analysis, participation in academic-industry research relationships and engagement in the commercialisation of university research were significantly associated with delays in publication.[175] Research also indicates that secrecy is more common in academic research projects that are funded by industry in line with expectations of the industrial partners than in research supported through federal funding;[176] and that publication delays and secrecy among scientific researchers are sometimes meant to allow time to secure patent protection.[177]

It should also be noted that in most cases universities usually cannot develop inventions arising from their basic and preliminary research into finished goods, but must transfer them to industry for optimisation, clinical trials and eventual commercialisation. Industry acquiring this research or invention from universities sometimes requires some degree of exclusivity to give them control over the invention and prevent competitors from copying them at least for a limited period of time. In order for universities to own and provide this research or inventions to industry with exclusivity, they must secure ownership on the research through intellectual property rights protection and thereafter licence the patents to industry for royalties and other forms of remuneration.

[173] Blumenthal *et al* (n 172 above) 1224.
[174] As above.
[175] As above.
[176] D Blumenthal *et al* 'Relationship between academic institutions and industry in the life sciences—an industry survey' (1996) 334 *The New England Journal of Medicine* 368, 372.
[177] Blumenthal *et al* (n 172 above) 1225.

2.5.2 Access to medicines in the United States

It is worth noting at this point that even though most of the leading pharmaceutical companies are based in the United States, and that basic research into most of the currently available blockbuster medicines was originally funded by the NIH and conducted by United Sates universities,[178] access to medicines in the United States, particularly when compared to other developed countries, is a cause for concern. Research indicates that people living the United States pay far more for prescription medicines than any other consumers in the world.[179] The primary reason for this is that in other developed countries like Canada[180] and European countries,[181] governments regulate the pricing of medicines and impose price control mechanisms to ensure affordability.[182] Through these regulations, countries negotiate the launch price of medicines with the pharmaceutical manufacturers, forbid price increases altogether, or limit price increases to the inflation rate.[183] Given that these price control mechanisms are non-existent in the United States, pharmaceutical manufacturers therefore rely on the United States market to compensate for the less profitable international market, where consumers are charged far less for the same prescription medicines.[184]

2.5.3 An alternative approach (socially responsible licensing)

Socially responsible licensing refers to the licensing of intellectual property to industry in a way that ensures access to health technologies or products, particularly medicines, for underserved populations at affordable cost, while also seeking to

[178] Public Citizen 'Rebuttals to PhRMA responses to the public citizens report "RX R&D myths: The case against the drug industry's R&D "Scare card"" 07 July 2001 http://www.citizen.org/congress/article_redirect.cfm?ID=6514 (accessed 10 April 2014).
[179] 146 Cong Rec S7193, (daily ed. 19 July 2000) (statement of Sen Jeffords).
[180] Creech (n 124 above) 611 - 612.
[181] Research estimates that Europe spends 60% per head less on medicines than the US. 'The trouble with cheap drugs' *The Economist* 29 January 2004; 'Border line drugs' *The Economist* 29 January 2004.
[182] Creech (n 124 above).
[183] In the US however, the average price inflation for pharmaceuticals sometimes exceeds the general rate of inflation six times. Creech (n 121 above) 594; J Stanton 'Comment, lesson for the United States from foreign price controls on pharmaceuticals' (2000) 16 *Connecticut Journal of International Law* 155.
[184] Creech (n 124 above) 593.

encourage commercial dissemination of know-how in all relevant markets.[185] The first recorded case of socially responsible licensing was the voluntary licence granted by Bristol-Myers Squibb to Aspen Pharmacare, a leading South African generic company in June 2001. The story of this case dates back to the 1960s when Dr. Jerome Horowitz synthesized a number of compounds that would inhibit DNA replication in the expectation that they could cure cancer. These compounds included: AZT, ddC, ddI and d4T. The compounds proved to be ineffective against cancer and were shelved.[186] When the HIV epidemic emerged in the early 1980's, several of these same compounds were evaluated against HIV and found to be effective.[187] Scientists at Yale University evaluated d4T's activity against HIV with funding from the NIH and Bristol-Myers Squibb, and found it to be effective. Yale University filed for a patent on d4T and granted an exclusive licence thereon to Bristol-Myers Squibb as part of the sponsored research agreement. Yale University gave Bristol-Myers Squibb the right to file in foreign countries in the University's name and Bristol Myers Squibb filed corresponding applications in Japan, Canada, South Africa, Mexico, Egypt and Europe where d4T was sold and trademarked under the name Zerit®.[188] In 1998, Zerit® 'became a critical component of the "triple cocktail" that turned HIV infection from a death sentence to a manageable, chronic condition' as it 'became the most frequently prescribed anti-retroviral in the world.'[189]

Through a socially responsible licence granted by Bristol-Myers Squibb to Aspen Pharmacare to manufacture generic version of d4T, and authorisation granted to Medécins Sans Frontiéres to import the medicine from India following internal negotiations between Medécins Sans Frontiéres, Yale University and Bristol-Myers and intense criticism from activists, lower prices for the medication was secured for people living in Sub-Saharan Africa.[190] Today, a number of leading biotechnology universities in the United States have incorporated socially responsible licensing in

[185] R Busang & R Wolson 'Socially responsible licensing guide for technology transfer offices: Adoption and implementation of socially responsible licensing practices' 30 April 2013 http://ship.mrc.ac.za/SRLGuide.pdf (accessed 23 March 2013).
[186] AJ Stevens & AE Effort 'Using academic license agreements to promote global social licensing' 43 *Journal of the Licensing Executives Society International Les Nouvelles* (2008) 86 - 87.
[187] As above.
[188] As above.
[189] P Demenet 'Le Monde Diplomatique' 4 February 2002 http://mondediplo.com/2002/02/04stavudine (accessed 05 April 2014); Stevens & Effort (n 182 above) 86; D Lindsay 'Amy and Goliath' 01 May 2001 http://www.salon.com/2001/05/01/aids_8/ (accessed 05 April 2014).
[190] As above.

licence agreements with industry. Some of these universities include: the University of California Berkeley;[191] University of Washington;[192] and Stanford University.[193]

Socially responsible licensing enables leveraging of intellectual property to accelerate the development of solutions in a manner that leads to optimised access to medicines and other health technologies by populations most in need.[194] Optimised access includes availability, affordability and acceptability of such technologies by populations in need.[195] To ensure this, universities include reservation clauses in licensing agreements with industry that will allow for the manufacture and distribution of medicines in resource-constrained countries while the patent is still valid and without being restrained by industry.

2.6 Conclusion

The passing of the United States Bayh-Dole Act was not a day's job. It took a long time to come up with a law that would for the first time comprehensively and uniformly address the problem of underutilisation of government-funded research and ensure its commercialisation. The several commissioned research reports that preceded the Bayh-Dole Act described the pros and cons of allowing contractors to obtain rights over government-funded research and guided Congress on the approach to adopt. While it was evident that the practice at the time needed change, it was also clear that care had to be taken to ensure that a balance was struck between the interests of taxpayers, consumers, private industry and the federal government. Even though some of the provisions of the Bayh-Dole Act address some of these competing interests, the Act's implementation, particularly with

[191] University of California Berkeley 'Socially responsible licensing and IP management' nd http://ipira.berkeley.edu/socially-responsible-licensing-ip-management (accessed 23 March 2014); Office of Intellectual Property and Industry Research Alliances 'Socially responsible licensing at U.C. Berkeley: An intellectual property management strategy to stimulate research support & maximise societal impact' nd http://www.ipadvocate.org/mission/pSociallyResponsibleLicensing_Berkeleydfs/.pdf (accessed 23 March 2914).
[192] P Kelley 'Choosing the greater good in promotion of UW intellectual properties' 04 January 2007 http://www.washington.edu/news/2007/01/04/choosing-the-greater-good-in-promotion-of-uw-intellectual-properties/ (accessed 23 March 2014).
[193] Stanford University Office of Technology Licensing 'Why we do it' nd http://otl.stanford.edu/about/about_why.html?headerbar=0 (accessed 23 March 2014).
[194] Busang & Wolson (n 185 above).
[195] Busang & Wolson (n 185 above).

respect to access to medicines invented out of or incorporating publicly funded research, raises some concerns.

Other impacts which Congress probably did not foresee at the time the Bayh-Dole Act was enacted have also emerged. While some universities have resorted to practices like socially responsible licensing to mitigate some of these challenges, others persist with their hard line stance. This perhaps explains why while some developed and developing countries have enacted laws similar to the United States Bayh-Dole Act to deal with the management of intellectual property originating from government-funded inventions, other countries have opted for different approaches. The next chapter focuses on the regulation of intellectual property emanating from publicly funded research in selected countries where different approaches have been adopted.

CHAPTER III

THE REGULATION OF GOVERNMENT-FUNDED RESEARCH IN OTHER COUNTRIES (OTHER MODELS)

3.1. Introduction

Different countries have adopted different laws or policies in the area of technology transfer from academia to industry. While Germany for instance introduced a centralised system similar to the United States Bayh-Dole Act in 2002,[196] Britain allows different universities to deal with intellectual property emanating from government-funded research as they deem fit. Again, Italy and Sweden have adopted the professor's privilege where the inventor retains title to, and singlehandedly decides on how such intellectual property should be managed and commercialised.[197] This section looks into some of these alternative ways of regulating intellectual property emanating from government-funded research in the United Kingdom (UK) and Sweden. The choice of these countries is based on the fact that they are among the few countries that have opted for approaches that differ from the United States Bayh-Dole model. In addition to these two countries, the case of Switzerland which has a thriving biotechnology and pharmaceutical industry with no laws or policies on technology transfer from academia to industry will be looked into.

The last decade or so has witnessed increased attention being paid to the role of European universities in boosting innovation and technological advancement through the commercialisation of their research. 'The perception of a strong European science base which is not translated into economic growth is often labelled the "European Paradox"'.[198] It is perhaps in a bid to reverse this paradox that countries like Italy, Germany and Denmark changed their laws and policies in this area with the intention of getting academic institutions to contribute more meaningfully to the economy.

[196] The German Act on Employees Inventions was amended in 2002 to replace the professor's privilege with University ownership of inventions originating form government-sponsored research.
[197] B Verspagen 'University research, intellectual property rights and European innovation systems' (2006) 20 *Journal of Economic Surveys* 619.
[198] European Commission *Green Paper on Innovation* 20 December 1995 http://europa.eu/documents/comm/green_papers/pdf/com95_688_en.pdf (accessed 20 December 2013).

Unlike the previous chapter, this chapter will not delve so much into access to medicines in Britain and Sweden because healthcare in both countries is largely subsidised by the government, hence, accessible.[199] Secondly, unlike in the United States, Britain and Sweden, like several other European countries, have medicine pricing control mechanisms;[200] hence, there is a set limit for the prices of medicines. Therefore, the aim of analysing the regulation of technology transfer in these two countries is not to examine the access to medicines implications but mainly to provide an alternative to the much celebrated Bayh-Dole model. This will also contribute to the model law that this research aims to develop and recommend for developing countries seeking to better regulate government-funded research.

While it was easy to access information on technology transfer in the United States from journal articles, the internet and other research facilities available for this research, this was not the case for European countries. This situation identified another limitation in this research. To overcome this limitation Skype interviews, email exchanges and phone conversations with individuals involved in technology transfer in these countries were relied on. Again, and particularly with respect to Sweden, language barriers led to having to make use of translated documentation (secondary sources).

[199] In Sweden, 80% of healthcare is funded by the government, and only 4% of the population go for voluntary health insurance, most of which is paid by their employers. Government spends 9.9% of its GDP on healthcare. A Anell *et al* 'Sweden: Healthcare system review' (2012) 14 *Healthcare Systems in Transition* xvi-xvii; The Local Sweden's news in English 'Swedish healthcare: All you need to know' 27 March 2013 http://www.thelocal.se/20130327/46910 (accessed 08 January 2014); InterNations 'Healthcare in Sweden' nd http://www.internations.org/sweden-expats/guide/living-in-sweden-15471/healthcare-in-sweden-3 (accessed 08 January 2014). The UK provides public healthcare to all permanent residents, healthcare is free at the point of need, and about 8.4 % of the country's GDP is spent on healthcare. J Chang *et al* 'The UK healthcare system' nd http://assets.ce.columbia.edu/pdf/actu/actu-uk.pdf (accessed 08 January 2014); R Ramesh 'NHS fares best on free access to healthcare' *The Guardian* 19 November 2010.

[200] US Department of Commerce International Trade Administration 'Pharmaceutical price controls in OECD countries implications for US consumers, pricing, research and development, and innovation' (2004) 3 - 9; T Worstall 'You can't have free trade and price controls: Pharmaceutical Drugs Edition' 23 June 2012 *Forbes* http://www.forbes.com/sites/timworstall/2012/06/23/you-cant-have-free-trade-and-price-controls-pharmaceutical-drugs-edition/ (accessed 08 January 2014).

3.2 Regulation of technology transfer in Britain

Technology transfer from publicly funded research institutions to industry has over the years become an inherent third mission of universities in the UK aside from teaching and research. In 1948, the Development of Inventions Bill was passed to create the National Research and Development Corporation (NRDC).[201] The NRDC was the first technology transfer organisation formed by a government and the largest technology transfer organisation in the world.[202] The NRDC was charged with securing the development or exploitation of inventions resulting from publicly funded research; acquiring, holding, disposing of; and granting rights (whether gratuitously or for consideration) in connection with inventions emanating from publicly funded research where the public interest so required.[203]

In 1981, the British Technology Group (BTG) was formed by the UK Government from the merger of the NRDC and the National Enterprise Board to licence and commercialise publicly funded research inventions.[204] BTG was granted a right of first refusal to all inventions emanating from government-funded research.[205] However, following missed opportunities to patent inventions like the monoclonal antibodies,[206] and the privatisation of BTG,[207] Parliament in 1985 withdrew BTG's

[201] Unpublished: K Harvey 'Managing the exploitation of intellectual property: An analysis of policy and practice in nine UK universities' unpublished PhD thesis, University of Sterling 1992 2 - 3.
[202] As above.
[203] As above.
[204] As above.
[205] R Jennings 'Adventures in knowledge transfer' paper presented at PraxisUnico Annual Conference on Inspiring Futures in Nottingham 13 June 2013 http://www.praxisunico.org.uk/uploads/1%20-%20RichardJennings.pdf (accessed 05 November 2013).
[206] The missed opportunity to patent the monoclonal antibodies was to become the subject of much controversy in the late 1970s, a time of economic and political anxiety in the wake of the decline in Britain's manufacturing sector, and consequent rising unemployment. In July 1975 Milstein gave a presentation on monoclonal antibodies at an internal Medical Research Council (MRC) meeting convened to discuss the safety of genetic engineering. After his presentation, Tony Vickers who was a scientist by training and an administrative official of the MRC, was struck by the commercial possibilities for hybridoma technology and sought to patent the technique as soon as possible given that Milstein and Köhler were about to publish an article about this experiment in *Nature.* Because British patent law does not allow for the disclosure of any work such as publication of an article prior to filing an application for a patent, there was need to act immediately. While Vickers was quick off the mark in his attempt to get a patent for Köhler and Milstein's technique and intervening before the *Nature* article went into print, it took the NRDC several months and some prompting by the MRC before any action was taken. The NRDC response came in the form of a letter written in October 1976. By this time the opportunity for patenting the technique in Britain had been lost as the method had been published in *Nature*. The NRDC had not filed for patent. One of the most vehement critics of the failure to patent the technique for monoclonal antibodies was Margaret Thatcher, a chemist by training who was elected Prime Minister in 1979. In a 1980 report investigating the commercialisation of biotechnology in Britain, scientists were mostly blamed for failure to patent their inventions. The

right to first refusal and allowed universities to own, manage and seek exploitation of their inventions and intellectual property themselves.[208]

Another important development that took place in Britain in the late 1980s worth noting was the 36% drop in government funding for teaching in England. This gave rise to an urgent need to generate income from non-governmental sources on the part of British universities. These non-government sources of funding were referred to as third-stream funding.[209] Today, through government support, the translation and commercialisation of research results by means of knowledge transfer from academia to industry has become an inherent duty of British universities both to advance science, and to boost the UK economy.[210]

Unlike in the United States, there is currently no single national piece of legislation that specifically addresses technology transfer from research institutions to industry in the UK. Different universities have different regulations. In addition to these institutional regulations, recourse is sometimes made to the UK Patents Act 1977, which ascribes ownership of inventions created by employees to their employers. [211]

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relevant paragraph read: 'There appears to be a lack of awareness in practice of the obligations on recipients of government money and of the rights of the NRDC. This must be remedied. We are concerned that a lack of appreciation of the NRDC, particularly by young scientists, may continue to result in situations such as that which occurred over monoclonal antibodies where patent protection was not sought early enough and British advantage was reduced'. Following this failure to patent the monoclonal antibodies, Hilary Koprowski, Carlo Croce and Walter Gerhard obtained two patents for making monoclonal antibodies against tumours and influenza virus antigens in October 1979 and April 1980. This was created using the X63 myeloma cell line originally supplied by Milstein to Koprowski back in September 1976. These patents provoked major controversy in Britain and in the international scientific community which attached very little importance to commercialisation in the 1970s. Several years after this incident, it is reported that Milstein came to consider NRDC's failure to patent as a blessing. This is because it allowed him greater freedom to publish and get on with his research. Had the NRDC moved forward on a patent, he might have been forced to become more secretive about his work, and many scientists were able to move much faster in working out their application. In the 1980s, the MRC established a new scheme allowing for the sharing of royalties with inventors. This of course required commercialisation of research. EM Tansey *et al* 'Technology transfer in Britain: The case of monoclonal antibodies*; self and non-self: A history autoimmunity; endogenous opiates; the committee on safety of drugs*' *Wellcome Witnesses to Twentieth Century Medicine* vol 1 (1997) 1 - 33; Skype communication with Richard Jennings on 23 September and 12 November 2013; Jennings (n 201 above).

[207] J Nelles & T Vorley 'Entrepreneurship architecture in the UK Higher Education Institutions: Consolidating the Third Mission' 17 - 20 June 2008 http://www2.druid.dk/conferences/viewpaper.php?id=3275&cf=29 (accessed 18 December 2013).

[208] Harvey (n 201 above); Jennings (n 206 above).

[209] Leadership Foundation for Higher Education *Commercialisation and Enterprise: History and Context* (2012) 1.

[210] Nelles & Vorley (n 207 above) 5. Sype Communication with Richard Jennings (n 206 above).

[211] Sec 39(1)(a) - (b).

Under the Patents Act, an invention made by an employee automatically belongs to his employer when the invention is made in the course of the employee's normal duties, or in the course of duties falling outside his normal duties, yet specifically assigned to him by the employer, and where the circumstances in either case are such that an invention might reasonably be expected to ensue. Neither the Patents Act, nor any other national legislation speaks specifically to ownership and management of inventions emanating from government-funded research in universities and other research institutions.

While some universities interpret the above provision in the Patent Act to include universities as employers, and faculty researchers as employees with the corresponding result that inventions made by university researchers in the course of their research at the university belongs to the university, other universities do not.[212] According to Richard Jennings,[213] because university researchers are sometimes neither specifically recruited to carry out particular research, nor to do so in a particular way, British universities are not in breach of any law whether they retain title to inventions, or allow the faculty inventor to retain title to the intellectual property depending on the circumstances under which the research results came about.[214]

Furthermore, contrary to the United States where universities involved in technology transfer do not receive funding from the government specifically for setting up and maintaining appropriate technology transfer systems, the UK government provides funding to universities for technology transfer activities. This funding is provided by the British Research Councils on a competitive basis based on third-mission performance.[215] The British Higher Education Innovation Fund (HEIF) assists

[212] At Oxford University and Imperial College London inventions arising from research done by university researchers belong to the university. This is however not the case at Cambridge University. Sype Communication with Richard Jennings (n 206 above).
[213] Deputy Director of Cambridge Enterprise, the technology transfer office (TTO) at Cambridge University.
[214] Jennings (n 205 above).
[215] As above; E Källblad 'The organisation of third mission funding in the UK: An overview of the Higher Education Innovation Fund (HEIF) and its impact' nd http://www.vinnova.se/upload/dokument/Verksamhet/Kommersialisering/Nyckelaktorer/HEIF_EK.pdf (accessed 03 November 2013); A Langlands 'Research commercialisation is changing. Are you ready?' *The Review* 2010 - 2011 7.

universities in linking research to business, and also provides technology transfer support (including funding) to universities to fulfil their third mission.[216]

Given that British universities individually regulate technology transfer and commercialisation of their research, an appraisal of the laws relating to ownership and management of government-funded research and technology transfer from academia to industry can better be done by examining the situation in selected universities. For this purpose, the next part of this chapter will examine the regulation of technology transfer in two leading UK universities, namely: Cambridge University and Oxford University. The choice is based on the fact that these top UK universities are also ranked among the first five worldwide and are among the most advanced, if not the most advanced, in technology transfer in Britain.

3.2.1 Cambridge Enterprise

Cambridge Enterprise is the TTO at the University of Cambridge. Intellectual property emanating from government-funded research at Cambridge University is regulated by Chapter XIII of the Statutes and Ordinances of the University of Cambridge (the Statute). The paragraphs quoted below provide insight into some of the main provisions of the Statute.

Retention of title and patenting

Under the Statute, retention of title to inventions depends on a number of factors. The relevant provision reads as follows:[217]

> Research undertaken by University staff in the course of their employment by the University shall include all research conducted under the obligation to do so, expressed or implied, in their terms of employment. The time when, and the place where, particular research results are reached or achieved shall be factors to be taken into consideration in assessing whether the research is in the course of employment.

With respect to patenting, licensing, and commercialisation, the retention of title depends on whether title to an invention is held by the university or the researcher. Where the university retains title:[218]

[216] Källblad (n 215 above).
[217] Sec 5.
[218] Sec 6.

> The University shall have the initial right to apply throughout the world for a patent for an invention, … belonging to [it] … The University or its delegated nominee … will become the proprietor of any intellectual property right that is in consequence granted or registered.

Where title to the intellectual property is held by the researcher, for example where the research leading to the invention was not conducted under the expressed or implied obligation to do so in the terms of employment, the following applies:[219]

> The relevant creator of the subject matter … may decide that they do not wish it to be exploited through Cambridge Enterprise and then may require the University to assign the rights … to the creators for a fixed percentage of royalty income in the case where the creators decide to license or assign the rights to a third party; or under negotiated licence/equity terms when the creators are forming a company to exploit the rights…

The Statute further provides that where the University staff decides to commercialise the invention through Cambridge Enterprise, both the creator and Cambridge Enterprise shall agree on whether patent application should be sought in the UK or elsewhere and whether a company should be formed to exploit the technology.

Interestingly, apart from the university and the university staff, university students are also allowed to retain title to intellectual property created by them. The relevant provision reads as follows:[220]

> … intellectual property rights … created by a student shall rest with the student, with the following exceptions: … Where a student is sponsored by a third party, a condition of sponsorship may be that the sponsor may own any intellectual property developed during the period of sponsorship. … Where a student is working on a sponsored project as part of his or her course-work or research, the sponsor may own any intellectual property that the student develops … When the University obtains an assignment of student-created intellectual property, it undertakes to provide the student with a share in such financial returns from the exploitation as there may be on the same basis as that applying to University staff …

The idea of retaining title to intellectual property emanating from their research is a motivation for both University staff and students to engage and collaborate with industry in seeking commercialisation of university inventions or creating start-ups without feeling compelled to.

However, problems may arise when a University staff leaves one university for another. For instance, would University staff have to abandon research projects that were started at their previous university, especially if the universities have different intellectual property management policies on ownership of inventions? Secondly, even if the two universities have similar intellectual property management policies,

[219] Sec 21.
[220] Sec 14(a) - (c).

would the faculty researcher or inventor be compelled to continue providing guidance and assistance in the exploitation of the intellectual property he or she has developed to the TTO of the previous university when he or she has moved to another?

Disclosure and publishing

Under the Statute, researchers are required to disclose inventions arising from their research to the university and collaborate with the university in seeking protection and commercialisation. The relevant provision reads as follows:[221]

> If University staff decide that the results of their activities should be the subject of commercial exploitation, and that the rights to those results are reasonably capable of including rights to which the University is initially entitled … they must notify the University, … and provide the University with full disclosure of the relevant results … [and] assist the Research Services Division to take reasonable steps to determine … whether any agreements govern the ownership or exploitation of the subject matter…

Further to this, the researcher shall discuss the path for exploitation with Cambridge Enterprise; whether or not a patent application should be filed; and whether a spin-off should be formed to exploit the technology.[222]

With respect to publishing, inventors are free to elect to publish or disclose their research unless they decide to secure patent protection, in which case a patent application must be filed before any form of disclosure to the public is made. The relevant provision reads as follows:[223]

> University staff are entitled to decide that the results of any research undertaken by them … shall be published or disseminated … as they wish in accordance with normal academic practice. However, if … [they] decide that the results of their research should be commercialized, they should be aware that, in respect of patents … protection … may be jeopardized if … the [invention] is made available to the public anywhere in the world before all relevant applications for protection have been lodged.

If a student is involved in sponsored research requiring prior examination by the sponsor before publication, the student will be prevented from publishing before such examination is done. To avoid delays, the Statute provides a specific timeframe within which such sponsors should complete the examination. Under the Statute:[224]

[221] Sec 18.
[222] Sec 19.
[223] Sec 4.
[224] Sec 14(c).

> A sponsorship agreement may … place a requirement on the student and his or her examiners to undertake to keep results confidential while steps are being taken to protect intellectual property or to establish exploitation arrangements. The student may also be required to submit the dissertation to the sponsor for scrutiny before submitting it for examination. Any confidentiality agreement whose purpose is to delay public disclosure for the purpose of protection should usually not have effect for longer than three months from the time the sponsor is notified of intent to publish. … Material or other subject matter … of which the copyright is owned by the University … may be released under Open Source or similar arrangements on the authority of the Head of Department in which the material is created.

Clearly, inventors are free to publish their research results according to university practice. According to Richard Jennings, making government-funded research available to the public remains a priority for British universities and researchers.

It should be noted that the provision enabling sponsors to hold back publication, or scrutinise papers before their publication only applies to research not funded by the government. By giving private sponsors a three month deadline, from when the intention to publish is made known to them, within which to hold back publication, the Statute clearly still prioritises making research available to the public as soon as possible.

At the national level, the Research Council UK (RCUK) Policy on Open Access emphasises the importance of open access to publicly funded research.[225] Under the policy, the RCUK requires that publicly funded research should be freely accessible not just to other researchers, but also to potential users in business, charitable and public sectors, and to the general public.[226] On 16 July 2012, the British government accepted the recommendations of the Working Group on Expanding Access to Published Research Findings in its report titled *Accessibility, sustainability, excellence: how to expand access to research publications.* This commission recommended, among others, *'*a balanced programme of action to enable more people to read and use the publications arising from research, and to accelerate the progress towards a fully open access environment.'[227]

The report also recommends a clear policy direction in the UK towards support for open access publishing, where publishers receive their revenues from authors rather than readers; and research articles become freely accessible to everyone

[225] http://www.rcuk.ac.uk/research/Pages/outputs.aspx (accessed 18 December 2013).
[226] As above.
[227] http://www.researchinfonet.org/publish/finch/ (accessed 18 December 2013).

immediately they are published.[228] In a bid to support the implementation of the policy, the Research Council in April 2013 introduced a new funding mechanism in the form of a block grant to universities and eligible research organisations to cover the cost of article processing charges.[229]

3.2.2 Isis Innovation

Isis Innovation is the TTO at Oxford University responsible for the management and commercialisation of Oxford University's intellectual property. Ownership and management of intellectual property emanating from university research at Oxford University is regulated by Statute XVI: Property, Contracts, and Trusts; and Regulations for the Administration of the University's Intellectual Property Policy, Council Regulations 7 of 2002 (the Regulations).

Retention of title and patenting

As a general rule and unlike the system of retention of title at Cambridge University, intellectual property originating from research carried out by Oxford University researchers belongs to the University, unless there is an agreement to the contrary. The relevant provision reads as follows:[230]

> The University claims ownership of all intellectual property … which is devised, made, or created: by persons employed by the University in the course of their employment; by student members in the course of or incidentally to their studies; by other persons engaged in study or research in the University who, as a condition of their being granted access to the University's premises or facilities, have agreed in writing that this Part shall apply to them; and by persons engaged by the University under contracts for services during the course of or incidentally to that engagement. If the University decides not to seek to exploit intellectual property to which it lays claims, or if, after [it] has initiated or sanctioned exploitation, [it] decides … that the process … be abandoned, [it] shall … [assign] the intellectual property to the researcher.

The Regulations further provide that Isis Innovation, is the University's preferred route of exploitation,[231] and is entitled to, and responsible for exploitation of government-funded research.[232] Nonetheless, if a researcher prefers to exploit and commercialise an invention through an alternative means, provided such will result in

[228] As above.
[229] n 225 above.
[230] Sec 5(1)(a) - (d) & (2); sec 10.
[231] Sec 1(2)(c).
[232] Sec 1(b).

reasonable return to the University, the researcher can seek an alternative mode of commercialisation.[233]

With respect to exploitation, the Regulations provide that interested parties, that is, the University staff and Isis Innovation will engage with each other to determine whether a patent application needs to be filed, identify potential licensees, or to form a company to exploit the technology.[234]

As regards licensing, Oxford University on its website has a number of ethical provisions for access to essential medicines in least developed countries. The relevant provision reads as follows:[235]

> The University of Oxford is mindful of the importance of development and distribution of new health-related technologies for less developed countries. Its policy when licensing its technology for commercial exploitation purposes is, as far as is practicable: to prosecute patent applications in less developed countries only as necessary (for example, to provide development and marketing leverage for new products, or to exert leverage over global licensees); [and] to grant licences with provisions that seek to increase the availability of medicines at affordable prices to less developed countries. It expects its commercial licensing partners to appreciate and cooperate with this policy.

Although the above are merely ethical provision and therefore not mandatory, they may however exert some moral obligation on potential licensees.

Disclosure and Reporting

With respect to reporting, the Regulations provide that:[236]

> Where … ('a researcher') creates intellectual property … which is capable of commercial exploitation, he or she shall report its existence to the Head of Department (or equivalent) and, in the case of intellectual property arising from research, to the Director of Research Services … and shall provide … all necessary information concerning the provenance of the intellectual property and the circumstances in which it was created.

As regards disclosure, as mentioned above, the RCUK Policy on Open Access requires publicly funded research to be made freely accessible to other researchers; potential users in business, charitable and public sectors; and to the general public.[237]

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[233] Sec 1(2)(c).
[234] Sec 3(1) - (2).
[235] http://isis-innovation.com/university-members/commercialising-technology/ip-patents-licenses/marketing-confidentiality/ (accessed 18 December 2013).
[236] Sec 1 (1).
[237] n 225 above.

3.3 Regulation of technology transfer in Sweden

3.3.1 Introduction

At the national level, Sweden does not have a national law that specifically deals with the management of intellectual property emanating from government-funded research. The role of universities is spelt out in the Swedish Higher Education Act (1992:1434). This Act provides that higher education institutions shall co-operate with the community and make available information about their activities.[238] According to Gerald Maguire Jr, although the original emphasis seems to have been to inform the public of research results, over the years a third mission has evolved from this provision among Swedish universities.[239] This third mission consists of increased collaboration with industry, public administration, organisations, culture, and popular education.[240]

Under the Swedish Act 345 on Rights to Employees´ Inventions 1949, any invention created by an employee in the course of employment belongs to his employer.[241] However, as an exception, researchers and academics working in colleges and universities are allowed to retain title to intellectual property originating from their research.[242] The researcher has full powers to decide on whether or not to patent, commercialise or licence the intellectual property.[243] This special treatment is referred to as the professor's privilege.

3.3.2 The professor's privilege

While countries like Denmark, Germany, Japan and Norway which previously allowed University staff to retain title to intellectual property developed out of government-funded research have amended their laws to adopt laws similar to the United States Bayh-Dole Act,[244] Sweden has maintained inventor ownership for University staff. Italy in 2001 changed its laws from university ownership of

[238] Sec 2 (1)-(2) of the Higher Education Act (Högskolelagen 1992).
[239] G Maguire Jr (2008) 'The third assignment ("Tredje uppgiften")' 05 March 2008 3 - 4 http://web.it.kth.se/~maguire/Talks/graz-20080304d.pdf (accessed 24 December 2013).
[240] As above.
[241] L Tottie 'The professor's privilege' *Valea Technology & Law* 1 nd http://valea.episerverhosting.com/Global/Dokument/Nyheter/Professors%20privilege.pdf (accessed 20 December 2013).
[242] As above.
[243] As above.
[244] EF Damsgaard & MC Thursby 'University entrepreneurship and professor privilege' (2013) 2 *Industrial and Corporate Change* 185.

inventions to inventor ownership.[245] Both at the national level and at the Organisation for Economic Co-operation and Development (OECD) level, the Swedish government is constantly requested to replace the professor's privilege with a different approach to managing publicly funded research results.[246]

It is common practice in Sweden for university researchers to collaborate with industry in government-funded research projects. In most cases these researchers allow industry to retain title to inventions arising from such research collaborations.[247] Hence, intellectual property that in other contexts would be classified as arising from universities are actually classified as arising from industry. Again, because inventors are not obliged to report on inventions arising from government-funded research,[248] such inventions go unnoticed.

In 2004, the Swedish government commissioned an inquiry into the professor's privilege and the reason behind the country's low records on the exploitation of academic research. The Swedish Official Report (SOU 2005:95), which was the outcome of this inquiry, recommended two possible solutions. Firstly, that the professor's privilege could be maintained with the additional requirement that researchers must report inventions emanating from their research.[249] Secondly, that the professor's privilege could be replaced with university ownership of government-sponsored research in return for reasonable compensation to the inventor. In this case, where the academic institution fails to commercialise the invention, title thereto should revert to the inventor.[250]

Nonetheless, the 2008/2009:50 Government Bill, while acknowledging the above recommendations, highlighted the importance of the professor's privilege as an incentive to researchers. The Government Bill further noted that in the absence of a better system that would both secure the commercialisation of inventions and

[245] Verspagen (n 197 above) 619.
[246] A Dahlstrand 'Is the commercialisation of European R&D weak? A critical assessment of the dominant belief and associated policy responses' paper presented at the Birkbeck Workshop on "Intellectual property and university entrepreneurship" 2013.
[247] F Montobbio 'Intellectual Property Rights and Knowledge Transfer from Public Research to Industry in the US and Europe: Which Lessons for Innovation Systems in Developing Countries' (2009)186.
[248] Damsgaard & Thursby (n 244 above) 187.
[249] As above.
[250] As above.

incentivise researchers, the professor's privilege should be maintained. Therefore, the status quo is still the same in Sweden.[251]

3.4 The case of Switzerland

Unlike the United States and other European countries which have either national or institutional regulations on technology transfer from academia to industry, or have over the years developed common practices in this area, Switzerland has no such law or policy as this is not a priority for the government.[252] Innovative firms in Switzerland seek collaboration with research institutions as least often as firms in other European countries, yet the country has a thriving pharmaceutical industry,[253] and the highest pharmaceutical industry growth rate in Europe. About a third of market capitalisation on the SIX Swiss Exchange[254] is attributable to life sciences companies, and 42% of the capitalisation of European life sciences companies are listed on the SIX.[255] According to Jo Whelan, the success of the Swiss pharmaceutical industry is mainly attributed to the lack of obvious resources in the country which led the country to focus on high-value speciality products that it could sell to the rest of the world.[256] To achieve this, government, companies and academic institutions strive to attract and retain high-calibre researchers and other forms of expertise from all over the world. For instance, although Switzerland is not a member of the European Union, Government has relaxed work and residency restrictions for European Union citizens in Switzerland, and there is no limit on the number of European Union workers allowed into Switzerland.[257] In addition, Swiss scientists can compete for funding from the European Union's Framework research programmes.[258]

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[251] As above.
[252] S Arvanitis *et al* 'Knowledge and Technology Transfer between Universities and Private Enterprises in Switzerland an Analysis based on Firm and Institute Data' A study on behalf of the ETH-Board 2006 3.
[253] Arvanitis (n 252 above).
[254] The SIX Swiss Exchange is Switzerland's principal stock exchange. It also trades other securities such as Swiss government bonds and derivatives such as stock options.
[255] Between 2002 and 2012 the growth rate amounted to an average of 9.1% each year. This makes Switzerland the most important stock exchange for Life Sciences companies in Europe. Switzerland Global Enterprise http://www.s-ge.com/global/invest/en/content/switzerland-pharmaceutical-hub-key-points-glance accessed (3 December 2015).
[256] Whelan 'Switzerland's thriving pharmaceutical industry: high-altitude thinking' *New Scientist* 6 May 2006.
[257] Whelan (n 256 above).
[258] As above.

At the level of research institutions, one fifth of students and one third of academic staff in Switzerland are foreigners.[259] These figures are even higher in leading scientific research institutes. For example, Basel's Friedrich Miescher Institute has almost forty nationalities among its ninety PhD students and seventy-five Postdoctoral students,[260] and academic salaries are some of the best in Europe.[261] The main science funding body, the Swiss National Science Foundation funds Assistant Professor positions for selected researchers of any nationality starting an academic career.[262] Over 7000 researchers receive project-based funding each year.[263] The Federal Institutes of Technology in Zurich and in Lausanne are bolstering these efforts with tenure tracking wherein Assistant Professors in the scheme are offered a tenured professorship within six years, subject to a performance evaluation.[264] As a result of these policies which attract foreign expertise, and in spite not having a policy or law on technology transfer, Switzerland's pharmaceutical industries perform exceedingly well when compared to other European countries. The case of Switzerland is a clear indication that there is no one-size fits all approach to promoting R&D, bolstering technological development and innovation.

According to Erika Damsgaard and Marie Thursby, the adoption of university ownership of government-funded inventions by other countries as a panacea for technology transfer and commercialisation of university inventions is quite ironic. This is because of the growing scepticism in the United States among academics and policy makers about the merits of the Bayh-Dole Act.[265] In addition, some scholars have expressed doubt that policies that work well in the United States would transplant to other countries (particularly those where professors historically retained title to their inventions).[266] Other scholars have also criticised the United States model on grounds that university research commercialisation as it is practiced

[259] As above.
[260] As above.
[261] Experienced Post doctorate students earn up to 100,000 Swiss francs (£44,000) per year. Whelan (n 256 above).
[262] Whelan (n 256 above).
[263] As above.
[264] As above.
[265] Damsgaard & Thursby (n 244 above) 186.
[266] DC Mowery & BN Sampat 'Universities in national innovations systems' in J Fagerberg *et al* (eds) *The Oxford Handbook of Innovation* (2005) 225.

today threatens the pursuit of basic research and stifles entrepreneurial efforts.[267] Universities have also been accused of acting like profit centres, with the patent system interfering with the widespread dissemination of publicly funded research.[268] Even, industries to which these universities licence government-funded research have also commonly noted that university TTOs are difficult to deal with, not only in licensing publicly funded research, but also with respect to licensing terms.[269]

3.5 Conclusion

From the information available one may therefore say that there is no one-size-fits all approach to regulating technology transfer. Developing countries considering regulating technology transfer from academia to industry should use the United States' Bayh-Dole Act simply as a guide. They should be able to examine the merits and demerits of the Act and to come up with laws and policies that are better suited to their contexts and guarantee access to technologies and inventions arising from government-funded research, particularly in the case of biopharmaceutical technologies. While it is important for countries to ensure that optimum use is made of government-funded research results, it is also important to ensure that this is done in a way that preserves and does not divert the original mission of universities; safeguards the public interest; and guarantees reasonable rather than excessive profit for private companies through which universities seek to commercialise their inventions. Access and accountability must also be taken into account.

[267] J Thursby & M Thursby 'University licensing: Harnessing or tarnishing faculty research? in J Lerner & S Stern (eds) *Innovation Policy and the Economy* vol. 10 (2010) 160 - 161 .
[268] Damsgaard & Thursby (n 244 above) 186.
[269] As above.

CHAPTER IV

THE REGULATION OF PUBLICLY FUNDED RESEARCH IN SELECTED EMERGING COUNTRIES

4.1 Introduction

The advent of diseases like HIV/AIDS served as a lens through which international organisations and institutions, charity organisations, and individual countries, particularly developing and least developed countries, were able to re-examine laws and policies relating to access to healthcare services, medicines, and human rights more broadly. At the international level, this re-examination resulted in the creation of institutions like the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund); UNITAID; the President's Emergency Plan for AIDS Relief (PEPFAR); the Clinton Foundation; the Joint United Nations Program on HIV/AIDS (UNAIDS); just to name a few, all of which were either fully or partially motivated by the need for a better response to the HIV/AIDS pandemic. At the national level, most if not all countries introduced new laws or policies aimed at containing the disease and boosting access to HIV-related healthcare services and medicines.[270]

In spite of the emergence of these structures and programmes aimed at scaling up access to medicines in developing and least developed countries in general, Sub-Saharan African countries still lag behind in terms of efficient and sustainable access to healthcare services and medicines for HIV/AIDS and related diseases. Out of the estimated 35 million people living with HIV/AIDS, 71% of which are in Sub-Saharan Africa,[271] as of 2014, an estimated 87% of those eligible for treatment were accessing treatment.[272] The region relies more on donor funding (from some of the above named international institutions among several others and independent

[270] In Cameroon for instance, the National AIDS Control Programme was put in place in 1987, and the National AIDS Control Committee oversees the implementation of HIV/AIDS related programmes. In South Africa the National Policy on HIV and AIDS for Learners and Educators in Public Schools and Students and Educators in Further Education and training Institutions was introduced in 1999. This policy has been proceeded by several other HIV/AIDS related policies such as the Policy and Strategic Framework on HIV and AIDS for Higher Education; the third National Strategic Plan (NSP) on HIV, STDs and TB for 2012-2016 was launched in 2011. In Kenya, the National AIDS Council created in 1999 developed the Kenya National HIV/AIDS Strategic Plan 2000-2005; the Kenya National HIV/AIDS Strategic Plan 2005-2010; the Kenya National HIV/AIDS Strategic Plan 2009/10 to 2012/13; and the current Kenya AIDS Strategic Framework -KASF 2014/15-2018/19.
[271] UNAIDS *The gap report* 2014 26.
[272] UNAIDS (n 271 above) 12.

developed countries) for most of the finances needed to purchase ARVs and medicines for other HIV-related infections.[273] It is also thanks to these external sources of funding that most human rights organisations, community and faith based organisations in Sub-Saharan Africa have been able to promote and provide access to healthcare services, medicines, and to sensitise communities on HIV prevention, treatment, care and support.

Even though these external sources of funding have been, and continue to be the key in scaling up access to treatment in developing countries generally, and Sub-Saharan African countries in particular, the fact is these sources are stagnating or even shrinking. Developed countries are reducing the amount of funding dedicated to HIV/AIDS prevention and treatment due to the ongoing global financial crisis.[274] This raises serious questions on the sustainability, let alone the continued scale-up of these funding sources.

Parallel to the above realities, neglected tropical diseases, prevalent predominantly in developing and least developed countries in general and Sub-Saharan Africa in particular, continue to face a dearth of R&D.[275] All the world's leading pharmaceutical companies are based in developed countries.[276] These pharmaceutical companies conduct little or no R&D at all into these diseases because they occur predominantly in countries that constitute a very small proportion of the world pharmaceutical market. In Sub-Saharan Africa where these diseases are predominant, the pharmaceutical market value of the region is barely 2%.[277] This represents very little for pharmaceutical companies, which are all out to make profit and are making huge

[273] UNAIDS (n 271 above) 47.
[274] JM Kirigia *et al* 'Effects of global financial crisis on funding for health development in nineteen counties of the WHO Africa region' 11 *Biomed central health and human rights* (2011) 1.
[275] WHO *Global strategy and plan of action on public health, innovation and intellectual property* (2011) 3; NEPAD Health Strategy 05 September 2003 http://www1.chr.up.ac.za/undp/regional/docs/nepad5.pdf (accessed 24 October 2013).
[276] These include Pfizer, Johnson & Johnson Abbot Laboratories, Merck & Co, Bristol-Myers Squibb, Eli Lilly and Company, Amgen, Genentech and Baxter International (US); Hoffmann-La Roche, Novartis (Switzerland); GlaxoSmithKline, AstraZeneca (United Kingdom); Sanofi-Aventis (France); Boehringer Ingelheim, Bayer (Germany) and Takeda Pharmaceutical Co (Japan).
[277] According to IMS health market prognosis, as of June 2013, the global pharmaceutical market for Africa, Asia (excluding Japan) and Australia combined was 18%. It should be noted that in 2005 the market share for Africa alone was 1.3%. JCG Martin 'The pharmaceutical industry: A key player in development' nd http://www.eoi.es/blogs/juancarlosgomezmartin/2014/01/08/the-pharmaceutical-industry-a-key-player-in-development/ (accessed 12 February 2014); B Baker 'Economics of the pharmaceutical industry' paper presented during the 2011 IP and access to medicines short course at the University of KwaZulu-Natal.

profits from developing medicines for diseases that predominantly affect people living in developed countries.[278] It should however be noted that the market value for the African market is growing.[279]

Moreover, even after African countries were the main champions in the process leading to the adoption of the Doha Declaration on TRIPS and Public Health in 2001 and the 30 August 2003 Decision, African countries have not been able to fully make use of these flexibilities to source cheaper medicines. This is in part due to a lack of local manufacturing capacity. While the governments of India and Brazil have been able to obtain better pricing on ARVs and cancer medicines from pharmaceutical companies by threatening to, and in some cases actually, issuing compulsory licences and manufacturing generic medicines locally,[280] most Sub-Saharan African countries cannot because they lack local manufacturing capacity.

Pharmaceutical manufacturing remains very low on the African continent as very few countries have significant manufacturing capacity and even fewer conduct manufacturing operations at global standards of good manufacturing, distribution and storage practice. In West Africa, Nigeria is the leading country in terms of pharmaceutical manufacturing capacity. Some of the local pharmaceutical companies operating in the country include: Bolar Pharmaceuticals Nigeria Ltd,[281] Evans Medical Plc,[282] and Emzor Pharmaceutical Industries Ltd.[283] However, most of these companies are all still working towards improving their production processes in order to comply with WHO pre-qualification.[284] Most of these companies are not

[278] B Baker (n 277 above).
[279] IMS Health 'Africa: A ripe opportunity understanding the pharmaceutical market opportunity and developing sustainable business models in Africa' 12 March 2013 http://www.imshealth.com/ims/Global/Content/Insights/Featured%20Topics/Emerging%20Markets/IMS_Africa_Opportunity_Whitepaper.pdf (accessed 20 October 2013).
[280] J Von Braun 'Use of compulsory licenses selected national experiences' nd http://unctad.org/Sections/dite_totip/docs/tot_ip_0018_en.pdf (accessed 13 October 2013); J Thurston 'Compulsory licenses: necessary or threat' 23 May 2013 http://www.rsc.org/chemistryworld/2013/05/compulsory-licence-license-patent-drugs-debate (accessed 13 October 2013).
[281] Which produces medicines for certain forms of cancer, hepatitis, and diabetes. http://bolarpharm.com/ (accessed 30 December 2013).
[282] http://www.evansmedicalplc.com/ (accessed 30 December 2013).
[283] Which produces anti-malarial, cough, and cold medicines http://www.emzorpharma.com/index.php/our-company (accessed 30 December 2013).
[284] 'Local pharmaceutical companies need government support – Pharm. Ezekwesili' *Pharmanews* 18 September 2013; O Sotunde 'Over 44 million invested in Nigerian pharmaceutical industry - PGM-MAN Chairman' 10 October 2013 http://www.ventures-africa.com/2013/10/44m-investments-made-nigeria-pharmaceutical-industry-pmg-man-chairman/ (accessed 30 December 2013).

supported by the government in any way, and are not able to access funding from local banks in Nigeria. Not even the Central Bank of Nigeria would grant them a loan to boost their manufacturing capacity in a bid to attain WHO pre-qualification.[285] In East Africa, two leading local pharmaceutical companies, Quality Chemicals Industry Ltd in Uganda and Universal Corporation Ltd in Kenya, have already attained WHO prequalifications. Zenufa Laboratories in Tanzania is also working towards attaining qualification for some products.[286] However, most of the countries in this sub-region are not making maximum use of the TRIPS flexibilities like compulsory licensing to exploit local manufacturing capacity and have medicines manufactured locally and sold at lower prices. 70% of the generic medicines used in these countries are still imported from China and India.[287] Other challenges to pharmaceutical manufacturing faced by Sub-Saharan African countries include a scarcity of healthcare personnel;[288] poor healthcare systems (in hospitals, clinics, laboratories); and very minimal or no government funding.[289] South Africa is the only country in Sub-Saharan Africa with a few global standard local pharmaceutical companies. Aspen Pharmacare for instance now supplies branded and generic pharmaceuticals to more than 150 countries worldwide and operates in Asia Pacific; Europe CIS; Latin America; Sub-Saharan Africa, and rest of the world, having 18 manufacturing facilities across the six continents.[290]

Although African countries import cheaper generic medicines from India, given the national budgets and the amount of funds allocated to healthcare in these countries, these medicines are still very expensive for governments, hence, the heavy reliance on donor funding. In addition to the fact that there is an acute shortage of local

[285] Sotunde (n 284 above).
[286] RM Hermann 'East African Community doubles efforts to boost local pharmaceutical manufacturing' *Intellectual Property Watch* 28 March 2013.
[287] As above.
[288] All 47 countries in sub-Saharan Africa experience a critical shortage of healthcare workers. The deficit amounts to 2.4 million doctors and nurses. 'In these countries, there are 2 doctors and 11 nursing/midwifery personnel per 10,000 population, compared with 19 doctors and 49 nursing/midwifery personnel per 10,000 for the Americas, and 32 doctors and 78 nursing/midwifery personnel per 10,000 for Europe.' S Naicker *et al* 'Shortage of healthcare workers in sub-Saharan Africa: a nephrological perspective' (2010) 74 *Clinical Nephrology* 1.
[289] M van der Wolf 'Africa's pharmaceutical industry faces numerous challenges' 10 May 2013 http://www.voanews.com/content/challenges-ahead-for-africas-phamaceutical-industry/1658686.html (accessed 27 December 2013).
[290] 'African firms up for the fight' *African Business* 27 November 2012; see also http://www.aspenpharma.com/ (accessed 27 December 2013); see also 'Aspen Pharmacare Holdings Ltd (APNJ.J) *Thomson Reuters* n.d.

manufacturing capacity which might have provided a cheaper option, the few existing local manufacturing companies are not fully exploited. As a result, the continent spends huge amounts of money on the import of generic medicines from India which might have been obtained at lower prices if they were manufactured at sub-regional level or domestically.[291] The absence of local pharmaceutical manufacturing also robs the sub-continent of research, innovation and technological advancement that come with high manufacturing capacity and technology transfer. This also deprives the sub-continent of employment opportunities for its growing dynamic youth population.

The above realities portray the dire consequences of the absence of a minimum degree of pharmaceutical manufacturing in a country. This has led some developing countries to consider and explore possible ways of boosting R&D as well as promoting local manufacturing. These countries hope to achieve this by: increasing funding for scientific research in public research institutions (Universities, National Research Councils, Councils for Scientific and Industrial Research and similar government-funded research institutions); allowing and facilitating collaboration between these research institutions and private industries to enable industries acquire promising technologies from research institutions to develop into tangible products. In South Africa for instance, the Department of Science and Technology (DST) encourages collaborative research between academics, industry and policymakers, to develop health research priorities through the National Science and Technology Forum. Another example is the South African Malaria Initiative and the South Africa AIDS Vaccine Initiative.[292] The National Science and Technology Forum in its October 2013 newsletter quote Roy du Pré who opines that:[293] 'Universities can function as research and innovation cores for networks of technology, institution, companies and new enterprises that will develop and commercialise information and technology.'

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[291] n 284 above.
[292] J Chataway *et al* 'Building the case for national systems of health innovation' (2007) a background policy paper prepared for NEPAD in advance of the AMCOST meeting and the African Union Summit January 2007 http://www.nepadst.org/doclibrary/pdfs/nsi_case_jan2007.pdf (accessed 24 October 2013).
[293] S Burger (2013) 'Strong university-industry links key to tapping knowledge-economy spin-offs' 18 October 2013 http://www.nstf.org.za/nstfWebPortal/appmanager/nstfWeb/nstf?_nfpb=true&_pageLabel=nstf_portal_page_1 (accessed 24 October 2013).

As noted by David Mowery and Bhaven Sampat, university research advances tend to affect industrial innovation more significantly and directly in the biomedical sector (particularly biotechnology and pharmaceuticals) than any other.[294] Increased support for domestic R&D could enable pharmaceutical companies to acquire biomedical inventions made by public research institutions to further develop and translate into pharmaceutical products that can be commercialised to meet national healthcare-related needs.

During the last decade, a number of countries from different parts of the world notably Africa (South Africa);[295] Asia (India, Japan);[296] South America (Brazil),[297] have either enacted or are considering enacting legislation designed to promote technology transfer and the commercialisation of publicly funded academic research. Interestingly, a close look at most of these fairly new laws reveals that they tend to follow the United States Bayh-Dole approach with differing levels of adaptation.

This chapter analyses the regulation of publicly funded research in three countries, namely: India, South Africa and Brazil. The main question that will be answered throughout this chapter is: to what extent can these legislation ensure that medicines invented out of publicly funded research are affordable; that further research is not blocked; and that the public's interest is prioritised?

4.2 INDIA: The Protection and Utilisation of Public Funded Intellectual Property Bill 2008

4.2.1 Background to the Bill

The Protection and Utilisation of Public Funded Intellectual Property Bill (the Bill) was tabled before the *Rajya Sabha* (Upper House of Parliament in India) in 2008 for consideration and possible endorsement. The idea of enacting such a law was first discussed in 2004 during a meeting of the National Knowledge Commission (NKC).[298] In a letter written by the chairman of the NKC to the Prime Minister in

[294] Mowery & Sampat (n 37 above) 116.
[295] The Intellectual Property Right from Publicly Financed Research and Development Act No 51, 2008 was passed in 2008.
[296] The Protection and Utilisation of Public Funded Intellectual Property Bill 2008 of India is currently being considered by the Indian Parliament; the Japanese Law No 131 of 1999 was passed in 1999.
[297] The Innovation Law No. 10.973/04 of 2004.
[298] The National Knowledge Commission is an Indian think-tank that seeks to, amongst others, strengthen the education system, promote domestic research and innovation, and facilitate

2007, the NKC recommended that government needed to introduce a new approach to government-funded research in order to ensure knowledge creation and to ensure that government-funded research is transformed into commercially relevant and useful applications that will benefit the Indian community.[299] According to the chairman, conferring ownership rights of such research to universities and linking such ownership with the patent system and the market, was the way to make research more attractive, and to bring about a radical change in the research landscape in India.[300] This would also 'create wealth for Indian academic institutions and wean them off government support…'[301] The chairman in his letter further briefly highlighted what some of the main provisions of such a legislation could be, and a number of public welfare safeguards that could be introduced in the law.[302]

Drafted in 2005, the Bill was only made available by the government to key stakeholders for inputs and to the public at large for public viewing and comments in 2008 when it was introduced in the *Rajya Sabha* and to the Standing Committee.[303] According to Shamnad Basheer and Shouvik Guha, the Indian Institute of Science, which is a leading public scientific and technological research and higher education institution in the country and therefore a key stakeholder to involve in the drafting of such a Bill, was only consulted about the Bill in January 2010.[304] After the Bill was tabled before the *Rajya Sabha,* it fuelled wide criticism by the media and stakeholders. A conference was organised by the National University of Juridical Sciences and attended by representatives from public-funded laboratories, industry, prominent scientists from academia, and civil society to discuss the Bill. During the conference, the Bill was severely criticised by most these stakeholders.[305]

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knowledge application in sectors like health, agriculture, and industry. http://knowledgecommission.gov.in/ (accessed 24 August 2013).

[299] Letter by Sam Pitroda, Chairman of the National Knowledge Commission to the Prime Minster 16 January 2007 http://knowledgecommissionarchive.nic.in/downloads/recommendations/LegislationPM.pdf (accessed 24 August 2013).

[300] As above.

[301] It should be noted that in the US where the Bayh-Dole has now been in force for 30 years, government has not weaned universities from its support. In fact, between 1970 and 2000, government funding for research has risen from 2.3% to 8%. Basheer & Guha (n 167 above) 284.

[302] (n 299 above).

[303] Basheer & Guha (n 171 above) 293.

[304] As above.

[305] R Nagarajan 'Scientists fume over new patent bill' *Times of India* 22 January 2010 (accessed 04 July 2010).

Very importantly, and perhaps for the first time in Indian history, the Standing Committee returned the Bill to the government for review in consultation with the different stakeholders involved before it would consider it.[306] The *Rajya Sabha* felt that government had failed to take into account the interests of the various stakeholders.[307]

The next part of this chapter analyses the provisions of the Bill, paying particular attention to whether or not, if passed in its current form, the Bill will promote research, facilitate technology transfer from academia to industry, and the possible implications of the Bill with respect to access to medicines developed out of, or incorporating publicly funded research.

4.3 Analysis of key provisions of the Bill

4.3.1 Objective of the Bill

The stated objective of the Bill is to provide for the protection and utilisation of intellectual property originating from government-funded research and to enable India compete in global markets, thereby ensuring that products manufactured through government-funded research are accessible to all stakeholders for the public good.[308] The Bill also aims to promote collaboration between government and private enterprise; promote the culture of innovation; enhance awareness about intellectual property within public academic and research institutions, so as to increase the responsibility of these institutions to encourage students and faculty scientists to innovate.[309] Innovation will raise revenue for the universities and promote self-reliance, hence, minimising their reliance on government funding.[310] In spite of these ambitious objectives, and as noted by Shamnad Basheer and Shouvik Guha, 'there is a serious disconnect between the Bill's objectives and the proposed method for achieving them'[311] as some of the provisions do not seem to tally with the overall objective.

[306] Basheer & Guha (n 171 above) 294.
[307] As above.
[308] Statement of Objectives and Reasons of the Bill 8.
[309] As above.
[310] As above.
[311] Basheer & Guha (n 171 above) 295.

4.3.2 Retention of title, patenting and licensing

The question of who retains title to intellectual property in the case of government-funded research and how the intellectual property is licenced to industry is critical as this determines whether or not the fruits of this intellectual property can actually be transformed into finished products and how accessible the products would be. This is particularly so in the case of pharmaceutical products like medicines where access or lack thereof could be a question of life or death. The Bill grants title to recipients and requires them to seek intellectual property protection on intellectual property arising from such research. The relevant provision stipulates that recipients shall:[312]

> … within ninety days … intimate … to the Government, its intention to retain the title of the … intellectual property with respect to the designated countries and … apply for … protection … [and] … initiate the process for utilisation of the public funded intellectual property immediately after the application for protection … is filed … and submit a written report within six months and biannually thereafter … specifying the steps to take for utilisation …

The word utilisation as used above is defined by the Bill to mean[313] 'the manufacture of a composition or product, the practice of a process or method, operation of a machine or system, or commercialisation thereof.'

Most frequently, commercialisation is achieved through the granting of a licence to industry interested and specialised in the development of the particular technology. With respect to licensing, the Bill provides that:[314]

> … no recipient … and no assignee of such recipient shall grant, to any person, the exclusive right to use or sell any public funded intellectual property in India …, unless such persons manufacture such products … substantially in India … Provided that the Government may, for reasons to be recorded in writing allow such sale or use for manufacture in countries other than India.

Based on this provision research institutions can, after obtaining intellectual property protection over public-funded research, grant an exclusive licence thereon to industry for commercialisation provided that the licensee manufactures the product involved substantially in India.

The above proviso provides clarity as to who may hold title to intellectual property resulting from government-funded research, which clears any inconsistences or uncertainty which may have existed before. Institutions are sometimes better placed

[312] Sec 5(1); 7(a) - (c).
[313] Sec 2(h).
[314] Sec 12.

and may have a higher bargaining power in licence negotiations with industry compared to individual scientists. Unlike scientists, institutions are also more likely to be able to afford prosecution fees in legal actions against infringers. In addition, based on the United States experience examined in chapter two, if title is held by the government without the ability of the government to transfer exclusive rights, private industry might be deterred from investing in product development and commercialisation for fear of not being able to recoup their investment costs.

The above patenting and licensing provisions does raise a number of concerns. Firstly, the Bill provides for rather strict deadlines, namely ninety days for recipients to indicate intention to retain title to inventions and immediate commercialisation of the intellectual property. The provision on immediate commercialisation may place universities in an unequal bargaining position vis-a-vis industry during licensing negotiations as it gives universities very little time to balance the costs of patenting and licensing and establishing the potential commercial value of the intellectual property before engaging in negotiations with industry. This also gives universities limited time to assess and decide on whether patenting is indeed the most appropriate means of ensuring that society benefits from publicly funded research before deciding whether or not to do so.[315] As a result, universities may accept a bad deal over a no-deal situation for compliance purposes, and to avoid losing title to the intellectual property all together.[316] Kathy Nair and Balu Nair note that the Indian Council for Scientific and Industrial Research (ICSIR) currently faces a number of challenges resulting from hasty patenting of basic research as several patents have been obtained on upstream research at very early stages of research processes. As a result, further research that must be carried out before any product can be developed and made available commercially is blocked.[317] Rather than making patenting compulsory, the Bill should require each recipient to assess each invention to first determine what the best way of exploiting it from a public interest point of view would be before deciding whether to patent, how widely to patent, and on what terms

[315] Basheer & Guha (n 171 above) 284.
[316] K Nair & B Nair 'Protection and Utilisation of Public Funded Intellectual Property Bill 2008 - A critical analysis of the Indian Bayh-Dole Act' (2009) 2 *National University of Juridical Sciences Law Review Law Review* 705.
[317] As above; Spicy IP 'Guest post on the Conference on Publicly Funded Patents and Technology Transfer: A Review of the Indian "Bayh-Dole" Bill' 01 November 2009 http://spicyipindia.blogspot.com/2009/11/guest-post-on-conference-on-publicly.html (accessed 24 September 2013).

to licence the patent to industry.[318] It may also be important to explore the commercial prospects and the benefits of patent exclusivity in other countries.

Secondly, the near mandatory requirement to patent and commercialise places undue emphasis on market incentives for innovation, which may end up vitiating the more important goal of maximizing public and user interests.[319] Market incentives have been prioritised in the Bill, giving the impression that whenever funds are provided to universities for research, commercialisation must ensue. This is a rather false impression because most of the research done in universities is basic research, which sometimes fails to produce commercially viable innovations at least in the short or medium term, yet may prove to be of paramount importance in the long run.[320] In addition, not every single intellectual property held by a research institution can be commercialised. In fact, in most research institutions involved in technology transfer, the majority of the inventions are never licenced for commercialisation.[321] Even in India, the ICSIR (which is also a leading public research institute and involved in technology transfer) generates only approximately $1 million in licensing revenue, while it spends more than twice this amount in filing and licensing processes. Although it may be argued that the limited profit can be attributed to the fact that the ICSIR just recently started pursuing aggressive patenting,[322] Stanford University (a leading United States university in terms of technology transfer) sometimes successfully patents and licences only about 50% of its inventions. In fact, in 2011 only 101 inventions out of the 504 generated by the University were licenced to industry.[323]

Furthermore, the importance accorded to commercialisation in the Bill gives the impression that commercialisation is the only benchmark for measuring the success or failure of technology transfer. This may be very dangerous as it may result in a situation where universities channel public funds to research that only has promising

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[318] Basheer & Guha (n 171 above) 285.
[319] A Lin *et al* 'The Bayh-Dole Act and promoting the transfer of technology of publicly funded-research UAEM White Paper on the proposed Indian Bayh-Dole Analogue' nd http://archive.uaem.org/sites/default/files/archive/uaem-white-paper-on-indian-bd-act.pdf (accessed 24 September 2013); Nair & Nair (n 316 above) 709.
[320] Lin *et al* (n 319 above).
[321] Stanford University 'Technology licensing at Stanford University' nd http://otl.stanford.edu/about/resources/about_resources.html (accessed 24 September 2013).
[322] Basheer & Guha (n 171 above) 282.
[323] Stanford University (n 321 above).

commercial prospects to the detriment of research that would ensure greater public welfare or academic advancement. The success of technology transfer can also be measured in terms of social and humanitarian contributions, such as level of patient access to the end pharmaceutical products; the degree to which university knowledge was useful in creating further innovations; and the number of new jobs generated from patented research.[324]

Given that intellectual property is based on secrecy, overemphasis on commercialisation may result in research silos as there may be limited collaboration and mistrust among researchers resulting in inefficiencies and lost opportunities. In a bid to avoid the negative effects of market forces, the ICSIR is using an open source drug discovery model to research a cure for tuberculosis in order to mitigate the research gap on the disease.[325] The Bill as it currently stands does not support this kind of venture.

In addition, when it comes to biopharmaceutical technology and considering the public health challenge relating to access to medicines faced by developing countries generally and India in this instance, the above provision on immediate licensing could be problematic. The granting of an exclusive licence as allowed by the Bill will prevent competition, which is usually the main force behind lower prices.[326] With exclusive licences come high unaffordable prices, which may, in the case of medicines, be equated to death as was true in the early years of the HIV/AIDS pandemic. By authorising the granting of exclusive licences with no further restrictions designed to increase affordability or to ensure access, the Indian government basically gives away taxpayers' money to industry with no consideration of the public's wellbeing because pharmaceutical companies are out to make profit and would use their exclusive monopoly rights to charge high prices.

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[324] Lin *et al* (n 319 above).
[325] J Napa 'Open Source Drug Discovery: A feasible business model?' nd http://www.pharmafocusasia.com/strategy/open-source-drug-discovery (accessed 06 July 2015); S Singh 'India Takes an Open Source Approach to Drug Discovery' (2008) 133 *Cell* 201 - 203.
[326] According to MSF, 'Competition among generic producers of HIV medicines, primarily in India, is what caused the price of treatment to drop by a dramatic 99% over the last decade, from more than US$10,000 per person per year to roughly $120 today'. MSF 'As US FDA approves promising new HIV drug dolutegravir, MST asks when people in developing countries will have access' 13 August 2013 http://www.msfaccess.org/about-us/media-room/press-releases/us-fda-approves-promising-new-hiv-drug-dolutegravir-msf-asks-when (accessed 24 September 2013).

India is the principal supplier of generic medicines to Sub-Saharan Africa. India has stringent laws on what constitutes novelty in pharmaceutical patent applications, and unlike other developing countries, has made reasonable progress in utilising some of the flexibilities of the TRIPS Agreement to promote access to medicines both locally and internationally. India also has a robust pharmaceutical manufacturing industry of high standard which produces quality medicines. It is somewhat surprising that the Indian Bill does not prioritise non-exclusive licenses on government-funded intellectual property.

Moreover, for purposes of commercialisation, contrary to the United States Bayh-Dole Act which provides that the fruits of research originating from government funding shall be made available to the public on 'reasonable terms' which courts have interpreted in non-Bayh-Dole related cases to mean reasonable pricing,[327] the Indian Bill is silent on the terms upon which proceeds of government-funded research shall be commercialised.[328] Given that pharmaceutical companies are out for profit, the absence of such an express provision gives room for industry to charge high prices on products manufactured from research that was initially funded by the government with taxpayers' money. Were this to happen, taxpayers will be paying both for the research and the proceeds of the research at exorbitant prices. The fact that the 'reasonable terms' provision is not enforced in the United States does not serve as justification for India to omit it from the Bill.

4.3.3 Manufacture substantially in India

With respect to manufacturing, the Bill provides that:[329]

> … no recipient … and no assignee of such recipient shall grant, to any person, the exclusive right to use or sell any public funded intellectual property in India …, unless such persons [manufacture] such products … substantially in India … Provided that the Government may, for reasons to be recorded in writing allow such sale or use for manufacture in countries other than India.

The word substantially as used in the above provision has not been defined. However, borrowing from the interpretation under United States policy as discussed earlier under a similar provision in the United States Bayh-Dole Act, this requirement may perhaps be met if for example the cost of the components mined, produced or

[327] Arno & Davis (n 19 above) 662, 650 & 651.
[328] Nair & Nair (n 316 above) 703.
[329] Sec 12.

manufactured in India exceed 50% of the cost of all components required by the licensee to make the product.[330] The Bill provides that a government authorisation can however be obtained to allow an exclusive licensee to not manufacture substantially in India but fails to prescribe under what circumstance the authorisation may be granted. This means that a foreign pharmaceutical company having a branch in India can obtain an exclusive licence on inventions originating from intellectual property emanating from government-funded research and be allowed to manufacture more than 50% of the compounds required to manufacture the said product outside India.

4.3.4 March-in right

A march-in right is a safeguard measure available to the government whenever an exclusive licensee or an assignee of intellectual property emanating from government-funded research fails to develop or commercialise the intellectual property, or does so in a manner that does not meet the public's need. This intervention can either take the form of compelling the exclusive licensee or assignee to develop and commercialise the invention, or granting a licence to a third party who can develop the invention and make it available for use in a manner that meets the public's need. While this safeguard measure is included in the United States Bayh-Dole Act,[331] the South African Intellectual Property Right from Publicly Financed Research and Development Act No 51 of 2008,[332] and the Brazilian Innovation Law,[333] it is lacking in the Indian Bill. Under appropriate legislation, government can resort to march-in rights whenever necessary to ensure the development of a technology or to alleviate health, military, security or safety needs in a country. It may be important to note that in his recommendations of this legislation, the Chairman of the NKC expressly mentioned that it would be important to include safeguards like march-in right.[334]

In the specific case of biopharmaceutical technology, the absence of march-in rights results in a dangerous lacuna. Borrowing from the United States where similar

[330] United States Office of the Federal Register (n 123 above).
[331] 35 USC 203.
[332] Secs 11(2)(e); 14(1) - (4).
[333] Art 6 § 3.
[334] Letter by Sam Pitroda (n 299 above).

legislation has been in place for over 30 years, the practice has been for some pharmaceutical companies that are exclusive licensees of intellectual property emanating from government-funded research to not develop and commercialise the intellectual property if so doing will not be profitable. For example, a pharmaceutical company which obtained a licence on an invention may decide not to develop the treatment or cure because very few people suffer from the disease it is meant to treat or cure, which means that the company will make little or no profit from developing the treatment or cure.[335] A pharmaceutical company may also obtain an exclusive licence on an invention simply to prevent other companies from obtaining the licence where this can be used to develop commercially competing products. Even though the march-in provision has never been used by the United States government or courts when such situations arose, the mere fact that the Bayh-Dole Act provides for this has provided a legal basis for CSOs to bring actions against, pressurise, name and shame pharmaceutical companies exclusive licensees of intellectual property emanating from government-funded research which failed to develop and commercialise inventions, or which did so in a manner that was detrimental to the public's interest. Again, because the Bayh-Dole Act provides for march-in rights, CSOs have been able to advocate for march-in right, which has sometimes contributed to exclusive licensees granting licences to other companies to develop inventions on their behalf.[336]

4.3.5 Government-use right

This refers to the right of the government to obtain an unrestrictive and royalty free licence to intellectual property resulting from piggybacking on research it has funded. With respect to government-use right, the Bill provides that:[337]

> Notwithstanding anything contained in this Act, the Government shall have the right to practice and to assign any … intellectual property to carry out its obligations under any international treaty or agreement.

This is an important safeguard measure as it confers on the government an irrevocable royalty free right to exploit the intellectual property to meet its obligations. This provision is particularly important because unlike the government, industry to

[335] Knowledge Ecology International 'Fabrazyme March-In Request' 2 August 2010 http://keionline.org/fabrazyme (accessed 24 September 2013).
[336] Discussion with James Love, Director of Knowledge Ecology International nd.
[337] Sec 13.

which universities licence intellectual property, mainly seek profit and sometimes do not necessarily care about the public's interest. Because of this difference in objectives, it is important for government to retain powers to intervene whenever the public interest so requires.

Government-use right may also be used by the government to allow for broad research, educational, and experimental use of intellectual property and research results between public research institutions and researchers involved in government-funded research. Enabling such research collaboration between researchers is very important as it prevents duplication of research, wastage of resources and time. Particularly in the context of biopharmaceutical technology, where research is often very costly and spans a long duration, experimental use exception is critical as collaboration between researchers may play a great role in curbing unnecessary spending, and ensuring that research actually moves forward. In the absence of research and experimental use exceptions, the tragedy of the anti-commons situations may arise.[338]

4.3.6 Disclosure and reporting

With respect to disclosure, the Protection and Utilisation of Publicly Funded Intellectual Property Rights Bill provides that the intellectual property creator shall:[339]

> … immediately after the creation of publicly funded intellectual property, make a disclosure to the recipient … [and] shall not publish, exhibit or publicly disclose the public funded intellectual property …

Once notified by the inventor, the recipient shall also not publicly disclose, publish or exhibit the intellectual property till an application for the protection of the same in designated countries is made [340].

With respect to reporting, the recipient shall:[341]

> … submit a written report within six months and biannually thereafter to the Government, specifying the steps taken for utilisation … [and] maintain proper accounts and other relevant

[338] The tragedy of the anti-commons arises when basic research discoveries necessary for subsequent research are owned, not by one entity, but by a number of different entities. Rai & Eisenberg (n 172 above) 295 - 298; McManis & Noh (n 172 above) 19; Blumenthal *et al* (n 172 above) 1224 - 1225.
[339] Secs 9(1) - (3); 4; 6.
[340] Sec 6(c); 14 & 15.
[341] 7 (c); 14(1) - (4).

> records and prepare an annual statement of accounts … [the recipient] shall be audited by the Comptroller and Auditor-General of India … The accounts … together with the audit report thereon shall be forwarded to the Government …

With respect to the disclosure provision, it is important that recipients do not disclose inventions for which they opt to seek intellectual property protection until patent applications are filed. This is because once the invention is disclosed it becomes public knowledge – part of the prior art, thus not novel – and is no longer eligible for patent protection. Globalisation and the advent of the TRIPS Agreement have brought along rather selfish modes of knowledge creation and management, which developing countries have to embrace to avoid being exploited and robbed as is sometimes the case through biopiracy. Not only does concealing intellectual work until a patent application is filed prevent third parties from claiming ownership over the intellectual property, hence, excluding others from using it, it also secures exclusive rights (patents) to recipients which they can then licence to industry in return for royalties.

Equally as important is the need for these inventions to be published and made available to the public on an open and accessible basis. This is not addressed by the Bill. In the United States for instance, the NIH has a Public Access Plan through which research funded by the federal government through the NIH is made available to the public in a private journal within a year of publication. In addition there is a proposed law, the Federal Research Public Access Act (FRPAA), which has been introduced in the United States Senate to require eleven of the biggest public-funded agencies of the country to publish their research online within six months from publication in a journal.[342] The idea is to make publicly funded research available to the public on an open source basis.[343] It should be noted that secrecy comes at some social cost. The lack of collaboration between university researchers results in inefficiencies and lost synergies. Plus, the pace of incremental, follow-on, or translation innovation might also be affected.

Reporting on intellectual property created from government-funded research is also very important as it notifies government about such inventions. In the case of

[342] J Reinhardt 'Bill aims to provide taxpayers access to publicly funded research' 21 July 2009 http://ohmygov.com/blogs/general_news/archive/2009/07/21/bill-aims-to-provide-taxpayers-access-to-publicly-funded-research.aspx (accessed 25 October 2009).
[343] http://sparc.arl.org/advocacy/national/frpaa (accessed 22 September 2013).

biomedical research, knowledge by government of such patents is even more crucial because government can facilitate or support the further development of the invention into pharmaceutical products to meet emergency health related crises through march-in right or government-use right. In addition, reporting is a form of accountability to the government and to the tax paying public. Reporting is also important for monitoring and evaluation purposes.

Apart from having this reporting provision in the text of the legislation, appropriate measures need to be put in place to ensure that recipients actually report on eventual inventions arising from government-funded research. The onus should not only be on recipients to report with no mechanism in place to ensure compliance. As is frequently the case in the United States,[344] recipients may fail to report on intellectual property created and commercialised, and government will not know which intellectual property protected products result from the research it has funded. Also, without knowledge of which products incorporate or have been developed using intellectual property emanating from government-funded research, government will not be able to exercise march-in or government-use rights in the interest of the public if the need arises.

4.4 Other provisions of the Act

4.4.1 The intellectual property management committee

Under the Bill, the intellectual property management committee is the TTO that will be responsible for the management of intellectual property emanating from the research institution. The relevant provision reads as follows:[345]

> Every recipient shall, within one hundred and eighty days of the receipt of the funds … constitute an intellectual property management committee within its organisation. The intellectual property management committee … shall identify, assess, document, and protect public funded intellectual property having commercial potential; perform market research and market the intellectual property; create an intellectual property management fund; monitor the process of licensing and assignment; manage revenues from licensed … intellectual property for the organisation … establish mechanisms to promote the culture of innovation …

While it is important for research institutions to have efficient and effective intellectual property management structures, the above provision raises serious concerns. Firstly, the Bill makes it mandatory for each and every research institution to have its

[344] De Larena (n 45 above).
[345] Sec 10(1)(a) - (f).

own TTO. Experience from the United States Bayh-Dole Act indicates that running an efficient TTO in each university is very costly as it also requires recruiting and maintaining expert technology transfer staff members. Research indicates that while some TTOs in the United States are barely able to break even, others operate on a net loss.[346] An option could be to have a single TTO in each state, or for a number of universities in each state to jointly establish a single TTO. This will cut the cost of negotiating for each and every patented bit of research as it will be possible to bundle rights of multiple patentable and interrelated research innovations, and involve fewer negotiations with perhaps fewer industries.[347]

4.4.2 Royalty sharing and reinvesting

Under the Bill recipients of government funds for research are required to share royalties derived from the commercialisation of intellectual property originating from government-funded research with the researchers, and to reinvest some of these royalties in ongoing research. The relevant provision reads as follows:[348]

> … subject to any agreement which may be entered into between the intellectual property creator and the recipient, not less than thirty per cent of such income or royalties, after deducing the expenses incurred in protection and utilisation, shall be given to the creator of intellectual property: Provided that where such agreement has a provision for a lesser amount than thirty per cent of the net income, the provision of this section shall prevail:

In addition, the Bill provides that from the remaining royalties, another 30% shall be paid into a fund created by the intellectual property management committee,[349] and any other amount left shall be used for further research and other fees necessary for the protection and maintenance of the intellectual property.[350]

To sum up one may say that the Indian Bill, though ambitious in trying to secure maximum use of the outcome of government-funded research for public welfare through practical application and commercialisation, the drafters do not seem to have taken into account some of the negative impacts of the Bayh-Dole Act. This is evident from the fact that most of the provisions are seriously lacking in terms of

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[346] L Nelsen 'The rise of intellectual property protection in the American university' (1998) 279 *Science* 1460.
[347] D Greenbaum 'Academia to industry technology transfer: An alternative to the Bayh-Dole system for both developed and developing nations' (2008) 19 *Fordham Intellectual Property Media and Entertainment Law Journal* 384 (2009).
[348] 11(1)(a).
[349] 11(1)(b).
[350] 11(c).

public interest prioritisation. Interestingly, the fact that the *Rajya Sabha*h has rejected the Bill and requested the government to consult with stakeholders before it is reconsidered, is indicative of the *Rajya Sabha*'s concern for public interest and human rights. This is particularly because this is the first time in Indian history that the *Rajya Sabha* rejects a Bill asking government to review it.

4.5 SOUTH AFRICA: The Intellectual Property Rights from Publicly Financed Research and Development Act No 51, 2008

4.5.1 Background to the Act

The Intellectual Property Rights from Publicly Financed Research and Development Act No 51, 2008 (the IPR Act) was passed in 2008 as a result of a request for such a law by the South African DST. According to the DST, such a law was necessary for a number of reasons. Firstly, there was a significant leakage of intellectual property resulting from public-funded research in South Africa into overseas jurisdictions.[351] Secondly, the South African government could not exercise any walk-in (march-in) rights as it was constrained by the fact that different research institutions in South Africa had different approaches to managing intellectual property generated from public-funded research.[352] Thirdly, the value of intellectual property as an instrument of wealth creation was not really appreciated in South Africa. Moreover, the rights of the government, funding institutions, performing institutions and their staff were not defined.[353] As a result, South Africa, unlike other developing countries like Korea, China and India, is not a major player in the global intellectual property domain and has not substantially improved its performance in local or international patenting over the last decade.[354]

The DST further noted that an analysis of the patent patterns in South African institutions show very low levels of patenting when compared to other developing countries. For instance, South African academics secure patents at only 2 - 5% of the rate of their developed world counterparts, relative to the rate at which they publish their results in the open literature.[355] Meanwhile even though the scientific

[351] Department of Science and Technology 'Intellectual property rights (IPR) from publicly financed research framework' 2006 8.
[352] As above.
[353] Department of Science and Technology (n 351 above) 18.
[354] Department of Science and Technology (n 351 above) 12.
[355] Department of Science and Technology (n 351 above) 10 & 12.

research environment in South Africa is less resourced than that of developed countries like the United States, and South African scientists generate far less scientific research or potentially patentable research, those working in state-funded research institutions often perform equally important research in genetics, microbiology and pharmacology.[356] According to the DST, while South African universities are conducting research and making important discoveries, they are failing to patent and commercialise these inventions, which negatively impacts on the country's ability to contribute substantially in the knowledge economy.[357] To address this lacuna therefore, the DST recommended a better framework and approach in dealing with intellectual property emanating from government-funded research aimed at bringing South African research institutions up to speed with other emerging countries.

4.6 Analysis of key provisions of the Act

4.6.1 Objective of the Act

The Act seeks to ensure that intellectual property emanating from research that is funded by the government is identified, protected, utilised, commercialised and translated into finished goods for social, economic and other benefits.[358] An examination of the key provisions of the Act follows.

4.6.2 Retention of title, patenting and licensing

To achieve the above-mentioned aim, the IPR Act allows research institutions that receive public funds for research to retain title to intellectual property emanating from such research, seek intellectual property protection and ensure its commercialisation. The relevant provision reads as follows:[359]

> … intellectual property rights emanating from publicly financed research and development shall be owned by the recipient. A recipient that prefers not to retain ownership, or not to obtain statutory protection … must … notify NIPMO of the decision and the reasons therefor. NIPMO may … acquire ownership … should NIPMO decide not to acquire ownership … [it] must, in writing, notify the recipient of its decision. … the recipient must give the intellectual property creator the option to acquire ownership and obtain statutory protection …

[356] A Barratt 'Lessons from Bayh-Dole: Reflections on the Intellectual Property Rights from Publicly Financed Research and Development Act' (2010) 35 *Journal for Juridical Science* 53.
[357] Department of Science and Technology (n 351 above) 10 & 12.
[358] Sec 2(1) of the Act.
[359] Sec 4(1) - (4) of the Act.

Under the Intellectual Property Rights from Publicly Financed Research and Development Regulations (the Regulations), the desire to make the intellectual property available to the public through open source may serve as enough justification for not protecting inventions emanating from government-funded research. In this case, the recipient merely needs to demonstrate to the National Intellectual Property Management Office (NIPMO) that it is in the public interest that the intellectual property should be placed in the public domain.[360] Such a justification could perhaps be that the invention is a research tool, hence, not seeking intellectual property protection over it will foster innovation.[361]

In addition, the IPR Act requires that a recipient:[362]

> … protects intellectual property emanating from publicly financed research and development from appropriation and ensures that it is available to the people of the Republic; … identifies commercialisation opportunities for intellectual property …

The IPR Act defines commercialisation to mean the process by which intellectual property originating from publicly financed research is adapted or used to provide any benefit to the society through commercial use on reasonable terms.[363] In most cases, commercialisation of intellectual property is achieved through licensing. With respect to licensing, the IPR Act provides that:[364]

> Preference must be given to non-exclusive licensing; … to small enterprises; … to parties to 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; exclusive license holders must undertake, where feasible, to manufacture, process and otherwise commercialise within the Republic; …

Before the coming into force of this law, there existed no regulation determining who should hold title to intellectual property originating from publicly financed research in South Africa. This particular provision and the legislation in general therefore provide clarity in this domain.

Interestingly, the above provision puts the public's interest at the centre of intellectual property transactions between research institutions and industry by requiring that preference should be given to non-exclusive licenses, and that commercialisation should be sought on reasonable terms. This requires research institutions to be

[360] Sec 12 of the Regulations.
[361] Sec 2(13)(a) - (d) of the Regulations.
[362] Sec 2(2)(b) - (c) of the Act.
[363] Sec 1 of the Act.
[364] Sec 11(1)(a) - (d) of the Act.

mindful of the public's interest in their licensing negotiations with industry. This particular requirement may also be interpreted by courts whenever a case on its interpretation is brought before them to mean, or include reasonable pricing, and could perhaps be a ground for issuing a compulsory licence where the public interest so requires.

Again, unlike in the United States Bayh-Dole Act and in the Indian Bill, the IPR Act expressly gives preference to non-exclusive licences in intellectual property commercialisation transactions. The importance of non-exclusive licences lies in their ability to stimulate competition and lower prices. The alleged disadvantage is that non-exclusive licensees may be discouraged to invest in drug optimisation and clinical trials if competitors are merely going to piggyback on their research. Pharmaceutical companies often overcome this risk by obtaining secondary patents on top of the university patent. However, stricter patent standards in South Africa, if eventually adopted, may restrict the availability of secondary patents.

In addition, the IPR Act provides recipients with the option of not seeking intellectual property protection if doing so may prevent, or at the very least, reduce the patenting of research tools. If implemented by research institutions, this provision will prevent or reduce patent thickets that could be created on research tools and also ensure that these research tools are available to researchers for follow-on research. According to Arti Rai, patent thickets on research tools for a malaria vaccine have been an important barrier to R&D in a vaccine.[365] A patent analysis commissioned by the Malaria Vaccine Initiative noted that there was great complexity in the patent landscape surrounding just one antigen, MSP-1, likely to be the key to any vaccine that could ultimately be developed, as there exist thirty-four different sets of patents that describe and claim MSP-1, or the production and delivery of this antigen.[366] Though malaria may not be a priority health issue in South Africa, this research blockage may arise in the context of any biomedical research project. Having a provision that gives research institutions the option not to seek intellectual property

[365] AK Rai 'Proprietary rights and collective action: The case of biotechnology research with low commercial value' 10 April 2004 http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1993&context=faculty_scholarship (accessed 17 September 2013).
[366] Rai (n 365 above).

protection as the IPR Act allows may contribute in reducing the risk of such situations arising.

Under the United States Bayh-Dole Act, the phrase reasonable terms has been the subject of controversy. While the phrase has been interpreted by the courts in non-Bayh-Dole cases to include pricing, funding agencies in the United States have always been reluctant to exercise march-in rights in cases where products arising from government funded research are highly priced.[367]

Given this background, and the fact that the DST in the policy document which recommended the adoption of a the IPR Act explicitly cited the United States Bayh-Dole Act as reference, the use of these exact words in the IPR Act without clarification or definition raises questions as to how this may be applied in the South African context.[368]

Another important point worth noting is the fact that the Act defines intellectual property to mean: 'any creation of the mind … capable of being protected by law from use by any other person …' By providing such a broad scope of protectable intellectual property, particularly in the case of patents, the IPR Act fails to recognise the difference between applied research that can benefit from patenting, licensing and commercialisation, and upstream research that sometimes does not require exclusivity to promote its exploitation. Patenting upstream research has the potential to discourage a broad range of productive research activity that had previously thrived under a system of free and open academic exchange.[369]

4.6.3 Manufacture within South Africa

The IPR Act mandates that '… exclusive licence holders must undertake, where feasible, to manufacture, process and otherwise commercialise within the Republic …'[370] however, in the event that the exclusive licensee is no longer able to commercialise the inventions within South Africa and yet wishes to retain exclusivity,

[367] Arno & Davis (n 19 above) 662, 650 & 651.
[368] Letter by Ethan Guillen to Dr Boni Mehlomakulu Deputy Director-General: Research, Development and Innovation, Department of Science and Technology on 11 August 2009 in response to the Department's request for clarification from Universities Allied for Essential Medicines on some of the criticism it had made on the Draft Regulation and the Act.
[369] As above.
[370] Sec 11(d) of the Act.

the recipient shall furnish NIPMO with full reasons why it wishes to continue with the exclusive licence wherein:[371]

> NIPMO may request that the exclusive licence contemplated … be converted to a non-exclusive licence if a recipient fails to furnish the reasons within the period contemplated …, or if NIPMO is not satisfied with such reasons.

The emphasis on manufacturing in South Africa will ensure that the process of transforming intellectual property into a finished product takes place in the country. This will develop and strengthen the local manufacturing capacity in the country and also create jobs. However, where an exclusive licensee is no longer able to manufacture, process and commercialise within South Africa, NIPMO can either authorise manufacture outside South Africa, or require that the licence be converted into a non-exclusive one. Considering that the DST in the Intellectual Property Rights (IPR) from Publicly Financed Research Framework Act expressly mentioned that the Act was necessary to, among other reasons, address the assignment of intellectual property arising from government-funded research to overseas companies for commercialisation,[372] one wonders whether the Act has actually addressed this.

4.6.4 March-in right

Under the IPR Act:[373]

> Each intellectual property transaction must contain a condition to the effect that, should a party fail to commercialise the intellectual property to the benefit of the people …, the State is entitled to … conduct reviews of non-commercialised intellectual property in consultation with the recipient … to ensure that the intellectual property is commercialised. NIPMO may require a recipient to grant a licence in any field of use to any person on reasonable terms if, after consultation … the intellectual property is still not being commercialised; or no agreement can be reached with the recipient.

As mentioned above, sometimes exclusive licensees fail to commercialise inventions. The above provision on march-in right could ensure that in such a case a licence is granted to a third party who would commercialise the intellectual property on reasonable terms.

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[371] Sec 11(1)(f) - (g) of the Act.
[372] Department of Science and Technology (n 351 above). It should also be noted that according to Conraad Visser, South African publicly financed institutions often assign intellectual property arising from their research to foreign companies for commercialisation. C Visser 'Intellectual property rights from publicly financed research: The way to research hell is paved with good intentions' (2007) 19 *South African Mercantile Law Journal* 364. Also, the CSIR granted an exclusive licence on P57 a component of the Hoodia plant to Phytofarm which in turn granted an exclusive licence on same to Pfizer to develop and commercialise P57. http://www.life-enhancement.com/magazine/article/972-stifle-hunger-with-hoodia (accessed 29 September 2014.
[373] Secs 11(2); 14(1) - (4); 11(1)(e).

Given that all companies are out to make profit, it may be difficult to find a third party (another private company) that will be willing to commercialise the intellectual property if there is little or no prospect of making a profit. This may be addressed by the creation of a specific fund for such situations; providing tax breaks and other forms of benefits as incentives for industry to develop such inventions into finished goods. Alternatively, a law or policy similar to the United States Orphan Drug Act 1983 can be passed to provide special benefits as incentives for industries to invest in developing and commercialising research or inventions that are non-lucrative, hence, unattractive to industry.[374]

In order to ensure that whenever the public interest so requires government is held accountable and perhaps compelled to exercise march-in right, the Act or the regulation should have empowered any interested person to request NIPMO or any other competent authority to exercise march-in right. Giving members of the public such an option would not only hold government accountable for failing to exercise this right, but will also serve as a signal to potential licensees that they are accountable to the public in their dealings with intellectual property emanating from publicly funded research or inventions. CSOs in South Africa are very vocal and active in terms of advocacy on the right to access healthcare. This was evident in the struggle for universal access to ARVs for the prevention of mother-to-child-transmission of HIV and the high price of other ARVs between 1998 and 2008.[375] The constitutional provision of the right of access to healthcare services for all in South Africa could serve as grounds for holding government accountable and requiring it to exercise march-in rights if the need arises.[376]

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[374] The Orphan Drug Act is a law passed in the US to facilitate the development and commercialisation of medicines to treat rare diseases, termed orphan drugs. The orphan drug designation does not indicate that the therapeutic is either safe and effective or legal to manufacture and market in the US. Instead, the designation only means that the industry that develops and commercialises these medicines qualifies for certain benefits from the federal government, such as reduced taxes. Food and Drug Administration 'Designating an Orphan Product: Drugs and biological products' 14 August 2013 http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/default.htm (accessed 15 October 2013).

[375] M Heywood 'South Africa's Treatment Action Campaign: Combating law and social mobilization to realise the right to health' (2009) 1 *Journal of Human Rights Practice* 31 - 34; L Khondkar 'Access to anti-retrovirals the role of treatment activism in South Africa' 10 April 2008 http://centers.iub.edu.bd/chpdnew/chpd/download/seminar/2008/April10.pdf (accessed 31 October 2013).

[376] Sec 27(1)(a) of the South African Constitution.

4.6.5 Government-use right

The relevant provision reads as follows:[377]

> The recipient determines the nature and conditions of intellectual property transactions … 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 or emergency needs of the Republic.

Under the Regulation, before any proclamation shall be made by Parliament on the right to use the intellectual property, the State must determine the ability of a recipient or any licensee to commercialise the intellectual property; and to meet the specific health, security and other emergency need of the Republic.[378]

The fact that this provision expressly mentions that government can exercise the right to use the intellectual property for health reasons presupposes that, although this legislation speaks to research in general, biotechnology and biomedical research are key. Government-use right is a very important safeguard because government as a matter of principle has as its object to ensure the wellbeing of its citizens. By providing funds to universities for research, the government is in fact fulfilling part of its mission and should therefore retain rights to all intellectual property transactions that will enable it to continue to secure public welfare. Were this not to be the case, government will be transferring its duties to private industries, which sometimes have little or no consideration for public welfare.

In addition to the government, other research institutions equally involved in government-funded research should also be granted royalty free rights to access and use research results and intellectual property emanating from government-funded research for research, experimental, educational and other non-commercial uses. The United States cases of *Madey v Duke University* and *Association of Molecular Pathology v US Patent and Trademark Office* both portray the importance

[377] Secs 11(1)(e); 2(g) of the Act.
[378] Regulation 8(8)(a).

of experimental use exception.[379] In addition, broad research and scientific experimentation rights are permissible under Article 30 of the TRIPS Agreement.[380]

Also, very important to note is the fact that, sometimes the number of patents in need of licence negotiations by researchers before engaging in a single research project can be challenging, irrespective of the terms on which the licences are subsequently offered.[381] Although it may be argued that in such a case the government can issue a compulsory licence under the South African Patent Act no 57 of 1978,[382] the reality is that this may prove to be a daunting task, hence, the need to have a clear experimental use provision in the Act. Another alternative could be to create a licence of right system, with reasonable royalties, for research platform patents.

4.6.6 Disclosure and reporting

With respect to disclosure and reporting, the Act provides that:[383]

> … a recipient of funding from a funding agency assesses, [records] and reports on the benefit for society of publicly financed research and development … A recipient must provide effective and practical measures and procedures for the disclosure … and ensure that intellectual property emanating from any publicly financed research and development is appropriately protected before results of such research and development are published or publicly disclosed by other means … refer disclosures for which it elects not to retain ownership or not to obtain statutory protection to NIPMO within 30 days or such longer period as may be prescribed, of it making such an election;

With respect to researchers, under the IPR Act, the recipients are required to ensure that:[384]

> … personnel involved with research and development make a disclosure to it within 90 days or such longer period as may be prescribed, of identification … of possible intellectual property and before [it] is made public; assess the intellectual property to determine whether it merits statutory protection and, where appropriate, apply for and use best efforts to obtain statutory protection in its name;

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[379] *Madey v Duke University* (2002) 307 F 3d 1351 (No. 02-1007); *Association for Molecular Pathology v U.S. Patent and Trademark Office* No. 09-cv-4515 94 USPQ2d 1683 (S.D.N.Y. 29 March 2010); Barratt (n 338 above) 44-46.
[380] WIPO Committee on Development and Intellectual Property 'Patent related flexibilities in the multilateral legal framework and their legislative implementation at the national and regional levels' 26-30 April 2010 Geneva para 61-71; Canada-Patent protection of pharmaceutical product case (DS114) http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm; RS Eisenberg 'Patents and the progress of science: Exclusive rights and experimental use' (1989) 56 *Chicago Law Review* 1017.
[381] Barratt (n 356 above).
[382] Sec 55 - 56 of the Act.
[383] Secs 2(2)(a); 5(1)(b) of the Act.
[384] Sec 5(1)(c) - (d) of the Act.

In addition, the recipient shall:[385]

> … report to NIPMO twice a year and as provided for in this Act, on all matters pertaining to the intellectual property …, including all intellectual property from which it elects to obtain statutory protection and the state of commercialisation thereof, …; provide NIPMO with full reasons in respect of any intellectual properly that is not commercialised; and in respect of an institution, put in place mechanisms to annually assess, record and report to NIPMO on the benefits for society of … research conducted in that institution.

With respect to disclosure, the fact that research institutions are required to seek protection over intellectual property before publishing will give them ownership of the intellectual property before it is published.

While providing for recipients to seek intellectual property protection over their inventions before publishing, the Act fails to provide a deadline within which such research must be published and also whether the research should be made available on open source in the public domain or not. In view of the fact that the research is publicly funded, it is imperative that research results are made as widely available as possible through open source, at least in the Republic. In addition and as earlier stated, publication delays should be avoided by providing specific timeframes within which research must be published to prevent researchers from working on research that has already been concluded by others. This will save funds, time and other resources. Also, considering that protection and commercialisation of research results before publication may be new for most South African researchers, it is important to have very short timelines within which TTOs must secure protection to avoid interference with researchers' work. Early or first publication in a particular research field is very important in the academic world.

Reporting on intellectual property resulting from public-funded research and on its potential benefits to the society is crucial as it informs the government of intellectual property upon which it may need to exercise march-in right or government-use right. Reporting (supposing that such reports are public documents) also informs taxpayers and members of the society at large of the intellectual property and their potential benefit to society which is a form of accountability on the part of research institutions to taxpayers and the government. Reporting on the part of the researcher or the intellectual property creator notifies the recipient of the intellectual property to enable it to report to the government.

[385] Sec 5(1)(h) - (j) of the Act.

4.7 Other provisions of the Act

4.7.1 Royalty sharing and reinvesting

With respect to royalty sharing, the Act provides that the creator of a particular intellectual property shall receive:

> … 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 thereafter, at least 30 per cent of the net revenues accruing to the institution from such intellectual property. The benefits must be shared in equal proportions between the qualifying intellectual property creators or their heirs unless otherwise agreed between those creators and the recipient or determined in accordance with institutional policies.

After paying such royalties to the intellectual property creator the recipient may distribute the balance of the revenues as he deems fit, but must apportion part of it to funding more research, the operations of the TTO and cost of obtaining intellectual property protection.

4.7.2 The technology transfer office

With respect to TTOs, the Act requires recipients to:[386]

> … put in place mechanisms for the identification, protection, development, management of intellectual property, intellectual property transactions and, where applicable, the commercialisation of intellectual property and appropriate capacity-building relating thereto … [To ensure this, recipients shall], … unless determined otherwise … within 12 months of the coming into effect of this Act establish and maintain an office of technology transfer; or designate persons or an existing structure within the institution to undertake the … obligations of the institution in terms of this Act. Two or more institutions may with the concurrence of NIPMO establish a regional office of technology transfer. NIPMO may, on terms and conditions determined by it, provide assistance to institutions for the establishment of offices of technology transfer.

The functions of the TTOs will be to, among others:[387]

> … develop and implement … policies for disclosure, identification, protection, development, commercialisation and benefit-sharing arrangements; receive [and] analyse disclosures … for any commercial potential, the likely success of such commercialisation, the existence and form of the intellectual property rights, the stage of development thereof and the appropriate form for protecting those rights; attend to all aspects of statutory protection of the intellectual property [including transactions and commercialisation]; refer disclosures to NIPMO …; conduct evaluations on the scope of statutory protection … in all geographic territories subject to commercialisation potential …

386 Secs 5(1)(a); 6(1) - (3) of the Act.
387 Sec 7 (2)(a) - (h) of the Act.

The Act further requires that these functions be performed by appropriately qualified personnel having interdisciplinary knowledge, qualifications and expertise in identifying, protecting, managing, and commercialising intellectual property and in intellectual property transactions.[388]

One of the criticisms of the practice of technology transfer in the United States is the fact that each research institution sets up and runs a TTO for intellectual property management and technology transfer and the government does not provide financial assistance to run these offices. Therefore, universities rely on patenting and technology commercialisation to run these offices.[389] Under the South African Act however, this is addressed by the provision that two or more universities can jointly have a single TTO and that a regional TTO can be established.

The Act also provides that NIPMO, as a state agency, will assist university TTOs with co-ordinating the establishment of a regional office of technology transfer;[390] the development of appropriately skilled personnel for the offices of technology transfer;[391] and also provide financial assistance to TTOs.[392] Hopefully, these important mechanisms provided by the government will spare TTOs from patenting and licensing with no consideration of public interest simply to raise revenue to run and maintain their offices, and also enable the TTOs to actually go for the best mode of achieving the goals of the Act, even if so doing does not necessarily raise immediate financial revenue, or perhaps no financial revenue at all, but is in the public interest.

4.7.3 The National Intellectual Property Management Office

The Act establishes NIPMO within the DST. Under the Act, NIPMO, which is responsible for overseeing and managing intellectual property emanating from government-funded research, must ensure that it has the requisite capacity to consider intellectual property matters referred to it by a recipient and in addition, be responsible for the following:[393]

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[388] Sec 7(1) of the Act.
[389] Sype Communication with Richard Jennings (n 206 above).
[390] Sec 6(4)(b)(ii).
[391] Sec 6(4)(b)(iii).
[392] Sec 6(4)(b)(i).
[393] Sec 9(1) - (5).

1. Liaising with recipients or any other party it deems fit to determine the viability of obtaining statutory protection for the intellectual property referred to it, where this is in the national interest.

2. Concluding any intellectual property transactions including commercialisation and manage information in respect of intellectual property.

3. Providing incentives to recipients and their intellectual property creators, to reward them for proactively securing protection for intellectual property and commercialising it and, generally, for promoting innovation.

4. Providing assistance to institutions with the establishment of offices of technology transfer and related capacity building.

5. Providing appropriate standards and best practices in consultation with recipients, without limiting the power of the recipient to act in its own interests in terms of this Act.

6. Developing guidelines for intellectual property transactions involving non-South African entities and persons, and manage the implementation of such guidelines.

7. Monitoring, evaluating and reviewing the obligations of recipients in terms of this Act.

8. Do anything necessary to meet the objects of the Act and to carry out all other functions consistent with those objectives that may be prescribed.

Clearly, the South African Act, though with a few limitations, has more adequately addressed public interest challenges than the Indian Bill. The reason for this is perhaps that the legal system as a whole, as required by the constitution, is guided by human rights principles that prioritise access to basics like healthcare services and related products.

For purposes of having a wider representation of the trend in regulating public-funded research in emerging countries, the research provides a brief analysis of the Brazilian Innovation Law. It is impossible to follow the same format of quoting the exact provision of the legislation as a translated version of the law is used and not

the original text. However, given that the key provisions on similar legislations have already been discussed in the cases of India and South Africa, it is not necessary to delve into some of these in detail. Regular reference will be made to detailed explanations provided under the South African and Indian legislation and earlier chapters whenever necessary and applicable to Brazil.

4.8 BRAZIL: Law No 10.973 of December 2004 (Brazilian Innovation Law of December 2004)

4.8.1 Background to the Brazilian Innovation Law

The Brazilian Congress enacted the Technological Innovation Act, Law No. 10.973/04 in December 2004 (the Innovation Law). This Law seeks to encourage innovation, scientific and technological research with the goal of building the capacity of local industries and ensuring their technological autonomy and industrial development.[394] The Law provides special measures for technological development such as support for the establishment of strategic alliances and co-operative research projects between Brazilian public research institutions and industries.[395] Like the United States, Indian and South African legislation on publicly financed research, the technological sector that is most affected by the Innovation Law is the biopharmaceutical technology sector. Before 2004 when this law came into effect, very few Brazilian research institutions sought protection of their inventions for further development and commercialisation.[396] The few which actually did mainly sought partnerships with government-owned industries.[397] This perhaps explains why the Brazilian government deemed it necessary to pass the Innovation Law.

[394] Art 1.
[395] GE Goulart & AJV Gorini (2013) 'Brazil: The New Technological Innovation Act in Brazil' 21 March 2013 http://www.mondaq.com/x/226542/technology/The+New+Technological+Innovation+Act+In+Brazil (accessed 04 October 2013).
[396] MH Ehlers 'Patents and the Law of Technological Innovation' 30 September 2005 http://www.dannemann.com.br/dsbim/manager.aspx?ID_LAYOUT=211&ID=119 (accessed 4 October 2013).
[397] As above.

4.9 Analysis of some of the key provisions of the Law

4.9.1 Retention of title, patenting and licensing

Under the Brazilian Patent Law No 9.279 of 1996, in the absence of any agreement to the contrary, inventions created by an employee with the means and resources provided by the employer, including in research institutions, are owned by the employer.[398] In this context, as is the case in the United States and in South Africa, title to all intellectual property created by researchers in public research institutions vests with recipients.[399] Under the Innovation Law, recipients are required to seek intellectual property protection over such inventions[400] and to commercialise them through licences[401] to industry for further development and translation into finished products fit for commercialisation. Unlike in developed countries where private industries conduct far more biopharmaceutical research and own far more patents than public research institutions, Brazilian public universities are the leading patent holders in biopharmaceuticals.[402] After the coming into force of the Innovation Law, the State University of Campinas for instance has in the last two years signed 128 technology transfer agreements and licenced 45 technologies both to the private sector and to government industries.[403] Apart from the fact that royalties from these licences will serve as an additional source of funding for the universities, these will also secure the development of research results into tangible products that can be used to alleviate the social and economic needs of the people.

With respect to licensing, while providing for the granting of both exclusive and non-exclusive licences, the Innovation Law provides that inventions resulting from government-sponsored research and recognised by the government as being important for public welfare, shall only be licenced on a non-exclusive basis.[404] In the interest of the public, the Innovation Law provides different processes for granting exclusive and non-exclusive licences. For instance, before an exclusive licence can

[398] Art 8 - 90 of the Brazil Patent Act.
[399] Art 5.
[400] Art 16 §IV.
[401] Art 6.
[402] Universities hold 48% of all patents in biotechnology. LM Mendes 'Research and innovation in bio-technology: An analysis of the patents granted by Brazilian universities in the last decade' 05 July 2013 http://tha2013.org/index.php/tha/2013/paper/view/39 (accessed 13 October 2013).
[403] AB Bennett *et al* 'Technology transfer offices: facilitating intellectual property protection for agricultural innovation' in The World Bank (ed) *Agricultural innovation systems an investment* sourcebook (2012) 411 The World Bank.
[404] Art 6 § 5.

be issued, the recipient is required to put out a notice to this effect to notify the public.[405] Such a notice must contain a clear and brief description of the invention; other relevant aspects of the invention; and the commercialisation prospects in the form of an invitation to bid.[406] Once this is done, interested private industries are required to indicate their interest and the terms upon which they are willing to bid. Following these biddings, the recipient is required to choose and offer the exclusive licence to the private industry that offers the most favourable terms,[407] perhaps based on the one most likely to meet public interest needs. A recipient wishing to grant a non-exclusive licence to industry is not required to go through this process.

In addition, the Innovation Law provides for tax breaks for industries that partner with public research institutions to secure the translation of inventions into finished goods and their commercialisation.[408] The Law also provides for the granting of subsidies to industries involved in partnerships with public research institutions.[409] These tax breaks and subsidies are important incentives for private industries. According to Diana Jungmann, Intellectual Property Programme Coordinator at the National Confederation of Industry in Brazil, several inventions originating from government-funded research are not been licenced to industries for further development, translation and commercialisation mainly because some of the inventions have little or no commercial potential. This could be addressed by instituting targeted research at universities in the form of research that is meant to address specific existing problems in the country.[410]

4.9.2 March-in right

With respect to march-in rights, the Innovation Law provides that whenever an exclusive licensee of an invention originating from publicly financed research fails to develop and commercialise the invention in time and on conditions defined in the licence contract, the recipient shall licence the invention to a third party.[411] Brazilian

[405] Art 6 § 1.
[406] MC Foss 'Analysis of the legal arrangements for the technological innovation promotion' 19 June 2013 http://cglad.com.br/wp-content/uploads/2013/06/19.-Maria-Foss.-Analysis-of-the-legal-arrangements-for-the-technological-innovation-promotion.pdf (accessed 04 October 2013).
[407] Art 6 §1.
[408] Art 28 of the Law; Provisional Measures (MP) No. 252 of June 2005; Ehlers (n 378 above).
[409] Art 19 §2.
[410] Interview with Diana Jungmann in Durban 21 November 2013.
[411] Art 6 § 3.

1991 Decree No 3.201 also provides for the granting of compulsory licences in cases of national emergency, and in the public interest.[412] Because of the high level of local manufacturing capacity in Brazil, the government has on a number of occasions succeeded in negotiating and securing lower prices for HIV treatment from pharmaceutical companies by threatening to issue a compulsory licence authorising local pharmaceutical companies to manufacture generic versions of brand medicines.[413] Therefore, although the Innovation Law is silent about the exercise of march-in rights by the government, government may be able to issue a compulsory licence if an exclusive licensee fails to commercialise an invention arising from government-funded research, or does so in a manner that is detrimental to the public's interest.

4.9.3 Disclosure and reporting

The Innovation Law provides that recipients shall annually publish and report to the Ministry of Science and Technology on their intellectual property policy; inventions arising from government-funded research; patent applications filed; patents obtained; and licensing contracts.[414]

4.10 Conclusion

The realisation of the need to boost local R&D and promote the growth of local manufacturing capacity has brought with it the introduction of new technology-transfer legislation in a number of emerging middle-income countries. As ambitious as the goals of this legislation may be, ensuring that laws are actually framed and implemented in a manner that would meet these objectives is neither easy for legislators nor for public research institutions. Optimising the legal framework and incentivising both government-funded research and its commercialisation is not a day's job. In most cases it is only after several years of further R&D that inventions are actually developed into products. To ensure that this actually happens, and that public interest in the form of access to pharmaceuticals developed from this

[412] National emergency under the Decree is defined to mean 'the imminent public danger even if just in part of the national territory'. The Decree cites matters relating to health as matters of public interest. Decree 3.201 art 2 §1.
[413] URQ Marques *et al* 'Brazil's AIDS controversy: Antiretroviral drugs, breaking patents, and compulsory licensing' (2005) 60 *Food and Drug Law Journal* 476.
[414] Art 7 §I - IV.

research; and access to research by researchers from other research institutions are prioritised in all technology transfer negotiations between research institutions and industry, both governments and research institutions have to make it their daily business to put their people's interests first in all laws or policies and technology-transfer transactions.

It is only through such a united stance on the part of governments and research institutions that both will be able to negotiate and reach a win-win technology-transfer arrangement with private industries which are and will always be motivated by profit maximisation with little or no regard for public welfare. This perhaps explains why in countries like the United States where technology transfer is a daily practice, university students have formed organisations like Universities Allied for Essential Medicines to advocate for the advancement of access to medicines before profits. CSOs and perhaps students in countries that either have newly introduced technology-transfer laws or are considering such laws should be vigilant and act as watchdogs whenever human rights are threatened for the sake of profits in technology transfer negotiations and licensing agreements.

CHAPTER V

POLICY OPTIONS ON INTELLECTUAL PROPERTY EMANATING FROM PUBLICLY FUNDED RESEARCH FOR SUB-SAHARAN AFRICAN COUNTRIES

5.1 Introduction

Previous chapters examined the lack of R&D for diseases peculiar to developing countries; how the Bayh-Dole Act 1980 addressed technology transfer problems in the United States; the adoption of different approaches to regulating technology transfer in other countries; and the recent emulation of the Unites States Bayh-Dole model in some developing countries. This chapter proposes policy options on publicly financed research for Sub-Saharan African countries seeking to address the current healthcare challenges faced in the different countries and the sub-continent in general.

This chapter examines how, through legislation: (1) biomedical R&D can be stimulated and promoted; (2) how partnerships between research institutions and industries can be created and sustained for the translation of university developed intellectual property into products; and (3) how local manufacturing capacity can be boosted in this process to enable local pharmaceutical companies to become the primary suppliers of low cost generic medicines in their local markets in the long run with the overarching aim of providing better healthcare options to people living in Sub-Saharan Africa. The idea here is to think outside the box and move away from the notion that the same TRIPS Agreement flexibilities, which have proven to be ineffective in stimulating and promoting technology transfer from developed countries to developing and least developed countries, is the panacea for the current healthcare challenges faced by people living on the sub-continent.

Far from proposing a single legislative text and claiming it can address the access problem in all Sub-Saharan African countries, this chapter discusses factors that should be taken into account by lawmakers when considering legislation on publicly financed research with the view to promote R&D, local manufacturing and access. The principal question to be answered throughout this chapter is: what are the major issues that must be considered in legislation aimed at promoting R&D; increasing

effective management and transfer of technologies developed from publicly financed research from research institutions to industry; boosting local manufacturing capacity; and ensuring that products manufactured from publicly funded research, particularly pharmaceuticals, are accessible? However, before delving into this, the following paragraphs address the recurrent question of whether intellectual property generated from publicly financed research should be protected through monopoly rents instead of being made available for exploitation and use by any member of the public, and also provide some insights into the current state of R&D funding in some Sub-Saharan African countries.

5.2 The rationale for intellectual property protection over publicly financed research

At first thought, it seems unreasonable to protect and monopolise intellectual property emanating from publicly funded research. The reality is that the financial, human and infrastructural resources required to translate technologies developed by research institutions into pharmaceutical products lies with private industries (and a few organisations involved in public-private product development partnerships, such as the Drugs for Neglected Diseases initiative). This therefore results in the need for these technologies to be transferred to private industries in some form until alternative innovation or access systems are put in place.

Moreover, given that the translation and application of these technologies into tangible products (particularly pharmaceuticals) is sometimes very expensive, demanding several years of applied R&D and the fact that these pharmaceuticals can be easily copied by competitors[415] immediately after market entry, even before originators have recouped their investment costs, private industries often need an assurance that competitors will be prevented from piggybacking on their investments. In order for research institutions to guarantee an opportunity to recoup investments, they must first secure intellectual property protection over the technologies they develop. Following protection, research institutions would grant

[415] G Evans 'Strategic patent licensing for public research organizations: Deploying restrictions and reservation clauses to promote medical R&D in developing countries' (2008) 34 *American Society of Law, Medicine and Ethics* 192.

licences over the intellectual property to private industries authorising them to commercially exploit and translate the technology.

Protecting intellectual property generally, and publicly funded intellectual property in particular, is also important because with globalisation and the advent the TRIPS Agreement, all WTO countries[416] are obliged to implement universal minimum standards of intellectual property protection which provide substantive and enforcement provisions for intellectual property in domestic legislation. These universal minimum standards of intellectual property protection have significantly altered the parameters of economic catch-up.[417] Before the advent of the TRIPS Agreement, individual countries had the liberty to regulate intellectual property in a manner that best suited their national developmental needs irrespective of what was happening in other countries. In fact, a major contributor to the development of a robust self-sufficient pharmaceutical industry in India was the speed at which Indian scientists were able to develop cost-effective manufacturing processes for molecules already invented and patented in other, mainly developed, countries.[418]

However, this is not possible today in non-least developed country member states bound by the TRIPS Agreement. These countries are required to protect and enforce intellectual property rights on inventive products and processes, which in most cases are developed and owned by multinational companies from developed countries.[419]

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[416] Almost all countries of the world, namely 159, are WTO members. Of the remaining few, 24 are currently negotiating their WTO membership www.wto.org/english/thewto_e/acc_e/members_brief_e.doc (accessed 28 May 2014).

[417] R Mazzoleni & RR Nelson 'Public research institutions and economic catch-up' (2007) 36 *Science Direct* 1515; Evans (n 397 above) 177 - 178.

[418] This was supported by the Indian Patents Act 1970 which prohibited product patent protection for pharmaceutical inventions. Globally the Indian generic industry is ranked 4th in terms of volume and 13th in terms of value of production and enjoys a 22% share of the global generic market, while supplying control of 80% of the domestic market SE Smith 'Opening up to the world: Indian pharmaceutical companies prepare for 2005' 12 May 2000 http://fsi.stanford.edu/sites/default/files/Smith.pdf (accessed 28 May 2014); Planning Commission of India 'Report of the Working Group on Drugs and Pharmaceuticals for the Eleventh Five Year Plan' 01 December 2006 21 http://planningcommission.nic.in/aboutus/committee/wrkgrp11/wg11_pharma.pdf (accessed 28 May 2014); KM Gopakumar 'Product patents and access to medicines in India: A critical review of the implementation of TRIPS patent regime' (2010) 3 *The Law and Development Review* 329.

[419] It should be noted that under art 66.1 of the TRIPS Agreement, least developed countries were excluded from implementing the Agreement in the area of patents on pharmaceuticals until November 2005. This period was later extended to July 2013, and in June 2013, it was again extended to 01 July 2021, or until such a time when these countries cease to be least developed countries, whichever comes first. In spite of the grace period available to least developed countries some of these countries like 12 out of the 16 member countries of the *Organisation Africaine de la Propriété Intellectuelle*

Least developed countries that benefit from extended TRIPS transition periods, exclusion from granting patents on pharmaceutical products and data protection, have very limited or no R&D bases and also little or no manufacturing capacity. From the above, it is clear that government innovation policies can no longer only focus on promoting the manufacture of generic medicines, but should also look into supporting and sustaining the development of a strong research base and infrastructure in the manufacturing sector in general and in the biopharmaceutical technology sector in particular.[420] The following paragraphs provide an insight into the current state of R&D funding in some Sub-Saharan African countries.

5.3 The current state of R&D funding in some Sub-Saharan African countries

5.3.1 The case of Nigeria in West Africa

Nigeria is the first most populous country in Africa and the 7th in the world with a population of approximately 182 million people.[421] As of 2015, Nigeria was the world's 20th largest economy, worth more than $500 billion and $1 trillion in terms of nominal GDP and purchasing power parity respectively. In 2014 Nigeria overtook South Africa to become Africa's largest economy.[422] Nigeria is considered an emerging market by the World Bank and has been identified as an emerging global power.[423] The country is a member of the Mexico, Indonesia, Nigeria and Turkey (MINT) group of countries, which are widely seen as the globe's next "BRIC-like" economies. In spite of this strategic position the country occupies, the Nigerian government allocates only about 0.02% of its GDP to R&D in science, technological development and innovation.[424] The country so far has no law or policy regulating the management of intellectual property emanating from government funded research.

(OAPI), an Intellectual Property organisation of West and Central African countries, have already amended their laws to become TRIPS compliant.

[420] Mazzoleni & Nelson (n 417 above).

[421] D Thifa 'India and Nigeria: Countries With The Fastest Growing Populations' available at http://www.mbctimes.com/english/india-and-nigeria-countries-with-the-fastest-growing-populations (accessed 18 December 2015).

[422] PricewaterhouseCooper 'The World in 2050: Will the shift in global economic power continue?' (2015) 29.

[423] As above 2.

[424] Y Akinwaye *et al* 'Global best practices for R&D funding: Lessons for Nigeria' 4 *Interdisciplinary Journal of Contemporary Research in Business* (2012) 920. See also PA Donwa 'Funding of Academic Research in Nigerian Universities' available at http://ahero.uwc.ac.za/index.php?module=cshe&action=viewtitle&id=cshe_106 (accessed 18 December 2015).

5.3.2 The case of Cameroon in Central Africa

Cameroon, often referred to as Africa in miniature for its diversity in climate, culture, and geography which all epitomise the African continent is home to 22.8 million people.[425] The Cameroon economy was worth $67.78 Billion in terms of purchasing power parity and $32.162 Billion in terms of nominal GDP in 2014.[426] Although it is clear that R&D is highly underfunded, there is no available information on exactly what percentage of the GDP or national budget is allocated to R&D in the country. Individual universities determine how much to allocate to research from the subsidies they receive from the government.[427] In addition to this obviously meagre funding, government provides sporadic funding to universities from time to time, and individual researchers sometimes also receive nominal funding from the government on a competitive basis.[428] In a bid to promote R&D and technological development, parliament is currently considering a Bill aimed at establishing a sustainable R&D funding mechanism for universities.[429] Also interesting to note is the fact that there is very little or no collaboration between fulltime researchers employed to conduct R&D at national research councils and university researchers.[430] As a result of this lack of collaboration, while the research aim of a researcher at a research council is geared towards understanding, addressing or solving a particular societal problem to improve living standards in general, that of a university researcher is mainly aimed at receiving accolades and promotions.[431] This lack of synergy frustrates the whole purpose of carrying out research.

[425] http://agro-hub.com/general/asserting-cameroon-as-africa-in-miniature/#.Vne57RXRKko (accessed 21 December 2015).
[426] The CIA Factbook available at https://www.cia.gov/library/publications/the-world-factbook/geos/print_cm.html 9accessed 19 December 2015).
[427] YB Signing & S Nguiessi 'State of University Research Governance in West and Central Africa: The case of the University of Buea' (2009) 7; see also J Gaillard *et al* 'Science Granting Councils in Sub-Saharan Africa: Country Report Cameroon' (2013) 10.
[428] Signing & Nguiessi (n 427 above) 14, 32.
[429] Signing & Nguiessi (n 427 above) 26.
[430] Signing & Nguiessi (n 427 above) 12.
[431] Gaillard I *et al* (n 427 above) 9.

5.3.3 The case of Kenya in East Africa

Kenya is home to 47.8 million inhabitants.[432] The country's economy, worth $146 billion in terms of purchasing power parity and $ 60.94 Billion in terms of nominal GDP in 2014,[433] is the largest by GDP in East and Central Africa. The Kenyan Research Fund established under the Science and Technology Innovation Act, 2013 promotes and facilitates research for the advancement of science, technology and innovation.[434] Through the Research Fund the Kenyan government in 2015 increased R&D funding from 0.5% of the country's GDP to 2%.[435] According to the Principal Secretary in the Ministry of Education and Science and Technology, the National Innovations Agency, also created under the Science and Technology Innovation Act, will be particularly instrumental in providing the legal framework for public-private partnerships and linkages between academia, research, industry and the community.[436] Given that all of these developments are fairly new, time alone will tell about their fruition.

5.3.4 The case of Namibia in Southern Africa

Namibia, previously known as South West Africa has a population of 2.1 million people.[437] The country's economy was worth $18.800 Billion in terms of purchasing power parity and $ 13.064 Billion in terms of nominal GDP in 2014.[438] The National Science and Technology Investment Plan created under the Research Science and Technology Act no 23 of 2004 provides for the allocation of 0.3% of GDP spending to R&D.[439] Currently, there is no framework for the management of intellectual property rights emanating from government funded research.[440] The National Commission on Research Science and Technology and Business and Intellectual

[432] World Population Review 'Kenya Population 2015' available at http://worldpopulationreview.com/countries/kenya-population/ (accessed 23 December 2015).
[433] The World Bank: Kenya available at http://www.worldbank.org/en/country/kenya (accessed 23 December 2015).
[434] Science Africa 'Kenya leads Africa with 2% of GDP for Research & Development' available at http://www.scienceafrica.co.ke/index.php?option=com_content&view=article&id=183:kenya-leads-africa-with-2-of-gdp-for-research-and-development&catid=87&Itemid=586 (accessed 23 December 2015).
[435] Science Africa (n 434 above).
[436] Science Africa (n 434 above).
[437] The World Bank *Namibia Country Brief* 2009 Washington DC The World Bank 1.
[438] http://www.indexmundi.com/namibia/ (accessed 26 December 2015).
[439] The National Programme on Research, Science, Technology and Innovation 2014/2015 to 2016/2017 Republic of Namibia 8-9.
[440] As above.

Property Agency are working towards establishing an intellectual property rights framework in consultation with institutions and individuals whose inventions and innovations will require protection. The framework will address issues of technology transfer, ensure the efficient management of scientific discoveries, intellectual property and technological innovations developed by research institutions to ensure its alignment with the national R&D strategy.[441]

From the above, it is clear that most countries on the sub-continent provide very little funding for R&D. Also evident is the fact that most countries are beginning to understand the importance of R&D and technological development, and are working towards putting in place appropriate mechanisms to promote R&D and subsequently, partnerships between research institutions and industry in a bid to ensure that research contributes in alleviating some of the daily challenges people face. The following paragraphs discuss how legislation on publicly financed research can contribute to achieving this.

5.4 Key provisions for legislation on publicly financed research for Sub-Saharan African countries

5.4.1 Implementation oversight

Model legislation on publicly financed research must provide for the creation of an organ to monitor the proper implementation of the law or policy to ensure that its aims and objectives are clarified whenever ambiguities arise, and that its goals are met. This can either take the form of the creation of an agency or office with the sole function of overseeing the proper implementation of the legislation, or these functions can be assigned to an existing agency or office that deals with research, innovation, and or technology development like Departments or Ministries of Science and Technology, Scientific Research and or Higher Education. Borrowing from the South African legislation on publicly financed research, such an agency or office should, among others, be responsible for:

1. Monitoring the overall implementation of the law by research institutions for purposes of compliance and promoting the objectives of the legislation, namely: the statutory protection, management and commercialisation of intellectual

[441] As above.

property emanating from publicly financed research, and supporting research institutions in achieving these.[442]

2. Providing financial support to research institutions for the statutory protection and management of all issues relating to intellectual property protection; and also providing incentives to intellectual property creators.[443]
3. Granting special benefits to industries as an incentive for them to invest in the development and commercialisation of technologies developed from publicly financed research that would otherwise not be commercialised on terms that would render the particular product accessible when it is developed and commercialised.[444]
4. Providing assistance with the establishment of TTOs and related capacity-building within research institutions taking into account the fact that, while some research intensive universities may need to have their own TTOs, the vast majority of universities may be better served by a single regional or provincial TTO that caters for related services for a group of universities.[445]
5. Limiting offshore exclusive licensing of intellectual property emanating from publicly financed research to ensure that offshore exclusive licences and assignments are only granted when there is no local capacity to develop and commercialise the intellectual property competitively, in which case the licensee or assignee must undertake to make available to the licensor or assignor country products developed from the intellectual property, or which incorporate the intellectual property at affordable prices.[446]
6. Overseeing the exercise of march-in right and government-use right by the government when the need arises, and ensuring that exclusive licenses are only granted in exceptional cases.

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[442] Art 9(1) of the IPR Act.
[443] Art 9(4)(b) & (c) of the IPR Act.
[444] In South Africa for instance, the Technology and Human Resources for Industry Programme (THRIP) funding scheme is a partnership programme that is funded by the Department of Trade and Industry and managed by the National Research Foundation. THRIP promotes partnerships in pre-commercial research between business and research institutions, including universities and supports Science, Engineering and Technology research collaboration on a cost-sharing basis with industry and is focused on addressing the technology needs of the participating firms http://www0.sun.ac.za/research/thrip (accessed 28 August 2014); https://www.thedti.gov.za/financial_assistance/financial_incentive.jsp?id=52&subthemeid=1 (accessed 28 August 2014).
[445] Art 9(4)(c) of the IPR Act.
[446] Art 12 of the IPR Act.

5.4.2 Choice with respect to intellectual property ownership

Earlier chapters of this research discussed different models of ownership of intellectual property emanating from publicly financed research, namely: the United States Bayh-Dole model;[447] the Swedish professor's privilege;[448] and the UK hybrid model[449] where both the university or the intellectual property creator can retain title, with each of these models presenting its own merits and demerits. One of the underlying commonalities of these different models was that there is a need for a uniform system, policy or law in this area for purposes of certainty and clarity. Another regularly occurring feature in these different models was that ownership over intellectual property emanating from publicly financed research is not retained by the government.

Given that researchers sometimes come and leave institutions, for purposes of sustainability, continuity and better follow-up, retention of title by the recipient, appears to be the preferred option. Retention of title by the research institution, instead of the individual intellectual property creator, also implies that the third mission of seeking the application and commercialisation of technologies developed by the institution lies with the institution, which presumably has a greater capacity to do so than an individual inventor. In addition, in all countries examined, regulations providing for retention of title by the research institution always provide some reward for the inventor and even their inclusion in the commercialisation process with industry.

Another important and related aspect of intellectual property ownership that legislation should guard against relates to compelling recipients of public funding who develop innovative technologies to seek intellectual property protection over all new technologies they develop. This is because while intellectual property protection may be important in some cases, it may not be important in other cases. Hence, recipients should be allowed to freely elect whether or not to seek intellectual property protection, particularly when doing so may run counter to their primary mission of promoting research, sharing and disseminating knowledge and promoting

[447] Chapter 2 above.
[448] Chapter 3 above.
[449] Chapter 3 above.

access. This choice may also be important where the invention or innovation has limited commercial potential, but significant potential as a research platform for ongoing innovation. When the institution decides not to seek intellectual property rights, the individual inventor may be given the option to seek protection and to retain title over the intellectual property if she or he is convinced there is commercial potential and that derogation from the research institution's primary mission will be minimal. In such a case the research institution should still support and assist the intellectual property creator in securing intellectual property protection and commercialisation.

Where both the research institution and the intellectual property creator elect not to protect and retain title to the intellectual property, this should be communicated to the office responsible for oversight. This authority should review the intellectual property creation, taking into account the state of international research in the relevant field and the fact that while the intellectual property may not seem commercially viable in the local market, it may have significant value for the international market. Were this to be the case, the intellectual property can be protected and licenced to such foreign entities under the condition that products developed from or incorporating such technology must be made available to the country of origin and other resource constrained countries at reasonable prices,[450] particularly when this involves pharmaceuticals.

In some instances, even though a university may not be willing to seek protection over its intellectual property, it may be necessary to do so 'defensively', not to ultimately exclude access to the technology and competition, but rather to prevent third parties from seeking protection over the same technology, obtaining monopoly rights and excluding others from exploiting the particular technology. In particular, universities might want to preserve access to upstream and platform technologies for research. When the universities do engage in defensive patenting, they could

[450] Reasonable pricing in this context may be understood to mean a price at which the licensee who may be the distributor, the seller and or the manufacturer makes minimal profits. This may also mean pricing that does not include royalties payable by the licensee to the licensor. The latter may be achieved for instance by the licensor deferring payment of royalties for products developed from or incorporating the licensed technology when the products are meant to be sold in least developed and some developing countries.

promote access by granting licences of right and designating the same on the patents themselves.

Whatever the case, the intellectual property creator should be involved in all transactions relating to the technology she or he has developed. No matter to whom the technology is eventually licenced for translation and commercialisation, the intellectual property creator, the university concerned, other universities and research institutions involved in government-funded research projects should automatically be granted an irrevocable, royalty-free licence to use the intellectual property for scientific, academic and other non-commercial or even commercial research purposes depending on the terms of the licensing agreement.

Another provision that countries might include in their regulations on publicly financed research is that foreign applicants of intellectual property on products or services that are developed from or which incorporate intellectual property originating from publicly financed research should declare this fact, and such products and services must be provided at prices lower than they would otherwise have been offered for sale. In this regard, it may be appropriate to require licensees to provide information on their research and development costs so that recoupment and return on investment might be more accurately measured.

Clearly, there is no perfect model. Therefore, while retention of title by recipients of public funds may in most cases be the preferred option, there may well be cases which warrant that the intellectual property creator, or perhaps even government retains title. National laws should therefore be flexible enough to accommodate such instances.

5.4.3 Freedom to contract as a means to offset strong intellectual property rights

Patent licensing contracts offer public research institutions the opportunity to 'reclaim the space for public health policy that has been eroded by the strength of international patent law'.[451] This is because a technology licensing contract provides an opportunity for the parties to the contract, in this case universities and private

[451] Evans (n 415 above) 197 - 200.

industries, to each set their goals and priorities and negotiate while taking these into account. Unlike patenting where very limited derogations are allowed, in a contract, parties have the opportunity to implement their reasonable expectations and can negotiate mutually satisfactory terms. Public research institutions can therefore, in technology transfer contracts, include provisions that will offset strong intellectual property rights and promote social and economic welfare like access to products developed from publicly funded research at affordable or reasonable prices,[452] and the mutual benefit for producers and users of such technologies.[453] In addition, when a university negotiates with private industry for the development of a product, the dynamics of the situation change dramatically as the freedom to contract and draft the terms of the agreement provides an opportunity to address the conflict between the interests of the research institution in the broad dissemination of knowledge and those of the business partner in recouping the costs of development and manufacture. In other words:[454]

> …, the process of offer and acceptance involves the *quid pro quo* of contract law and the final consensus of the parties *ad idem*. When they are "of one mind," [this is because], intellectual property law becomes the background against which the parties negotiate and no longer the dominant factor in negotiations. Instead, the business deal becomes the dominant factor of negotiation. Whereas the [intellectual] property right is structured to provide an incentive to the investor [i.e. the industry partner], the licensing contract is designed to meet the expectations of the parties.

Given this flexibility, the contract therefore provides a structure against which the core values of research institutions can be protected. The core values of promoting research; maximising rights of access to knowledge; and ensuring widespread,

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[452] To achieve this, the licensor can demand less or no royalties for products manufactured for sale in least developed and some developing countries.

[453] P Drahos 'Doing Deals with Al Capone: Paying Protection Money for Intellectual Property in the Global Knowledge Economy' in PK Yu (ed) *Intellectual property and information world: Issues and practices in the digital age* (2007) 150); in addition, according to art 7 of the TRIPS Agreement; '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.'
In addition art 8 provides that; 'Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.'

[454] Evans (n 415 above) 197 - 200.

affordable, and equitable use can be effectively upheld.[455] When negotiating technology transfer licensing contracts, provisions that promote and favour access and the unrestricted dissemination of research can be included into the licence agreement.[456] Some of these may include provisions aimed at preventing an exclusive licensee from abusing his dominant position in the market,[457] and provisions allowing the development of dependent technologies. By exploring business models that contain alternative arrangements, private and public partners are able to experiment with alternative solutions to access problems. For instance, the parties might agree to place certain inventions in the public domain, or to create mechanisms for sharing the results and exploitation of research.[458] On another level, particularly where the intellectual property is licenced to industries abroad, parties may agree to adapt the product developed from publicly funded research to a particular market. For instance, a licence agreement may require the licensee to develop tablet or pill forms of medicines originating from or incorporating the technology that will not require refrigeration, if the original medicines developed are in a form that require refrigeration, for developing and least developed country markets where procurement, distribution chains, and households may not be properly equipped to store and distribute the medicines in its original form.[459] Therefore, licensing approaches can vary from case to case depending on circumstances peculiar to each specific invention, the business opportunity, the licensee and the university.

Another possible advantage the licensor has in a contract is that she or he can regain the patent either by revoking the licence or not renewing it when the contract comes to an end if the product is not commercialised, or if some of the terms of the licensing agreement are not being respected by the licensee. Furthermore, the licensor can include provisions in the licence agreement that will enable her or him to control the extent and manner in which the invention is being exploited.[460] For

[455] Drahos (n 453 above).
[456] Arts 7 & 8 of the TRIPS Agreement; Evans (n 415 above) 197 - 200.
[457] Examples of precluded anti-competitive practices include: price fixing of products incorporating the technology being licenced; preclusion from dealing with certain enterprises; cross licensing and patent pooling. WIPO *Exchanging value: negotiating technology licensing agreements: a training manual* (2005) 73.
[458] Busang & Wolson (n 185 above).
[459] WIPO (n 457 above) 19.
[460] As above.

instance, the licensor can in a licence contract limit the exploitation of the intellectual property to a specific field of use; or limit production and distribution only to certain geographic territories.[461] With such restrictions in place, the licensor can for instance grant a second licence to a third party on the same intellectual property for a use different from that of the first licensee when the technology has more than one application, or grant a second licence to a third party for the same use but in a geographic area where the first licensee does not intend to or is not permitted to commercialise the intellectual property under the licence agreement.[462] Moreover, parties can insert performance milestones in the licence contract, and an exclusive licensee might, under the contract, be required to prosecute the patent and to be responsible for litigation.[463]

The research institution can also negotiate to obtain co-ownership or a free licence over rights to improvements made by the licensee particularly when the licence contract involves early stage research or has a research component.[464] The rationale for this is that the licensee may not have been able to develop such an improvement had she or he not had access to the licensor's technology in the first place. Such a provision will grant access to improvements for research, certain commercial and or non-commercial uses (depending on the licence agreement) to the research institution. It should be noted that the licensee may also require the licensor to licence (on an exclusive or non-exclusive basis depending on the original licence agreement) all improvements made to the original technology that was licensed to the licensee. The idea here is that the licensee should have access to improvements held by the licensor that will enable her or him to better exploit the technology obtained from the licensor.

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[461] T Nanayakkara 'Negotiating technology licensing agreements' International Trade Centre Trade Forum nd http://www.tradeforum.org/Negotiating-Technology-Licensing-Agreements/ (accessed 19 November 2014).
[462] WIPO (n 457 above) 48 - 53.
[463] As above.
[464] Improvements here may be understood to mean '… a development within the field of the licensed technology that enhances the usability, functionality, efficiency, performance or other characteristic of the original technology.' DM Cameron & R Borenstein 'Key aspects of IP licensing agreements' 12 December 2003 http://www.jurisdiction.com/lic101.pdf 21 (accessed 10 August 2014); B Bai (2008) 'Avoiding IP licensing pitfalls in China' 20 February 2008 http://www.us-china-cerc.org/pdfs/Avoid_Lic_Pitfalls_China_BAI.pdf (accessed 10 August 2014).

It is therefore important to address each party's rights to improvements in the technology licence agreement because depending on the technology, such improvements may render the originally licensed technology obsolete.[465] The first step is usually for the licence agreement to include a provision that parties will notify each other as soon as possible of all improvements made to the original intellectual property.[466]

5.4.4 Licensing publicly financed research

As discussed earlier, the monopoly rent frequently required by private industries to invest in the translation and application of technologies developed by research institutions into pharmaceutical products is secured through the granting of a licence by the intellectual property right holder (the research institution) to industry, the latter always preferring exclusive licences. Given the private interest inclination of industries and the public interest mission of research institutions, conflicts of interests are likely to arise.[467] TTOs which are the pillars of technology transfer from universities to industry must therefore, in a bid to meet the legitimate commercial needs of private industries and the public interest mission of universities, adopt strategic licensing techniques that meet the interests of both parties. The following paragraphs discuss some licensing approaches.

Exclusive licences

Through legislation, recipients should be precluded from granting overly broad exclusive licences which may give industry the rights to exclude and prevent all other possible commercial and or non-commercial exploitation of the patent. At the same time, recipients should guard against impairing the legitimate business interest of the licensee.[468]

As a general rule, universities should be mandated to only grant exclusive rights when they are convinced that commercial exploitation of a particular technology cannot be guaranteed through a non-exclusive licence. Were this to be the case,

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[465] http://www.shenlaw.com/en/pat_lic_impr.htm (accessed 10 August 2014).
[466] http://www.shenlaw.com/en/pat_lic_impr.htm (accessed 10 August 2014).
[467] T Caulfield *et al* 'Open science versus commercialization: a modern research conflict' (2012) 4 *Genome Medicines* 6.
[468] Evans (n 415 above) 201.

TTOs must grant exclusive licences instead of assignments to industry partners to secure translation and commercialisation of technologies developed from publicly funded research. This is because an assignment grants the assignee the rights to exclude all others, including the assignor from exploiting the intellectual property. Meanwhile, in an exclusive licence, parties can negotiate and agree that the licensor and third parties retain rights to exploit the intellectual property for research, educational, experimental, non-commercial, and even some commercial uses as long as this does not pose any commercial risks to the legitimate interest of the exclusive licensee.[469] The aim here is to ensure that scholars from other research institutions are still able to exploit the intellectual property for research purposes without concerns over patent infringement, and scientists are still able to publish the results of their research in theses and journals.[470]

The exclusive licence may contain provisions that the licensor will not grant third parties the right to develop and commercialise like products provided the licensee complies with all the terms and conditions of the licence agreement as determined by the licensor.[471] It should be noted that the above proposed legislative provisions will be useless if TTOs do not implement them or fail to do so appropriately. Hence, without trying to reinvent the wheel, experiences of other countries should inform the way TTOs deal with industry in licence negotiations. For instance, TTOs must in licensing negotiations with industry, be mindful of a number of facts, including that a particular technology may possess several different important uses not known to the

[469] According to Evans, research and experimental use may be defined to mean, the right: '… to practice inventions and to use associated information and data for research and educational purposes, including research sponsored by commercial entities; and to transfer tangible research materials (such as biological materials and chemical compounds) and intangible materials (such as databases and know-how) to others in the non-profit and governmental sectors'. Evans further notes that such a reservation clause should include a definition of non-commercial use, to mean: 'The [research institution] reserves the rights, for itself and others, to i) make and use, solely for Non-Commercial Research Purposes, the subject matter described and claimed in patent rights and covered by property rights; and ii) provide to others the Biological Materials; each solely for Non-Commercial Research Purposes. As used herein, the term "Non-Commercial Research Purposes" means: Use of patent rights for academic research or other not for-profit or scholarly purposes which are undertaken at a non-profit or governmental institution that does not use patent rights in the production or manufacture of products for sale or the performance of services for a fee.' Evans (n 415 above) 211 - 212; AUTM 'In the public interest: Nine points to consider in licensing university technology' 09 March 2007 http://www.autm.net/Nine_Points_to_Consider1.htm (accessed 24 May 2014).
[470] AUTM (n 469 above).
[471] WIPO (n 457 above) 48.

parties at the time of the licence negotiations.[472] Hence, license agreements should clearly specify the intellectual property being licensed, as well as limit the use of the intellectual property strictly to that contemplated by the parties.

To address situations like failure to perform, technology transfer officers should strive to ensure that licence agreements specify the efforts that the licensee will have to make to develop and commercialise the technology being licensed and explicitly grant only those rights that are necessary to encourage the development of a particular technology.[473] In addition, technology transfer officers should employ approaches that balance a licensee's legitimate commercial needs against the university's overall educational, charitable and public interest mission of ensuring a broad practical application of the fruits of its research.[474] Examples of exclusive licences that would still promote access are discussed below.

Co-exclusive licence

A co-exclusive licence is an exclusive licence granted to a small and limited number of licensees, (say two) instead of a single one, to allow competitive product optimisation among the small group.[475] Such a licensing approach encourages the two licensees to compete to achieve product development and market penetration or to develop better products than existing ones.[476] In addition, such a licence approach reduces delays often associated with exclusive licences where failure to develop a product may sometimes require the licensor to terminate the licence and negotiate a new one with another industry partner.[477]

Hybrid licence

This is a licence agreement in which, in a bid to secure access to products developed from publicly funded research, the licensor within the same licence agreement includes terms granting some rights on an exclusive basis and others on a non-exclusive basis.[478] Conditions are also included which if violated will grant the

[472] Evans (n 415 above) 201.
[473] As above.
[474] As above.
[475] AUTM (n 469 above).
[476] As above.
[477] As above.
[478] AUTM (n 469 above) 13.

licensor the right to authorise third parties to fulfil obligations not fulfilled by the initial exclusive licensee. Such a licensing approach accommodates a variety of business models.[479] Examples of hybrid licensing agreements that TTOs in African countries may explore include: convertible exclusive licences; or a non-exclusive provision. These examples are discussed below.

A convertible exclusive licence refers to an exclusive licence agreement in which the licensor retains the rights to grant an exclusive licence, a co-exclusive licence, or a non-exclusive licence to a third party (or third parties) authorising them to develop products not yet made available by the initial exclusive licensee, after the latter has been given an opportunity to develop and market the product within a limited timeframe and has failed to do so.[480] A convertible exclusive licence may also take the form of a licence agreement in which the licensee is granted an exclusive licence subject to defeasance, in whole or in part, triggered by other performance shortfalls on the part of the licensee. These may include failure to meet performance or distribution requirements. These performance requirements could be extended to include provisions on affordability and equitable access to pharmaceutical products, developed out of or which incorporate the licensed technology, in developing and least-developed countries.[481] If triggered, defeasance may take one of several forms, namely, the conversion of the licence agreement from an exclusive one to a non-exclusive one or even total exclusion from the licence agreement.[482] A claw-back clause may also be used to remedy the licensee's failure to meet minimum net sales requirements or in respect of any performance requirements relating to drug development, distribution, affordability and access in resource constrained countries.[483]

A non-exclusive provision refers to an exclusive licence agreement in which both parties agree that the licensor retains the right to authorise third parties to develop

[479] Evans (n 415 above) 201 - 203.
[480] Evans (n 415 above) 202.
[481] This may include tiered pricing models like the licensor exempting the licensee from paying royalties on goods sold in least developed and some developing country markets; and or the licensor negotiating for the sale of the products at cost in least developed and developing countries. C Mimura 'Nuanced management of IP rights: Shaping industry-university relationship to promote social impact' 15 July 2009 http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1434545 (accessed 09 December 2014); Busang & Wolson (n 185 above).
[482] Evans (n 415 above).
[483] Evans (n 415 above) 202.

and commercialise the technology or like products in exchange for a reduction in royalties or on previously agreed remedies.[484] Such a licence arrangement may be important when the licensor for instance needs a new process for use in a new geographical area and can identify a manufacturing industry in that geographical area.[485]

Non-exclusive licences

Technologies developed by research institutions may sometimes be very advanced, presenting limited risks and high chances of commercial success to the extent that two or more industries may be interested in obtaining non-exclusive licences to develop and commercialise the technology. Therefore, taking into account the maturity of the technology being licensed, TTOs should also consider non-exclusive licences.[486]

5.4.5 Targeted research funding

For purposes of this research, targeted research funding is seen as the practice where government funds research in a specific area identified as being a priority at that point in time. This is common in both developed and developing countries. In the United States for instance in 1998, the National Institute of Dental Research and the National Institute of Allergy and Infectious Diseases introduced the Targeted Research on Oral Microbial Biofilms to fund basic research into microbial oral biofilms, particularly in the areas of antimicrobial resistance, gene transfer, and host defence to improve strategies to diagnose, prevent and treat biofilm-associated infectious diseases in the oral cavity.[487] In Australia the Targeted Research Fund, run by the Department of Health, provides funding for research projects that focus on the capacity of Western Australia Health to address significant issues that impact on the health of the population of Western Australia.[488] Both government-run targeted research funding programmes were or are directed towards specific priority health

[484] As above.
[485] As above.
[486] Evans (n 415 above) 201.
[487] National Institute of Health 'Targeted research on oral microbial biofilms' 21 July 1998 http://grants.nih.gov/grants/guide/rfa-files/RFA-DE-98-006.html (accessed 22 February 2014).
[488] http://www.healthinfonet.ecu.edu.au/uploads/funding/258_trf_application_pack.pdf (accessed 22 February 2014).

problems that the government deemed or deems important at a particular point in time.

Apart from governments, public institutional donors[489] and private foundations[490] also fund targeted non-profit biomedical R&D. For instance, the DNDi[491] is currently working on developing new treatments for neglected diseases like Leishmaniasis, human African trypanosomiasis, Chagas disease, malaria, filarial diseases and paediatric HIV.[492]

In a similar way, governments of Sub-Saharan African countries where neglected diseases are prevalent can either independently, (as is the case in Kenya with the Kenyan Medical Research Institute),[493] or through sub-Regional Economic Communities (RECs) jointly pool financial, human and other resources to fund targeted biomedical R&D into therapies and vaccines against diseases prevalent in their regions. While some countries can independently do this at the national level, sub-RECs could be more appropriate in some cases to avoid duplication, and also because some countries are currently politically unstable or lack the requisite research capacity.[494] For this to be effective, the numerous challenges faced by African research institutions and universities would have to be addressed. Some of these challenges include:[495]

1. Lack of, or inadequate basic infrastructure needed for health and biomedical research.
2. Poor research management, governance and support services.
3. Inadequate human resources.

[489] Like the Department for International Development in the United Kingdom among several others http://www.dndi.org/donors/donors.html#Private%20Foundations%20&%20Private%20Individual%20Donors for a full list (accessed 22 February 2014).
[490] Like the Bill & Melinda Gates Foundation and the Rockefeller Foundation among several others. http://www.dndi.org/donors/donors.html#Private%20Foundations%20&%20Private%20Individual%20Donors (accessed 22 February 2014).
[491] The DNDi is a collaborative, patients' needs-driven, non-profit drug R&D organisation that is developing new treatments for neglected diseases.
[492] http://www.dndi.org/about-us/overview-dndi.html (accessed 22 February 2014).
[493] http://www.kemri-wellcome.org/index.php/en/about (accessed 21 May 2014).
[494] At present, politically unstable countries in the sub-continent include: Burkina Faso, Burundi, Chad, Central African Republic, Democratic Republic of Congo, Libya, Mali, Somalia, and South Sudan.
[495] Marjanovic *et al* 'Research capacity building in Africa: Networks, institutions and local ownership' A joint Rand Europe/ESRC Innogen Centre working paper 3 and 16 13 February 2012 http://www.rand.org/pubs/external_publications/EP20121302.html (accessed 13 October 2013) 17.

4. Over burdening of lead researchers with administrative and management roles and responsibilities which impact on their ability to be involved in research.
5. Poor laboratory and information and communication technology infrastructure.
6. Limited funding and poor monitoring and evaluation procedures.

Some of the measures which have been proposed to address these challenges include the following: [496]

1. Identifying a few African research institutions which already have good research management and governance procedures and processes in place.
2. Establishing some form of collaboration between the latter institutions and those with little or no such procedures and processes for purposes of capacity building and sharing across research institutions.
3. Providing research management training to staff across the network of research institutions.
4. Prioritisation of research projects that will provide long-term local benefits like those requiring the building of physical infrastructure such as information and telecommunication technology facilities, installation of equipment and other laboratory facilities as these will have long-term benefits to the research institutions.

Furthermore, given the cost, infrastructure and human resources that such a programme would entail and the fact that some countries may not be able to single-handedly and within reasonable timelines achieve set goals, having a pool of researchers from different countries belonging to a REC may provide the critical mass of researchers and infrastructure needed to achieve this. University researchers and young graduates from the RECs are important human resources for basic and applied biomedical R&D in targeted neglected diseases identified as priority health problems. Government funding and support and the fact that this research is conducted at research institutions will guarantee the sustainability of such an endeavour and may also attract international donor funding.

[496] Marjanovic *et al* (n 495 above) 19.

It should be noted that funding R&D into the major diseases that disproportionately affect people living in Sub-Saharan Africa is sometimes difficult due to budget constraints and the fact that most of these countries are faced with several different competing national priorities. To meet this challenge, governments will have to prioritise and properly plan the allocation of funding for specific biomedical research projects. They must also put in place effective monitoring and evaluation mechanisms to guard against wasting limited resources. Private foundations, individuals and other charity organisations could be interested in funding some of these targeted biomedical research projects once they have been launched.

5.4.6 Promoting research in traditional knowledge-based medicines

According to the WHO, about 80% of people living in Sub-Saharan Africa rely on traditional medicine to meet their primary healthcare needs. Traditional medicines here refer to: [497]

> … the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.

Although the degree of reliance on these forms of medicines varies from country to country,[498] the bottom line is that traditional knowledge-based formulations developed from plant biodiversity are sometimes the first primary healthcare option for a good number people in Sub-Saharan Africa.

The potential for the existence of effective therapies in plant biodiversity lies in the fact that a good number of therapies developed by pharmaceutical companies are derived from plant sources.[499] Furthermore, Metrafaids, an HIV-treatment formulation developed by a group of African traditional knowledge holders, is an example of

[497] WHO 'Essential medicines and health products' nd http://www.who.int/medicines/areas/traditional/definitions/en/ (accessed 15 November 2014).
[498] According to the WHO, in Burundi and Ethiopia for instance, it is estimated that 90% of the population relies on traditional forms of medicine to meet their primary healthcare needs. In Burkina Faso, the Democratic Republic of Congo and South Africa the level of reliance on these forms of medicine is estimated to be 80%. Benin, Cote d'Ivoire, Ghana, Mali and Rwanda register a 70%, while Tanzania and Uganda register a 60% reliance on these forms of medicine. WHO (2010) 'Guidelines for registration of traditional medicines in the WHO African region' xi.
[499] SMK Rates 'Plants as a source of drugs' (2001) 39 *Toxicon* 603; J Gwynn & PJ Highlands 'Plants as a source of new medicines' (2000) 10 *Drug Discovery World* 54.

scientifically tested traditional medicine for HIV/AIDS treatments which seems to have potential in the treatment of HIV/AIDS.[500]

Funded by the Ford Foundation to the tune of $2 million,[501] clinical trials for Metrafaids were conducted between 1999 and 2002 at the Center for Experimental Traditional Medicine in Senegal under international scientific standards using NIH protocols and laboratory testing conducted by Institute Pasteur and Lab Corporation.[502] The formulation produced significant clinical and laboratory improvements, as over half of the patient population in a study, (54%) registered a viral load decrease of greater than 66%, while 44 patients (71%) registered increased CD4 counts by up to 70% during the trial. Opportunistic infections like dermatosis, weight and clinical symptoms were also improved in 85% of the patients. No adverse reactions were observed throughout the study and the study results were constantly reviewed by an international ethical and scientific committee.[503] Although there is no publicly available information as to whether this therapy has ever been verified as safe and efficacious in rigorous Phase I, II, and III clinical trials, and consequently on whether it has been registered for use as a medicine anywhere, it suffices to say that there may be value in considering and exploring the role of African traditional medicines in addressing some of the health problems faced by the sub-continent, provided that these go through Phase I, II and III clinical trials to determine their safety, efficacy and quality before they are introduced into the market.

In spite of the non-negligible reliance on traditional medicines developed from plants, national authorities in most African countries have made little or no effort to regulate this sector to ensure the safety, efficacy and quality of medicines marketed and

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[500] K Obom-Egbulem 'Another look at African roots and herbs' 01 March 2006 http://www.nigeria-aids.org/news/content.cfm?184 (accessed 11 March 2013).
[501] In this clinical trial, three cohorts of HIV-positive individuals (total of 62 patients) were followed for six months. CD4 counts and viral loads were monitored on a monthly basis while patients received an African traditional formulation. Metrafaids 'Manufacturers study nest phase of African anti-AIDS drug' 26 May 2003 http://www.panapress.com/Manufacturers-study-next-phase-of-African-anti-AiDS-drug--12-483106-66-lang2-index.html (accessed 24 May 2014); A Thom 'African herbal medicine is beating AIDS' 16 July 2002 http://www.health-e.org.za/2002/07/16/african-herbal-medicine-is-beating-aids/ (accessed 24 May 2014).
[502] Metrafaids (n 501 above); Thom (n 501 above).
[503] For information on other traditional knowledge-based therapies which may also not have been registered for use in any country yet G Bodeker & G Burford *Traditional, complementary and alternative medicine policy and public health perspectives* (2007) 281.

widely consumed by the populace.[504] For instance, producers of traditional medicines are not required to submit their products to national market regulatory authorities for purposes of testing their safety, efficacy and quality before they are introduced into the market.[505] As a result, it is not uncommon to find fake and unhealthy concoctions being offered for sale under the guise that they are based on traditional medicine. Some of these unlicensed products pose severe health risks to consumers.[506]

Another major challenge faced by traditional knowledge holders and consumers of traditional knowledge-based remedies relates to the storage of these formulations, which are mostly in liquid form. Although this could form the basis of interesting research topics for students in the medical and or biotechnology fields, general government neglect and non-recognition of this sector has resulted in a lack of funding. This has led to little or no interest on the part of researchers to investigate the possibility of optimising and perhaps converting these liquid formulations into tablets or powder form which can be encapsulated to ensure a longer shelf life.

To address the above challenges, there is a need for a change of mind sets at government level and at research institutions. Such a change can encourage the former to fund research into the properties of plants used to develop formulations for the treatment of specific ailments and for their optimisation, particularly where these options are cheaper, and for the universities to appreciate and initiate research into traditional knowledge plant-based medicines. Although this may be expensive and challenging, even for users of these forms of therapies, the value added of ensuring that only traditional medicines with proven safety, efficacy and quality enter the market is non-negotiable. Given that such research will be funded by government, price reductions and affordability may be addressed in the research contracts between the traditional knowledge holders, universities and industries that establish such research collaborations.

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[504] So far, Nigeria, Mali, Ghana, Uganda, Zambia, Zimbabwe are the only countries that have made important strides in the regulation of traditional medicine, and have put in place legislative measures to officially recognise and empower traditional medicine as part of the public healthcare delivery system. www.sahealthinfo.co.za/traditionalmeds/traditionalpart2.pdf (accessed 06 September 2014); SciDevNet 'Integrating modern and traditional medicine: facts and figures' 30 June 2010 http://www.scidev.net/global/disease/feature/integrating-modern-and-traditional-medicine-facts-and-figures.html (accessed 06 September 2014).

[505] www.sahealthinfo.co.za/traditionalmeds/traditionalpart2.pdf (accessed 06 September 2014).

[506] SciDevNet (n 504 above).

Furthermore, research institutions should be encouraged to partner with holders and practitioners of traditional knowledge on an equitable basis to gain access to the vast knowledge possessed by this group in strict compliance with national,[507] regional[508] and international laws[509] relating to biodiversity. Such partnerships will boost the value of traditional medicines and will also provide research institutions with important research opportunities for graduate students and scientific researchers whose research will have a direct bearing on people's lives. This may lead to the development of more affordable options to some of the medicines developed by pharmaceutical companies, ensuring better access. Traditional medicines are usually cost effective because they are based on readily available plants and may not need to go through several different phases of clinical trials to test their safety as this is sometimes already established through use from generation to generation.

5.4.7 Partnerships

University-industry partnerships

University-industry partnerships are very important for the translation of technologies developed at universities into tangible products. This is principally because most universities do not have the financial, human and infrastructural resources to engage in its translation into pharmaceutical products to address real-life problems, and must consequently transfer them to industry where these resources are available.

African countries considering legislation on publicly funded research should therefore encourage universities to seek partnerships with industry to ensure the translation of their research results into tangible products, particularly in the area of biopharmaceutical technology. Given that local pharmaceutical industries in Sub-Saharan African countries do not have the requisite skills, knowledge and equipment to appreciate the value of technologies developed by universities, university-industry partnerships could also be sought with foreign private industries.

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[507] Secs 83 - 84 of the South African National Environmental Management Biodiversity Act 10 of 2004; sec 3A - 3B of the South African Patents Amendment Act No. 20 of 2005.
[508] Preamble and secs 7 - 10 of the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore within the framework of the African Regional Intellectual Proper Office adopted on 09 August 2010.
[509] Art 8(j) of the Convention of Biological Diversity 1994; art 10 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Resources 2010.

However, whenever possible, government should also promote such partnerships with local private industries and provide tax breaks and other important benefits to local industries which partner with research institutions for technology transfer as an incentive.

University-university partnerships for research capacity building

In addition to university-industry partnerships, African universities should also seek university-university research partnerships with foreign universities. This is because in most cases, university research is primarily driven by curiosity and the quest to advance science.[510] It may thus be possible to find foreign university partners with advanced and sophisticated equipment to engage with in research into some of the diseases that disproportionately affect people living in developing countries generally and Sub-Saharan African countries in particular. In fact, the last quarter century has witnessed an increased transnational exchange of faculty scientists between publicly funded research institutions in developed and developing countries.[511] This transnational flow of faculty scientists has formed the basis for advanced knowledge and skills transfer; training of new faculty and healthcare service providers in underserved universities and better healthcare service delivery in resource constrained settings.[512] A case in point is the KEMRI-Wellcome Trust formally established in 1989 as a partnership between the Kenyan Medical Research Institute (KEMRI), Oxford University and the Wellcome Trust.[513] Given that these partnerships are across borders, and subject to differing laws which may sometimes

[510] Messer-Yaron (n 17 above) 8-12.
[511] S Dell 'International collaboration in African research – who wins?' *University World News* 07 February 2014.
[512] K Maitland *et al* 'Mortality after fluid bolus in African children with severe infection' (2011) 364 *The New England Journal of Medicines* 2483 - 2495; R Hoban *et al* 'Helping babies breathe' training in sub-Saharan Africa: educational impact and learner impressions' (2013) 59 *Journal of Tropical Paediatrics* 180 - 186.
[513] KEMRI conducts basic, epidemiological and clinical research, with results feeding directly into local and international health policy, with the aim of expanding Kenya's capacity to conduct multidisciplinary research that is strong, sustainable and internationally competitive. Strong community links are at the heart of the programme, with an emphasis on capacity building and training to build scientific leadership. For more information on the KEMRI-Wellcome Trust http://www.kemri-wellcome.org/index.php/en/about (accessed 21 May 2014). In 2014, a research group from the KEMRI-Welcome Trust identified new proteins from the malaria parasite that may be effective when used in combination in a malaria vaccine. Inclusion of these proteins may contribute to the development of highly effective malaria vaccines. FH Osier *et al* 'New antigens for a multicomponent blood-stage malaria vaccine' (2014) 6 *Science Translational Medicine* 247.

even work against the intended purpose and objectives of the institutions concerned, agreements and contracts under which these partnerships are created and sustained present an excellent opportunity for the parties to uphold the intended purpose and objectives of the partnerships in spite of the existence of such laws.

Furthermore, foreign universities may be interested in these research partnerships as research (particularly in the area of biopharmaceutical technology) sometimes leads to unanticipated yet exciting results even in science fields that may seem unrelated to the initial research project.[514] There is therefore a need for legislators to encourage and facilitate the creation of such partnerships, while strengthening existing ones. This will boost the research capacity of local research institutions, equip them and enable them to engage in research of high standards in the long term and possibly generate important intellectual property with marketable value to attract private industry investment in the biopharmaceutical technology industry to meet the healthcare needs of historically disadvantaged populations.

Although these partnerships are more about building a shared research capacity, partnering with universities in developed countries, which are more advanced in terms of engagement with industry and technology transfer, will put Sub-Saharan African universities in a better position to engage with local and international industry partners in technology transfer.

While collaboration with colleagues and research institutions from developed countries is important to boost the research capacity of African researchers and institutions, local researchers should guard against power imbalances in their collaborations with foreign researchers. Given that in most research collaborations involving researchers from developed countries the research is funded and led by researchers from developed countries, issues of unequal collaboration and diktat of the research agenda sometimes arise.[515] Often the values and objectives of the visiting researchers' research projects are different from that of their African research

[514] Viagra was originally developed as a possible treatment for heart conditions including high blood pressure and angina, a chest pain usually caused by narrowing of the arteries. http://circ.ahajournals.org/content/99/1/168.full (accessed 11 December 2014); JR Platt 'Federally funded research: The key to unexpected (and valuable) discoveries' 13 November 2013 http://www.todaysengineer.org/2013/Nov/Federally-Funded-Research.asp (accessed 15 May 2014).
[515] TT Edejer 'North-South research partnerships: The ethics of carrying out research in developing countries' (1999) 319 *British Medical Journal* 438 - 441.

counterparts, leading to inappropriate projects which are unrelated to local research needs, and conclusions that do not have any direct local benefit.[516] Furthermore, there are reports that some of these research collaborations sometimes disrupt the provision of local medical and educational services by taking already overworked healthcare service providers and researchers away from their clinical and teaching duties;[517] and the research is published by researchers from developed countries with little or no recognition of the contributions of their counterparts from developing countries.[518]

According to Kathryn Chu *et al*., the above reality gives rise to three major questions. The two most relevant to this research are: Firstly, how can African research institutions and physicians who participate in research benefit from international research collaborations without being exploited? Secondly, how can African scientists and governments co-ordinate the influx of academics from developed countries who view the continent as the next frontier in global health research?[519] Some of these challenges can be addressed through: (1) building research capacity among researchers from developing and least developed countries;[520] (2) regulating research collaboration to ensure that African researchers are involved in research agenda setting so that all approved research projects take into account national healthcare priorities by demonstrating mutual and equitable benefit for developed, developing and least developed country researcher(s) such as specific study objectives aligned with local health research priorities;[521] (3) establishing research ethics boards at African research institutions to monitor and co-ordinate research projects to ensure compliance and adherence to research ethics;[522] (4) sharing authorship and intellectual property ownership on research publications and other intellectual property that may arise from research collaborations;[523] and (5) wide

[516] I Wolffers *et al* 'Health research in the tropics' (1998) 351 *The Lancet* 1652 - 1654.
[517] Edejer (n 515 above); Wolffers *et al* (n 516 above).
[518] KM Chu *et al* 'Building research capacity in Africa: Equity and global health collaborations' (2014) 11 *PLoS Med* e1001612.
[519] As above.
[520] EJ Mills *et al* 'The financial cost of doctors emigrating from sub-Saharan Africa: human capital analysis' (2011) 343 *British Medical Journal* 2; EJ Mills *et al* 'Should active recruitment of health workers from sub-Saharan Africa be viewed as a crime?' (2008) 371 *Lancet* 685 - 88; Chu *et al* (n 518 above).
[521] J Trostle 'Research capacity building in international health: Definitions, evaluations and strategies for success' (1992) 35 *Social Science & Medicine* 1321 - 1324; *Chu et al* (n 479 above).
[522] Chu *et al* (n 518 above).
[523] As above.

dissemination of research results by local researchers in African countries where research is conducted to inform healthcare policy making and for broader access to the information for other researchers.[524]

Public-private partnerships

Public-private partnership refers to any research collaboration between public and private sector entities which jointly plan and execute activities with the view to accomplishing agreed objectives while sharing costs, risks and benefits incurred in the process.[525] In the context of biomedical research, product development partnerships, a class of public-private partnerships, are geared towards accelerating R&D in pharmaceutical products such as vaccines, microbicides, as well as treatments for otherwise neglected diseases prevalent in underserved populations that private industries are not interested in because they are unprofitable. Such partnerships may also entail a plan for access and availability of the products developed to those in need.[526] These partnerships are usually between pharmaceutical companies and international charitable foundations and organisations where funding is provided by the charitable organisation for research and product development for diseases prevalent in developing countries. In return, pharmaceutical industry partners allow the use of their intellectual property rights for specific markets. A few examples of public-private partnerships are discussed below.

PATH Malaria Vaccine Initiative

This public-private partnership is a global programme of the international non-profit organisation known as PATH. This partnership was established in 1999 through a grant from the Bill and Melinda Gates Foundation and seeks to accelerate the development of malaria vaccines and catalyse timely access to the vaccine in endemic countries.[527]

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[524] As above.
[525] DJ Spielman & K Von Grebmer, 'Public-private partnerships in international agricultural research' International Food Policy Research Institute 15 January 2004 http://www.ifpri.org/publication/public-private-partnerships-agricultural-research (accessed 15 August 2014).
[526] The PATH Malaria Vaccine Initiative for instance aims to accelerate the development of malaria vaccines and catalyse their timely access in endemic countries http://www.malariavaccine.org/about-overview.php (accessed 20 August 2014).
[527] As above.

Drug for Neglected Diseases Initiative

The DNDi is a collaborative, patients' needs-driven, non-profit drug R&D organisation that is developing new treatments for neglected diseases such as human African trypanosomiasis (sleeping sickness), visceral Leishmaniasis (kala-azar), and Chagas disease, to improve the quality of life and the health of people suffering from these neglected diseases to ensure equitable access to new and field-relevant health tools.[528] The DNDi's model is driven by the public sector, where a variety of players collaborate to raise awareness on the need for R&D and medicines for diseases that fall outside the scope of market-driven R&D.[529] The DNDi also develops new drugs, or new formulations of existing drugs, for patients suffering from the most neglected communicable diseases, and bridges existing R&D gaps by initiating and co-ordinating R&D projects in collaboration with the international research community, the public sector, the pharmaceutical industry and other relevant partners.[530] Other such public development partnerships include: the Aeras Global TB Vaccine Foundation; the Global Alliance for Vaccines and Immunisation;[531] the International AIDS Vaccine Initiative;[532] and the TB Alliance.[533]

5.4.8 Research-use right

Legislation on publicly funded research should provide for broad research-use exceptions to allow intellectual property creators and other research institutions equally involved in government-funded research to have free access to technologies developed from government-funded research for experimental, educational, and other non-commercial purposes. Given that patents prohibit third parties from making, using and selling the patented product or process, a research use exception should be broad enough to allow all research institutions in the country to freely use the protected intellectual property without unnecessary delays and formalities. In the specific context of biopharmaceutical technology where research is costly and spans over a long period of time, such a provision is particularly important as it will promote research collaboration between researchers from different research institutions. This

[528] http://www.dndi.org/about-us/overview-dndi/vision-mission.html (accessed 06 September 2014).
[529] (As above).
[530] (As above).
[531] http://www.gavi.org/ (accessed 06 September 2014).
[532] (As above).
[533] http://www.tballiance.org/ (accessed 06 September 2014).

will in turn curb unnecessary duplication of research and spending; prevent blocking and stagnation of research; and ensure that research actually moves forward.

5.4.9 Deliberate policy on reducing the import of medicines which can be manufactured locally

A protectionist policy which can be used by governments to secure long term sustainability for local pharmaceutical companies consists of progressively reducing the quantity of generic medicines being imported into the country when these can be produced locally. In Russia for instance, government has put in place measures to ensure that 70% of pharmaceutical products procured by the state are locally manufactured.[534] In Algeria and Tunisia, once a locally manufactured generic medicine is registered, the innovator is given two years within which to commence local production. This is followed by a ban on imports of the finished product so the market can solely be served by locally produced medicines.[535] While these strategies have been instrumental in the growth of private local pharmaceutical industries in these countries in addition to government owned laboratories, the market has seen the entry of a number of private sector players in the last ten years.[536] However, such restrictive policies can seriously backfire hence should be accompanied by direct support to industry to enable them to take advantage of the opportunity. It should also be noted that these local content and local production rules might result in retaliation by major economic powers under existing trade agreements. Such agreements often place restrictions on local content, local manufacturing and local procurement rules. Hence protectionist policies should be carefully weighed and balanced against any international restrictions before being implemented.

5.4.10 Innovation prizes

Apart from the grant of twenty years' monopoly, there are other ways of incentivising and promoting innovation that delink the cost of R&D from the price of products developed. One such incentive is an innovation prize. Innovation prizes, an idea currently spearheaded by James Love of Knowledge Ecology International,[537]

[534] AUC-UNIDO Partnership 'Pharmaceutical manufacturing plan for Africa-business plan' (2012) 40.
[535] AUC-UNIDO (n 495 above) 41.
[536] As above.
[537] T Rosenberg 'Prizes with an eye towards the future' *The New York Times* 29 February 2012.

consists of granting prizes to intellectual property creators and technology developers for their intellectual property creations and innovations. Once the prizes have been offered, the technology or intellectual property can then be made available to the public for commercial and non-commercial exploitation in lieu of granting twenty years' intellectual property protection. The use of innovation prizes dates to centuries ago. These were used by governments, corporations and non-profit organisations to reward innovation.[538] Apart from presenting an important alternative to intellectual property-enforced monopolies, innovation prizes would promote greater access to new technologies.[539] Several examples of the use of innovation prizes in recent years abound.

For instance, in September 2009, in his Strategy for American Innovation, the United States President called on government agencies to increase their ability to promote innovation by using tools such as prizes and challenges to solve tough problems faced by the United States.[540] In 2011 the president signed legislation granting federal and state agencies broad authority to conduct prize competitions to stimulate innovation to address technical and scientific challenges among others.[541]

In Burkina Faso, the Forum Nationale de la Recherche Scientifique et des Innovations Technologiques, which includes the Ministry of Education and the Ministry of Trade and Commerce, manages innovation prizes. The Grand Prize is awarded for a technical work, such as a process that highly contributes to the development objectives in the health, demography, energy and food sectors.[542]

In Bavaria, the regional government in 2004 established the GALILEO European Satellite Navigation Competition offering €10 000 annually for the best idea in satellite navigation technology as judged by a committee of 80 experts. Following this, private companies offered additional 'special topic' prizes for specific satellite-

[538] Innovation prizes consist of offering a once-off prize to reward innovation with the primary goal of stimulating innovation to address a particular problem. Knowledge Ecology International 'Selected innovation prizes and reward programs' nd 3 - 4 http://www.keionline.org/misc-docs/research_notes/kei_rn_2008_1.pdf (accessed 10 July 2014).
[539] (As above).
[540] https://challenge.gov/p/about (accessed 10 July 2014).
[541] (As above). Other innovation prize awards in the US include the Wearable Power Prize 2007; The Clear Prize for faster airport security technology 2007. Knowledge Ecology International (n 538 above) 3 - 4.
[542] Knowledge Ecology International (n 538 above) 3 - 4.

related problems.[543] Several such examples exist in different countries in different parts of the world.

While providing an alternative to the current intellectual property rights protection regime, innovation prizes can also promote competition among researchers for recognition and awards as some researchers (particularly in public research institutions) are not primarily driven by the desire to own intellectual property, but by the zeal to make a contribution in research, and to be recognised for that.[544]

5.4.11 Reporting

Reporting on intellectual property created from publicly funded research and on its potential benefit to society is crucial. Firstly, it notifies government of intellectual property created from research it has funded. Secondly, it provides information on how the intellectual property can be applied to solve real-life problems and the measures that research institutions intend to put in place, or have put in place, to ensure the translation of such research and its practical application. Thirdly, through reporting, the relevant funding agency or ministry is notified of technologies developed from government-funded research over which government can exercise government-use or march-in rights to address any health, security or national emergency situations that may arise. Reporting is also a form of accountability on the part of research institutions to taxpayers and the government. Again, through reporting, government-funded technologies upon which other researchers may rely for follow-on research, educational and experimental uses are made known to the government and other researchers. This creates synergies among researchers; increases the pace of incremental and follow-on research; and translation for commercialisation.

[543] Knowledge Ecology International (n 538 above).
[544] RS Berry (2001) 'Is electronic publishing being used in the best interests of science? The scientist's view' Presentation made at Second Conference on Electronic Publishing in Science held in UNESCO House Paris, France 19 - 23 February 2001 http://www.mdpi.org/ijms/htm/i2030133.htm (accessed 15 November 2014).

5.4.12 Safeguards

March-in right

As discussed in previous chapters, march-in rights is a safeguard against the mismanagement or misuse of intellectual property emanating from government-funded research on the part of exclusive licensees and or assignees that may abuse their monopoly over such intellectual property. Also referred to as walk-in rights, this right enables government to intervene in the execution of licence agreements in the interest of the public in the following situations among others:

1. Where the exclusive licensee or assignee has not taken effective steps to ensure practical application of the invention and is not expected to do so within a reasonable time.[545]

2. Where the action (march-in right) is necessary to alleviate health, security or military needs, or humanitarian needs which are not reasonably satisfied by recipients, assignees, or licensees.[546]

3. To meet public use requirements provided for under national regulations not reasonably satisfied by recipients, assignees, or licensees.[547]

5. Where a party fails to commercialise the intellectual property in a manner that is beneficial to the public.[548]

For countries which have a constitutional provision on the right to access to healthcare for all, this constitutional provision may serve as a ground for holding government accountable and requiring it to exercise march-in right whenever an exclusive licensee or an assignee abuse their monopoly through excessive pricing or otherwise.

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[545] Sec 203(a)(1) of the United States Bayh-Dole Act 1980.
[546] Sec 203(a)(2) of the United States Bayh-Dole Act 1980; sec 11(1)(e) of the Intellectual Property Rights from Publicly Financed Research and Development Act No 51 2008.
[547] Sec 203(a)(3) of the United States Bayh-Dole Act 1980.
[548] Sec 11(1)(e) of the Intellectual Property Rights from Publicly Financed Research and Development Act No 51 2008. This may be interpreted to mean for instance when a patented invention is not available to the public at a reasonable price. It should be noted that accessibility here includes economic accessibility, which is cost.

Borrowing from the experiences of countries like the United States, the law must be carefully drafted with roles and responsibilities clearly assigned to different stakeholders to ensure that situations that warrant intervention through march-in right are clarified to avoid ambiguity. Whenever an exclusive licensee or an assignee fails to make any pharmaceutical product emanating from publicly financed research accessible to the public,[549] government ministries or departments, members of the public, including CSOs and affected persons, should have the right to formally request the courts and or the relevant government ministries or departments to investigate and exercise march-in right. Granting the right to hold government accountable to CSOs and members of the public will keep government and private industries on the alert in their dealing with intellectual property emanating from publicly funded research. In addition, the process of requesting government march-in right should be as least cumbersome as possible, and should not involve any cost.

It should be noted that in the specific case of biopharmaceutical technology, government and funding ministries or departments may be challenged with the exercise of march-in right. This may happen for instance where it is not possible to find a pharmaceutical company that is willing to manufacture and commercialise a pharmaceutical product emanating from publicly financed research after the initial assignee or exclusive licensee fails to do so because the market for the particular pharmaceutical product is nominal. The nominal market problem may be addressed by the creation of a specific fund for such situations, providing tax breaks and other forms of benefits as incentives to industry for the latter to consider investing in the development of such products. Alternatively, a law and or policy similar to the United States Orphan Drug Act 1983 can be passed to provide special benefits as incentives to industries to get them interested in developing and commercialising technologies that are otherwise non-lucrative and thus unattractive to industry.[550]

[550] Food and Drug Administration (n 374 above).

Government-use right

Although already discussed in previous chapters, it should be noted that most laws aimed at regulating intellectual property, irrespective of whether the intellectual property emanates from publicly financed research or not, contain government-use rights to meet 'public, non-commercial use.'[551] This is also provided for in the TRIPS Agreement.[552] For purposes promoting the wide use of technological development emanating from government-funded research and their broader application, government-use right should also be allowed to enable all researchers and research institutions involved in government-funded research to freely access and use research results and intellectual property developed out of publicly funded research for experimental, educational and other non-commercial uses, particularly in the case of biopharmaceutical technologies.

5.5 Potential challenges

As is the case with several other industries, pharmaceutical manufacturing in Sub-Saharan Africa is minimal and there are several reasons for this. For a start in most countries the financial and legal infrastructure is generally unsupportive of the pharmaceutical industry when compared to other parts of the world. In India for instance, producers of final pharmaceutical formulations receive substantial government assistance in the form of duty free imports of raw materials and equipment for export products; ten years' tax holidays if located in Special Economic Zones; export credits; low utility rates; working capital credits; and enhanced depreciation allowances.[553] Hence, final formulation imports from India to Africa benefit from substantial government support in their country of origin and often do not attract duty.[554] Conversely, pharmaceutical manufacturers in most Sub-Saharan African countries frequently have to pay up to 25% import duty on imported active pharmaceutical ingredients (APIs) and other inputs. In addition, these pharmaceutical companies receive little or no financial or other forms of assistance

[551] SF Musungu & C Oh (2005) 'The use of flexibilities in TRIPS by developing countries: Can they promote access to medicines?' Commission on Intellectual Property Rights, Innovation and Public Health Study 4 C 20.
[552] Art 31(b) of the TRIPS Agreement.
[553] AUC-UNIDO (n 534 above) 40.
[554] As above.

from the government.[555] This is compounded by unreliable and expensive basic utilities such as electricity and water which are critical for any manufacturing industry.[556] This realities work against African pharmaceutical industries, posing a genuine threat to the sustainability of high quality pharmaceutical production on the sub-continent, and discouraging potential entrepreneurs and venture capitalists from investing in this sector.[557] These realities may also jeopardise any efforts taken by government to promote R&D and university-industry partnerships as the above mentioned unsupportive laws and policies prevent the few pharmaceutical industries currently operating from growing to a level that will enable them to take up the huge task of translating university developed technologies into tangible products for commercialisation.

On another level, the question of whether African manufacturers can emerge to the point of being able to compete with existing generic manufacturers from India and other emerging countries, at least in the local markets, should not be overlooked. This is because unlike Indian manufacturers, African manufacturers currently import rather than manufacture APIs.[558] A case in point is Quality Chemical Industries in Uganda which specialises in the local manufacture of ARVs and Antemisinin-based Combination Therapies against malaria. Despite expectations that the locally produced generic medicines will be cheaper than imported ones, it is reported that locally manufactured medicines are more expensive in Uganda than the imported ones.[559] Clearly, financing and supporting the emergence or local manufacturing companies alone may not be enough if locally manufactured medicines are priced out of the market. Therefore, any measures taken by governments to boost local

[555] Some off-patent HIV and even multi-drug resistant (MDR) TB medicines are still unaffordable for many on the sub-continent due to the high cost and vulnerability of supply of APIs, which are a source of security of supply of pharmaceutical products, of which Africa imports 95%. See S Ngozwana (2012) 'The pharmaceutical manufacturing plan of Africa – pathway to local production of generic medicines in Africa?' 26 February 2013 www.thedti.gov.za/business_regulation/.../generic_medicines.pdf 9 (accessed 01 September 2014); C Tomlinson & M Louw 'Local Production not a silver bullet' 10 June 2012 http://www.nspreview.org/2012/06/10/local-production-not-a-silver-bullet-2/ (accessed 07 August 2014).
[556] F Zhao 'Opportunities and challenges: African pharmaceutical sector' 9 http://www.hha-online.org/hso/system/files/3zhao_pharmaceutical_sector__africa_value_for_money_tunis.pdf (accessed 01 August 2014).
[557] AUC-UNIDO (n 534 above) 40.
[558] Tomlinson & Louw (n 555 above).
[559] WHO 'Local production and access to medicines in low - and middle income countries: A literature review and critical analysis' (2011) 31.

manufacturing capacity of pharmaceutical industries with which public research institutions will be partnering in technology transfer and commercialisation should be accompanied by deliberate measures aimed at ensuring that local manufacturers remain relevant by being competitive. Some of these measures include: providing financial assistance in the form of subsidies; tax breaks and tax holidays;[560] facilitating the process of obtaining loans on reasonable terms and interest rates for industries, particularly those that partner with research institutions.[561]

Also, before local companies can expand to regional and even global markets, and before they can supply global health initiatives like the Global Fund and PEPFAR, they must make critical investments in improving quality and in raising their standards to meet global good manufacturing practice (GMP) and other good practice standards. To achieve this, local companies and governments should, among others:

1. Work together to create and encourage collaborations and partnerships with local manufacturers of other African countries which have achieved GMP standards.[562]
2. Establish and maintain quality manufacturing standards within their local manufacturing communities.[563]
3. Make optimal use of quality control testing to complement other regulatory functions.[564]
4. Improve and prioritise the implementation of market surveillance based on risk, and its integration into other regulatory functions.[565]
5. Put in place effective measures to monitor and control adverse events like the introduction of counterfeit and substandard medicines into markets.[566]
6. Work towards greater synergies between those responsible for the approval of clinical trials and ethics committees, and ensure proper monitoring of clinical trials after approval.[567]

[560] AUC-UNIDO (n 534 above) 40; Art 19 §2 of the Brazilian Law No. 10.973/04 in December 2004 (the Innovation Law).
[561] This is the case in Brazil under Art. 19 § 2 of the Innovation Law.
[562] AUC-UNIDO (n 534 above) 49. Examples of these companies include Quality Chemicals Ltd in Uganda, and Universal Corporation Ltd in Kenya.
[563] AUC-UNIDO (n 534 above) 49.
[564] As above.
[565] AUC-UNIDO (n 534 above) 38.
[566] As above.

Once the above have been achieved, local manufacturing companies will still need support to obtain WHO pre-qualification and to file for registration in foreign markets. Only then will they begin to achieve economies of scale that might make their prices competitive.

Perhaps factors such as the steadily growing African pharmaceutical market estimated at US$ 18 billion in 2012 and projected at US$ 45 billion by 2020 could serve as a motivation to governments, local pharmaceutical manufacturers, and potential entrepreneurs. In addition, there is a growing consensus among African leaders that creating an enabling legal environment for local production of essential medicines; and advancing, and supporting industrial development are both necessary to sustain HIV, tuberculosis and malaria treatment programmes, and improve access to safe and effective medicines to treat or cure a broad range of current and even future communicable and non-communicable diseases.[568] These could serve as a starting point for synergies between governments and private industries on the sub-continent.[569]

5.6 Conclusion

As the Ebola outbreak in West Africa has revealed,[570] biomedical R&D, the pharmaceutical manufacturing and the healthcare sectors in general in most Sub-Saharan African countries remain largely under resourced and under developed for several different reasons. This reality has to date rendered the sub-continent a net importer of essential medicines and other healthcare products. As these countries individually and collectively through the African Union, consider changing the *status quo*, the principal question remains: how can these countries stimulate and promote R&D, ensure the effective management and transfer of technologies developed by research institutions to industry for translation into tangible products for commercialisation, and ensure that final products are accessible?

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[567] As above.
[568] As demonstrated in the Joint African Union (AU) Conference of Ministers of Economy and Finance and the Economic Commission for Africa (ECA) Conference of African Ministers of Finance, Planning and Economic Development held in Abuja, Nigeria in March 2014; UNAIDS (note 27 above).
[569] UNAIDS (n 271 above).
[570] Gomes *et al* n 9 above.

It is in an attempt to answer some of these questions that this chapter proposes a number of policy options aimed at promoting R&D; strengthening the local pharmaceutical manufacturing sector; and increasing access to locally manufactured pharmaceutical products in Sub-Saharan Africa. The idea is to build synergies between the different stakeholders involved in R&D and technological development to ensure that research institutions which carry out research; government which funds the research; and industries which may be interested in the translation of research outcomes into products ready for commercialisation, work together to find a lasting solution to some of the health problems faced by people living in Sub-Saharan Africa.

It is therefore the position of this research that lawmakers in Sub-Saharan African countries should consider introducing laws and or policies aimed specifically at requiring research institutions to not just limit their activities to teaching and research for publication, but to also seek the application of government-funded research to solving particular real-life problems generally and health-related problems in particular. Given the complexities that might arise from having government, research institutions and private industry working together because of their differing and sometimes conflicting goals, objectives, approaches, and interests, this chapter attempts to bridge the gap between the three, while at the same time ensuring that products developed from the collaboration between the three are affordable.

CHAPTER VI

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

This chapter provides a conclusion to the research questions addressed in this research and proposes some recommendations to governments of Sub-Saharan African countries which may be considering stimulating and boosting R&D at research institutions, and creating and managing partnerships between research institutions and private industries to improve the local manufacture of pharmaceutical products on the sub-continent.

The primary question that this thesis addresses is: how can policy makers through laws and or policies promote biomedical R&D to address diseases that disproportionately affect people living in developing and least developed countries; technology transfer to secure the translation of this research output into biopharmaceutical products; and to ensure that these products are accessible? To answer this question, the first chapter sets the overall scene for the research by briefly discussing States' commitments, responsibilities and obligations relating to the provision of better healthcare for all under various national, regional and international agreements and conventions. These include obligations to respect, protect, promote and fulfil the right to the highest attainable standard of physical and mental health of their populace through, among others, access to medicines. This is followed by a brief description of some of the diseases that are prevalent in least developed and developing countries in general, and Sub-Saharan Africa in particular.

The second chapter analyses the approach adopted by the United States to regulate intellectual property emanating from publicly financed research and technology transfer to secure the translation of technologies developed into products. The chapter begins with a background into the *raison d'être* for such a law, more particularly the United States Bayh-Dole Act 1980 as the Bayh-Dole Act is the first recorded piece of legislation ever enacted to achieve similar goals, and the fact that Bayh-Dole Act has served as an inspiration to several other countries, including countries that have adopted different approaches. The chapter explores the

contribution of the Bayh-Dole Act to the growth of the biopharmaceutical industry in the United States; and its merits and demerits with respect to access to intellectual property and medicines developed from publicly financed research.

For purposes of comparison, chapter three analyses different approaches to regulating intellectual property and technology transfer currently being implemented in Sweden and Britain. The idea here is to highlight that there is no one-size-fits all approach. Developing countries should therefore use the United States Bayh-Dole Act model and other models simply as guides and, taking into account their local realities and needs, should formulate laws that are better suited to encourage R&D and technology transfer, promote and enhance access to technologies developed from government-funded research in their contexts.

The fourth chapter explores the legal transplantation of the United States Bayh-Dole model to selected developing countries, namely South Africa, India and Brazil. This chapter examines the main provisions of the legislation in each of these countries and the potential implications for access to pharmaceutical products developed from, or incorporating, intellectual property emanating from publicly financed research in these countries, taking into account the experience of the United States.

Having examined the lack of R&D for diseases peculiar to developing countries and different approaches adopted by various countries to promote the application and translation of biomedical R&D into biopharmaceutical products through technology transfer and commercialisation, chapter five discusses policy options for Sub-Saharan African countries seeking to promote biomedical R&D at research institutions, technology transfer and enhance local manufacturing capacity in the pharmaceutical industry. Far from proposing a legislative text and claiming it can address the access to medicines challenge in all Sub-Saharan African countries, this chapter examines how, through legislation: (1) biomedical R&D can be stimulated and promoted; (2) how partnerships between research institutions and industries can be created and sustained for the translation of university developed technologies into products; and (3) how local manufacturing capacity can be boosted in this process to enable local pharmaceutical companies to contribute more significantly to the supply of low cost generic medicines in their local markets in the long run.

6.2 Recommendations

Heads of States of the African Union should respect their commitment to allocate at least 15% of their total annual government budgets to the health sector under the Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases, 2001. In countries like Rwanda where this commitment has been respected and implemented,[571] the healthcare sector has been completely revamped. As a result, life expectancy has risen, deaths of children under five years of age has reduced drastically, and the country is very close to having universal healthcare insurance as only 4% of the population is currently uninsured.[572] This funding will render states less reliant on unsustainable donor funding. A portion of this funding could be used to fund biomedical R&D at research institutions and to create and promote partnerships between these research institutions and industry on the one hand, and between local research institutions and foreign research institutions with advanced biopharmaceutical technology research capacity, particularly those involved in socially responsible licensing.

This funding can also be used for research into specific diseases; and to organise and facilitate innovation competitions where research projects with significant health impacts are selected for funding. These, among other measures will enable research institutions to take ownership of R&D in their countries and render R&D more meaningful as research will have a direct impact on people's lives.

In most African countries there is a very wide gap between academia and entrepreneurs. Most countries have high unemployment rates amongst university graduates and postgraduates who usually only dream of being recruited either by large companies or into the public sector and hardly think of creating jobs for themselves and for others. On the other hand, the vast majority of the few existing entrepreneurs are school dropouts. Given that one of the solutions to the access to medicine challenges faced by the sub-continent lies in getting research institutions and the private industries to work together, there is need for a change of mind-set

[571] As of 2011, the Rwandan government allocated 23.8% of its national budget to healthcare. AR Ocampo 'Health funding in Africa: How close is the AU to meeting Abuja targets?' 05 August 2013 https://www.devex.com/news/health-funding-in-africa-how-close-is-the-au-to-meeting-abuja-targets-81567 (accessed 24 February 2015).
[572] T Rosenberg 'In Rwanda, health care coverage that eludes the U.S.' 03 July 2012 http://opinionator.blogs.nytimes.com/2012/07/03/rwandas-health-care-miracle/?_r=0 (accessed 24 February 2015).

where those in academia and entrepreneurs are brought to understand the business side of R&D, particularly biomedical R&D. This will encourage private industries to partner with research institutions and graduates to be more entrepreneurial given that investing in the biopharmaceutical technology industry can be greatly rewarding from a strictly business point of view.

Governments should ensure that sourcing generic medicines from India and other developing countries is a short-term solution and should while doing this, plan for longer term solutions which entail local production of generic medicines at the lowest possible cost to meet national and regional demand. To achieve this, governments should, working together with local manufacturing companies, facilitate access to affordable long-term investment capital of sufficient magnitude for the upgrade of facilities to meet international standards, and develop a road map to assist these companies to attain and sustain compliance with GMP regulations within fixed timelines. New and existing companies developing new outlets could be required to immediately comply with WHO GMP standards, while existing companies should be required to, and assisted in attaining and maintaining the same standard.[573]

In addition, governments can provide options with respect to time limits and fiscal incentives to local pharmaceutical companies such as reduced interest rates, special economic zones, interest subsidies, working capital credits, Underwriting Letters of Credit to improve the credit terms that companies can obtain from suppliers, and export incentives. Protectionist policies such as marginal preference for procurement of locally manufactured products and increased tariffs on imported finished products can also be explored by governments.[574]

In a bid to achieve long-term sustainability in the local pharmaceutical manufacturing sector, government should also invest in enhancing human capital development in regulatory functions, technical and business aspects of pharmaceutical manufacturing, and policy making. Pharmalot estimates that between 2008 and 2011 about 43 014 highly skilled pharmaceutical personnel were retrenched in developed countries due to the economic recession. Governments in African countries could

[573] AUC & UNIDO (n 534 above) 59 & 65.
[574] AUC & UNIDO (n 534 above) 67 - 68.

increase the quota of expatriate working visas for pharmaceutical companies in a bid to attract these unemployed skilled personnel to their countries.[575]

[575] AUC & UNIDO (n 495 above) 61.

BIBLIOGRAPHY

Books

Bodeker, G & Burford G *Traditional, complementary and alternative medicine policy and public health perspectives* (World Scientific: Singapore 2007)

Burgdorf, JR *Health and medical research in Japan: health research observatory* (The Rand Corporation: U.S.A. 2008)

DeGeeter, MJ *Technology commercialization manual strategies, tactics and economics for business success* (University of Illinois: Urbana 2004)

May, ET *Homeward bound: American families in the Cold War* (Basic Books: New York 1988)

Nash, R & Rawicz, L *Patents and technical data* (George Washington University: Washington DC: 1983)

Tansey, EM; Catterall, PP; Christie, DA; Willhoft, SV & Reynolds, LA *Technology transfer in Britain: The case of monoclonal antibodies; self and non-self: A history autoimmunity; endogenous opiates; the committee on safety of drugs Wellcome Witnesses to Twentieth Century Medicine* vol 1 (Wellcome Trust: London, UK 1997)

UNAIDS *The gap report* (UNAIDS: Geneva 2014)

WHO *Global strategy and plan of action on public health, innovation and intellectual property* 3 (WHO: Geneva 2011)

WIPO *Exchanging value: negotiating technology licensing agreements: a training manual* (WIPO Publications: Geneva 2005)

United States Office of the Federal Register *Code of federal regulations*, *title 14: aeronautics and space revised as of January 1, 2013 (Government Printing Office: Washington D.C. 2013)*

Chapters in books

Bennett, AB & Chi-Ham C 'Technology transfer offices: facilitating intellectual property protection for agricultural innovation' in The World Bank (ed) *Agricultural innovation systems an investment sourcebook* (The World Bank: Washington D.C. 2012)

Bremer, HW 'Patent policies for government-supported research (U.S.A.)' in Gerstenfeld, A (ed) *Science Policy Perspectives: USA-Japan* 296 (Academic Press Inc: New York 1982)

Bremer, HW 'University Technology Transfer: Evolution and Revolution on the 50th Anniversary of the Council On Governmental Relations' in Kulakowski, EC & Chronister, LU (eds) *Research administration and management* 636 (Jones and Barlett's Publishers International: London 2006)

Drahos, P 'Doing Deals with Al Capone: Paying Protection Money for Intellectual Property in the Global Knowledge Economy' in Yu, PK (ed) *Intellectual property and information world: Issues and practices in the digital age* 150 (Praeger Publishers: Connecticut 2007)

Johnson, A 'The End of Pure Science: Science Policy from Bayh-Dole to the NNI' in Baird, D; Nordmann, A & Schummer, J (eds) *Discovering the nanoscale* 220 (IOS Press: The Netherlands 2004)

Mbewi, A & Mbanya, JC 'Cardiovascular diseases' in Jamison, DT; Feachem, RG; Malegapuru, WM; Bos, ER; Baingana, FK; Hofman, KJ & Rogo, KO (eds) *Diseases and mortality in Sub-Saharan Africa* 2nd ed (The World Bank: Washington D.C. 2006)

Mowery, DC & Sampat, BN 'Universities in national innovations systems' in Fagerberg, J; Mowery, DC; Nelson, RR (eds) *The Oxford Handbook of Innovation* (Oxford University Press Inc.: New York 2005)

Nyasse, B 'Overview of current drug discovery activities in Africa and their links to international efforts to combat tropical infectious diseases' in Chibale, K; Davies-Coleman, M & Masimirembwa, C (eds) *Drug discovery in Africa impacts of*

genomics, *natural products, traditional medicines, insights into medicinal chemistry, and technology platforms in pursuit of new drugs* (Springer: New York 2012)

Thursby, J & Thursby, M 'University licensing: Harnessing or tarnishing faculty Research? in Lerner, J & Stern, S (eds) *Innovation Policy and the Economy* vol. 10 (National Bureau of Economic Research: Maryland 2010)

Journal articles

Anell, A; Glenngard, AH & Merkur, S 'Sweden: Healthcare system review' (2012) 14 *Healthcare Systems in Transition* xvi-xvii

Arno, PS & Davis, MH 'Why don't we enforce existing drug price controls? The unrecognized and unenforced reasonable pricing requirement imposed upon patent deriving in whole or in part from federally funded research' (2001) 75 *Tulane Law Review* 640

Barratt, A 'Lessons from Bayh-Dole: Reflections on the Intellectual Property Rights from Publicly Financed Research and Development Act' (2010) 35 *Journal for Juridical Science* 53

Basheer, S & Guha, S 'Outsourcing Bayh-Dole to India: Lost in transplantation?' (2010) 23 *Columbian Journal of Asian Law* 284

Blumenthal, D; Campbell, EG; Anderson, MS; Causino, N & Louis KS 'Withholding research results in academic life science' (1997) 277 *Journal of the American Medical Association* 1224 - 1225

Blumenthal, D; Causino, N; Campbell, E & Louis, KS 'Relationship between academic institutions and industry in the life sciences—an industry survey' (1996) 334 *The New England Journal of Medicine* 368, 372

Busang, R; Boisjoly-Letourneau, K; Fourie, B; Mulder, Michelle; & Thangaraj, H 'Socially Responsible Licensing of Health Technologies: Policy And Practice in South Africa' XLVI *Les Nouvelles* (2011) 70-71

Caulfield, T; Harmon, SHE & Joly, Y 'Open science versus commercialization: a modern research conflict' (2012) 4 *Genome Medicines* 6

Chu, KM; Jayarama, S; Kyamanywa, P & Ntakiyiruta, G 'Building research capacity in Africa: equity and global health collaborations' (2014) 11 *PLOS Med* e1001612

Creech, ML 'Make a run for the border: Why the United States Government is looking to the international market for affordable prescription drugs' (2001) 15 *Emory International Law Review* 1 - 5

Damsgaard, EF & Thursby, MC 'University entrepreneurship and professor privilege' (2013) 2 *Industrial and Corporate Change* 185

De Larena, LR 'The price of progress: Are universities adding to the cost?' (2007) 43 *Houston Law Review* 1437

Dean, JR 'FDA at War: Securing the food that secured victory' (1998) 53 *Food & Drug Law Journal* 493 - 495

Dubowy, IR 'Subsidies code, TRIPS Agreement and technological development: some considerations for developing countries' (2003) 8 *Journal of Technology Law and Policy* 55 - 56

Edejer, TT 'North-South research partnerships: The ethics of carrying out research in developing countries' (1999) 319 *British Medical Journal* 438 - 441

Eisenberg, RS 'Patents and the progress of science: Exclusive rights and experimental use' (1989) 56 *Chicago Law Review* 1017

Eisenberg, RS 'Public research and private development: Patents and technology transfer in government-sponsored research' (1996) 82 *Virginal Law Review* 1663

Evans, G 'Strategic patent licensing for public research organizations: Deploying restrictions and reservation clauses to promote medical R&D in developing countries' (2008) 34 *American Society of Law, Medicine and Ethics* 192

Gomes, MFC; Piontti, APY; Rossi, l; Chao, D; Longini, I; Halloran, ME & Vespignani, A 'Assessing the international spreading risk associated with the 2014 West African Ebola outbreak' (2014) *PLOS* Currents Outbreaks doi: 10.1371/currents.outbreaks.cd818f63d40e24aef769dda7df9e0da5

Gopakumar, KM 'Product patents and access to medicines in India: A critical review of the implementation of TRIPS patent regime' (2010) 3 *The Law and Development Review* 329

Greenbaum, D 'Academia to industry technology transfer: An alternative to the Bayh-Dole system for both developed and developing nations' (2008) 19 *Fordham Intellectual Property Media and Entertainment Law Journal* 384

Gulbrandsen, CE 'Address Bayh-Dole: Wisconsin roots and inspired public policy' (2007) 1149 *Wisconsin Law Review* 1150 - 1151

Gwynn, J & Highlands, PJ 'Plants as a source of new medicines' (2000) 10 *Drug Discovery World* 54

Heywood, M 'South Africa's Treatment Action Campaign: Combating law and social mobilization to realise the right to health' (2009) 1 *Journal of Human Rights Practice* 31 - 34

Hoban, R; Bucher, S; Neuman, I; Chen, M; Tesfaye, N & Spector, JM 'Helping babies breathe training in sub-Saharan Africa: educational impact and learner impressions' (2013) 59 *Journal of Tropical Paediatrics* 180 - 186

Hotez, PJ & Kamath, A 'Neglected tropical disease in sub-Saharan Africa: Review of their prevalence, distribution, and diseases burden' (2009) 3 *PLOS Neglected Tropical Diseases* 1

Kalima, WL 'The 10/90 Gap in sub-Saharan Africa: Resolving inequalities in health research' (2009) 112 *Acta Tropica* 8

Kirigia, JM; Nganda, BM; Mwikisa, CN & Cardoso B 'Effects of global financial crisis on funding for health development in nineteen counties of the WHO Africa region' (2011) 11 *Biomed Central health and Human Rights* 1

Maitland, K; Kiguli, S; Opoka, RO; Engoru, C; Olupot-Olupot, P; Akech, SO; Nyeko, R; Mtove, G; Reyburn, H; Lang, T; Brent, B; Evans, JA; Tibenderana, JK; Crawley, J; Russell, EC; Levin, M; Babiker, AG; Gibb, DM & FEAST Trial Group 'Mortality after

fluid bolus in African children with severe infection' (2011) 364 *The New England Journal of Medicines* 2483 - 2495

Marques, URQ; Guimarães, VS & Sternberg, C 'Brazil's AIDS controversy: Antiretroviral drugs, breaking patents, and compulsory licensing' (2005) 60 *Food and Drug Law Journal* 476

Mazzoleni, R & Nelson, RR 'Public research institutions and economic catch-up' (2007) 36 *Science Direct* 1515

Mazzoleni, R 'Patents and University-Industry Interactions in Pharmaceutical Research before 1962: An Investigation of the Historical Justification for Bayh-Dole' (2010) 10 *Journal of High Technology Law* 173

Mills, EJ; Kanters, S; Hagopian, A; Bansback, N; Nachega, J & Alberton, M 'The financial cost of doctors emigrating from sub-Saharan Africa: human capital analysis' (2011) 343 *British Medical Journal* 2

Mills, EJ; Schabas, WA; Volmink, J; Walker, R & Ford N, 'Should active recruitment of health workers from sub-Saharan Africa be viewed as a crime?' (2008) 371 *Lancet* 685 - 88

Mireles, MS 'An examination of patens, licensing, research tools, and the tragedy of the anticommons in biomedical innovation' (2005) 38 *University of Michigan Journal of Law Reform* 191 – 194

Mowery, DC & Sampat, MN 'The US Bayh-Dole Act of 1980 and university-industry technology transfer: A model for other OECD governments?' (2005) 30 *Journal of Technology Transfer* 116

Naicker, S; Eastwood, JB; Plange-Rhule, J & Tutt, RC 'Shortage of healthcare workers in sub-Saharan Africa: a nephrological perspective' (2010) 74 *Clinical Nephrology* 1

Nair, K & Nair, B 'Protection and Utilisation of Public Funded Intellectual Property Bill 2008 - A critical analysis of the Indian Bayh-Dole Act' (2009) 2 *National University of Juridical Sciences Law Review Law Review* 705

Nelsen, L 'The rise of intellectual property protection in the American university' (1998) 279 *Science* 1460

Osier, FH; Mackinnon, MJ; Crosnier, C; Fegan, G; Kamuyu, G; Wanaguru, M; Ogada, E; McDade, B; Rayner, JC; Wright, GJ & Marsh, K 'New antigens for a multicomponent blood-stage malaria vaccine' (2014) 6 *Science Translational Medicine* 247

Pulsinelli, G 'Share and share alike: Increasing access to government-funded inventions under the Bayh-Dole Act' (2006) 7 *Minnesota Journal of Law, Science & Technology* 401

Rai, AK & Eisenberg, RS 'Bayh-Dole reform and the progress of biomedicine' (2003) 66 *Law & Contemporary Problems* 295 - 298

Rates, SMK 'Plants as a source of drugs' (2001) 39 *Toxicon* 603

Raubitschek, JH & Latker, NJ 'Reasonable pricing – A new twist for march-in rights under the Bayh-Dole Act' (2005) 22 *Santa Clara Computer & High Technology Law Journal* 158

Rives, AA 'Reorienting Bayh-Dole's march-in: Looking to purpose and objectives in the public's interest' (2013) 5 *American University Intellectual Property Brief* 89

Sampat, BN 'Patenting and US academic research in the 20th century: The world before and after Bayh-Dole' (2006) 35 *Research Policy* 778

Singh, S 'India Takes an Open Source Approach to Drug Discovery' (2008) 133 *Cell* 201 - 203

Stanton, J 'Comment, lesson for the United States from foreign price controls on pharmaceuticals' (2000) 16 *Connecticut Journal of International Law* 155

Stevens, AJ & Effort, AE 'Using academic license agreements to promote global social licensing' (2008) 43 *Journal of the Licensing Executives Society International Les Nouvelles* 86 - 87

Trostle, J 'Research capacity building in international health: Definitions, evaluations and strategies for success' (1992) 35 *Social Science & Medicine* 1321 - 1324

Trouiller, P; Olliaro, P; Torreele, E; Orbinski, J; Laing, R & Ford, N 'Drug development for neglected diseases: A deficient market and a public-health policy failure' (2002) 359 *The Lancet* 2188 - 2189

United States National Patent Planning Commission 'Government-owned patents and inventions of government employees and contractors' (1945) 27 *Journal of the Patent Office Society* 79 - 82

Van der Sande, MAB 'Cardiovascular diseases in sub-Saharan Africa: a disaster waiting to happen' (2003) 61 *Netherlands Journal of Medicine* 32 - 33

Verspagen, B 'University research, intellectual property rights and European innovation systems' (2006) 20 *Journal of Economic Surveys* 619

Visser, C 'Intellectual property rights from publicly financed research: The way to research hell is paved with good intentions' (2007) 19 *South African Mercantile Law Journal* 364.

Walterscheid, EC 'The need for uniform government patent policy: The D.O.E. example' (1990) 3 *Harvard Journal of Law & Technology* 103 - 104

Wolffers, I; Adjei, S & Van de Drift, R 'Health research in the tropics' (1998) 351 *The Lancet* 1652 - 1654

Akinwaye, K; Ogundari, I; Olaopa, O & Siyanbola, W 'Global best practices for R&D funding: Lessons for Nigeria' 4 *Interdisciplinary Journal of Contemporary Research in Business* (2012) 920

Cases

United States

American Liberty Oil Co v Federal Power Commission (1962) 301 F 2d 15

Association for Molecular Pathology v U.S. Patent and Trademark Office No. 09-cv-4515 94 USPQ2d 1683 (S.D.N.Y. 29 March 2010)

Byars v Bluff City News Co (1979) 609 F 2d 843

Chisom v Roemer 501 US 380, 404 (Scalia, J dissenting) (1991)

Demarest v Manspeaker 498 US 184, 190 (1991)

Madey v Duke University (2002) 307 F 3d 1351 (No. 02-1007)

International treaties and other international instruments

African (Banjul) Charter on Human and Peoples' Rights (1981) OAU Doc. CAB/LEG/67/3 rev.5, 21 I.L.M. 58 (1982), entered into force 21 October 1986

African Charter on the Rights and Welfare of the Child (1990)

Convention of Biological Diversity (1992)

Convention on the Elimination of all Forms of Discrimination Against Women General Assembly Resolution 34/180 of 18 December 1979, entered into force 3 September 1981

International Covenant on Economic, Social and Cultural Rights, U.N. Doc. A/6316 (1966)

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Resources 2010

Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa Adopted by the 2nd Ordinary Session of the Assembly of the Union, 11 July 2003

Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore within the framework of the African Regional Intellectual Property Office adopted on 09 August 2010

Trade Related Aspects of Intellectual Property Rights Agreement Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco 15 April 1994

Universal Declaration on Human Rights adopted by the United Nations General Assembly on 10 December 1948

Legislation

Angola

Constitution of the Republic Angola 1992

Brazil

Brazilian Law No. 9.279 of 14 May 1996 (Industrial property Law) (2001)

Brazilian Law No. 10.973/04 in December 2004 (The Innovation Law)

Decree No. 3.201 of 1999 (Compulsory Licenses in Cases of National Emergency and Public Interest) Brazil

India

Protection and Utilisation of Public Funded Intellectual Property Bill 2008 of India

Japan

Japanese Law No 131 of 1999

Kenya

Constitution of Kenya Act 1966

The Science and Technology Innovation Act, 2013

Namibia

The Research Science and Technology Act no 23 of 2004

South Africa

Constitution of the Republic of South African, 1996 (as set out in sec 1(1) of the Citation of Constitutional Laws Act 5 of 2005 C

Regulations made in terms section 17 of the Intellectual Property Rights from Publicly Financed Research and Development Act No. 51 of 2008

South African National Environmental Management Biodiversity Act No. 10 of 2004

South African Patents Amendment Act No. 20 of 2005

The Intellectual Property Rights from Publicly Financed Research and Development Act No 51, 2008 passed in 2008

Sweden

Swedish Higher Education Act (Högskolelagen 1992)

United States

The Constitution of the United States of America 1787

Reports and papers

Arvanitis, S; Kubli, U; Sydow, N & Worter M (2006) 'Knowledge and Technology Transfer between Universities and Private Enterprises in Switzerland an Analysis based on Firm and Institute Data' A study on behalf of the ETH-Board http://www.kof.ethz.ch/static_media/upload/filer/public/2011/04/11/synthesis_report_ktt_2006_03.pdf (accessed 23 December 2015)

AUC-UNIDO Partnership 'Pharmaceutical manufacturing plan for Africa-business plan' (2012)

Chataway, J; Chaturvedi, K; Hanlin, R; Mugwagwa, J; Smith, J & Weild, D (2007) 'Building the case for national systems of health innovation' a background policy

paper prepared for NEPAD in advance of the AMCOST meeting and the African Union Summit January 2007 http://www.nepadst.org/doclibrary/pdfs/nsi_case_jan2007.pdf (accessed 24 October 2013)

Congressional Research Service Report for Congress 'Federal R&D, drug discovery, and pricing: Insights from the NIH-university-industry relationship (2011)

Donwa, PA 'Funding of Academic Research in Nigerian Universities' http://ahero.uwc.ac.za/index.php?module=cshe&action=viewtitle&id=cshe_106 (accessed 18 December 2015

Department of Science and Technology 'Intellectual property rights (IPR) from publicly financed research framework' (2006)

European Commission 'Green Paper on Innovation' 20 December 1995 http://europa.eu/documents/comm/green_papers/pdf/com95_688_en.pdf (accessed 20 December 2013)

Food and Drug Administration 'Designating an orphan product: Drugs and biological products' 14 August 2013 http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/default.htm (accessed 15 October 2013)

Gaillard, J; Van Lill, M; Nyasse B & Wakata A 'Science Granting Councils in Sub-Saharan Africa: Country Report Cameroon' (2013)

Harbridge House 'Government patent policy study', final report for the FCST Committee on Government Patent Policy (1968) VIII

Montobbio, F 'Intellectual Property Rights and Knowledge Transfer from Public Research to Industry in the US and Europe: Which Lessons for Innovation Systems in Developing Countries' (2009)186

Musungu, SF & Oh, C (2005) 'The use of flexibilities in TRIPS by developing countries: Can they promote access to medicines?' Commission on Intellectual Property Rights, Innovation and Public Health Study 4 C 20

NEPAD Health Strategy 05 September 2003

Patent and Trademark Law Amendments Act (Pub. L. 96-517, Dec 12 1980) The Bayh-Dole Act

Planning Commission of India 'Report of the Working Group on Drugs and Pharmaceuticals for the Eleventh Five Year Plan' 01 December 2006 21 http://planningcommission.nic.in/aboutus/committee/wrkgrp11/wg11_pharma.pdf (accessed 28 May 2014)

PricewaterhouseCooper 'The World in 2050: Will the shift in global economic power continue?' (2015)

Schacht, WH 'Federal R&D, drug discovery, and pricing: Insights from the NIH-university-industry relationship Congressional Research Service Report for Congress (2011)

Signing, YB & Nguiessi S 'State of University Research Governance in West and Central Africa: The case of the University of Buea' (2009)

The World Bank 'Namibia Country Brief' 2009

The National Programme on Research, Science, Technology and Innovation 2014/2015 to 2016/2017 Republic of Namibia

UNAIDS 'Cooperation for the local manufacturing of pharmaceuticals in Africa intensifies' 2014

UNESCO 'Research and development: Africa is making great progress despite major challenges' 8 November 2010

United States Congress Joint Economic Committee 'The pivotal role of Government investment in basic research' (2010) https://www.aau.edu/WorkArea/DownloadAsset.aspx?id=10828 (accessed 11 February 2015)

United States Congressional Record proceedings and debates on the 96th second session 126 part 2 1980

United States Department of Commerce International Trade Administration 'Pharmaceutical price controls in OECD countries implications for US consumers, pricing, research and development, and innovation' (2004) 3 - 9

United States Government Accounting Office 'Technology transfer reporting requirements for federally sponsored inventions needs amendment' (1999) 3

United States of America 'Investigation of government patent practices and policies' report and recommendations of the Attorney General to the President (1947)

US General Accounting Office 'Technology transfer: Agencies' rights to federally sponsored biomedical inventions' (2003)

WHO 'Essential medicines and health products' nd http://www.who.int/medicines/areas/traditional/definitions/en/ (accessed 15 November 2014)

WHO 'Guidelines for registration of traditional medicines in the WHO African region' (2010) xi

WHO 'Local production and access to medicines in low and middle income countries: A literature review and critical analysis' (2011) 31

WHO Report of the Commission on Intellectual Property Rights, Innovation and Public Health 2006 22

WIPO 'Exception and limitations to patent rights: Private and/or non-commercial use' Standing Committee on the Law of Patents Geneva 27-31 January 2014 2

WIPO 'Exchanging value: Negotiating technology licensing agreements: a training manual' 2005

WIPO Committee on Development and Intellectual Property 'Patent related flexibilities in the multilateral legal framework and their legislative implementation at the national and regional levels' Geneva 26-30 April 2010

Other articles

African Development Bank Group 'Revitalizing Africa's pharmaceutical industry' 04 June 2014 http://www.afdb.org/en/news-and-events/article/revitalizing-africas-pharmaceutical-industry-13289/ (accessed 09 February 2015)

AUTM 'In the public interest: Nine points to consider in licensing university technology' 09 March 2007 http://www.autm.net/Nine_Points_to_Consider1.htm (accessed 24 May 2014)

Bai, B 'Avoiding IP licensing pitfalls in China' 20 February 2008 http://www.us-china-cerc.org/pdfs/Avoid_Lic_Pitfalls_China_BAI.pdf (accessed 10 August 2014)

Bauer, N 'Government mulls state pharmaceutical company' 19 July 2011 http://mg.co.za/article/2011-07-19-govt-mulls-state-pharmaceutical-company accessed 27 October 2013)

BayhDole25 'The Bayh Dole Act at 25' 26 April 2006 http://www.bayhdole25.org/about (accessed 01 February 2013)

Burger, S 'Strong university-industry links key to tapping knowledge-economy spin-offs' 18 October 2013 http://www.nstf.org.za/nstfWebPortal/appmanager/nstfWeb/nstf?_nfpb=true&_pageLabel=nstf_portal_page_1 (accessed 24 October 2013).

Busang, R & Wolson, R 'Socially responsible licensing guide for technology transfer offices: Adoption and implementation of socially responsible licensing practices' 30 April 2013 http://ship.mrc.ac.za/SRLGuide.pdf (accessed 23 March 2013)

Bush, V 'Science: the endless frontier' 25 July 1945 http://www.nsf.gov/od/lpa/nsf50/vbush1945.htm (accessed 10 August 2012)

Cameron, DM & Borenstein, R 'Key aspects of IP licensing agreements' 12 December 2003 http://www.jurisdiction.com/lic101.pdf (accessed 10 August 2014)

Canada-patent protection of pharmaceutical product case (DS114) nd http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm (accessed 07 August 2013)

Chang, J 'The UK healthcare system' nd http://assets.ce.columbia.edu/pdf/actu/actu-uk.pdf (accessed 08 January 2014)

Choudhary, K & Ritiraj, S 'India: The trickle-down effect of product patent in India and on the developing world' 12 September 2013 http://www.mondaq.com/india/x/262416/Patent/The+TrickleDown+Effect+Of+Product+Patent+In+India+And+On+The+Developing+World (accessed 10 February 2015)

Conley, J 'Government refuses to march-in Under Bayh-Dole again' nd http://www.genomicslawreport.com/index.php/2011/01/18/government-refuses-to-march-in-under-bayh-dole-again/ (accessed 22 March 2014)

Demenet, P 'Le Monde Diplomatique' 04 February 2002 http://mondediplo.com/2002/02/04stavudine (accessed 05 April 2014)

Ehlers, MH 'Patents and the Law of Technological Innovation' 30 September 2005 http://www.dannemann.com.br/dsbim/manager.aspx?ID_LAYOUT=211&ID=119 (accessed 04 October 2013)

Essential Inventions 'Petition to use authority under the Bayh-Dole Act to promote access to Ritonavir, supported by National Institute of Allergy and Infectious Diseases' 29 January 2004 http://www.essentialinventions.org/legal/norvir/norvir-29jan04petition.pdf (accessed 16 March 2013)

Essential Inventions 'Pressure mounts for U.S. to open competition on two Gov't funded medicines' 30 March 2004 http://www.essentialinventions.org/drug/ngos03302004.html (accessed 01 April 2013)

Food and Drug Administration 'Designating an orphan product: Drugs and biological products' 14 August 2013 http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/default.htm (accessed 15 October 2013)

Foss, MC 'Analysis of the legal arrangements for the technological innovation promotion' 19 June 2013 http://cglad.com.br/wp-content/uploads/2013/06/19.-Maria-

Foss.-Analysis-of-the-legal-arrangements-for-the-technological-innovation-promotion.pdf (accessed 04 October 2013)

Goulart, GE & Gorini, AJV 'Brazil: The New Technological Innovation Act in Brazil' 21 March 2013 http://www.mondaq.com/x/226542/technology/The+New+Technological+Innovation+Act+In+Brazil (accessed 04 October 2013)

IMS Health 'Africa: A ripe opportunity understanding the pharmaceutical market opportunity and developing sustainable business models in Africa' 12 March 2013 http://www.imshealth.com/ims/Global/Content/Insights/Featured%20Topics/Emerging%20Markets/IMS_Africa_Opportunity_Whitepaper.pdf (accessed 20 October 2013)

InterNations 'Healthcare in Sweden' nd http://www.internations.org/sweden-expats/guide/living-in-sweden-15471/healthcare-in-sweden-3 (accessed 08 January 2014)

J Napa 'Open Source Drug Discovery: A feasible business model?' nd http://www.pharmafocusasia.com/strategy/open-source-drug-discovery (accessed 06 July 2015)

Källblad, E 'The organisation of third mission funding in the UK: An overview of the Higher Education Innovation Fund (HEIF) and its impact' nd http://www.vinnova.se/upload/dokument/Verksamhet/Kommersialisering/Nyckelaktorer/HEIF_EK.pdf (accessed 03 November 2013)

Kelley, P 'Choosing the greater good in promotion of UW intellectual properties' 04 January 2007 http://www.washington.edu/news/2007/01/04/choosing-the-greater-good-in-promotion-of-uw-intellectual-properties/ (accessed 23 March 2014)

Khondkar, L 'Access to anti-retrovirals the role of treatment activism in South Africa' 10 April 2008 http://centers.iub.edu.bd/chpdnew/chpd/download/seminar/2008/April10.pdf (accessed 31 October 2013)

Knowledge Ecology International '15 frequently asked questions about the 2012 - 1023 ritonavir march-in petition' nd http://keionline.org/node/1815 (accessed 22 March 2014)

Knowledge Ecology International 'EB134: Statement of South Africa on access to essential medicines (in the Wake of Pharmagate)' 23 January 2014 http://keionline.org/node/1913 (accessed 09 February 2015)

Knowledge Ecology International 'Fabrazyme march-in request' 02 August 2010 http://keionline.org/fabrazyme (accessed 24 September 2013)

Knowledge Ecology International 'Four NGOs ask NIH to grant open licenses to ritonavir patents under the Bayh-Dole march-in provisions' 25 October 2012 http://keionline.org/node/1573 (accessed 15 March 2013)

Knowledge Ecology International 'Selected innovation prizes and reward programs' nd http://www.keionline.org/misc-docs/research_notes/kei_rn_2008_1.pdf (accessed 10 July 2014)

KPMG 'The state of healthcare in Africa' 05 August 2012 4-8 https://www.kpmg.com/Africa/.../The-State-of-Healthcare-in-Africa.pdf (accessed 06 September 2014)

Lewis, R 'Fighting the 10 /90 Gap' 13 May 2002 http://www.the-scientist.com/?articles.view/articleNo/14016/title/Fighting-the-10-90-Gap/ (accessed 10 February 2015)

Lin, A; Sorscher, S; Gupta, N & Guillen, E 'The Bayh-Dole Act and promoting the transfer of technology of publicly funded research UAEM White Paper on the proposed Indian Bayh-Dole analogue' nd http://archive.uaem.org/sites/default/files/archive/uaem-white-paper-on-indian-bd-act.pdf (accessed 24 September 2013)

Lindsay, D 'Amy and Goliath' 01 May 2001 http://www.salon.com/2001/05/01/aids_8/ (accessed 05 April 2014)

Love, J 'Birch Bayh's competing interests and evolving views' 23 August 2012 http://keionline.org/node/1537 (accessed 10 March 2013)

Maguire, G Jr 'The third assignment ("Tredje uppgiften")' 05 March 2008 3 - 4 http://web.it.kth.se/~maguire/Talks/graz-20080304d.pdf (accessed 24 December 2013)

Makholwa, A 'State's pharmaceutical firm yet to build a plant' 25 February 2013 http://www.financialmail.co.za/life/health/2013/02/25/state-s-pharmaceutical-firm-yet-to-build-a-plant (accessed 27 October 2013)

Marjanovic, S; Hanlin, R; Diepeveen, S; & Chataway, J 'Research capacity building in Africa: Networks, institutions and local ownership' A joint Rand Europe/ESRC Innogen Centre working paper 3 and 16 13 February 2012 http://www.rand.org/pubs/external_publications/EP20121302.html (accessed 13 October 2013)

Martin, JCG 'The pharmaceutical industry: A key player in development' nd http://www.eoi.es/blogs/juancarlosgomezmartin/2014/01/08/the-pharmaceutical-industry-a-key-player-in-development/ (accessed 12 February 2014)

McManis, CR & Noh, S 'The impact of the Bayh-Dole Act on genetic research and development: Evaluating the arguments and empirical evidence to date' 13 August 2006 https://www.google.co.za/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&ved=0CC0QFjAA&url=http%3A%2F%2Fwww.law.berkeley.edu%2Ffiles%2Fmcmanis(1).doc&ei=VvpsUu-hFoLBhAeT_oD4Aw&usg=AFQjCNHcAi1XazcC56FUEy_qoS-Z_HPK1g (accessed 20 October 2013)

McManis, CR & Noh, S 'The impact of the Bayh-Dole Act on genetic research and development: Evaluating the arguments and empirical evidence' Washington University in St. Louis Legal Studies Research Paper 10 July 2011 http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1840639 (accessed 20 October 2013)

Medical Research and Human Experimental Law 'Report of the National Institute of Health (NIH) Working Group on research tools presented to the Advisory Committee to the Director' 04 June 1998 http://biotech.law.lsu.edu/research/fed/NIH/researchtools/Report98.htm#compet (accessed 17 March 2013)

Mendes, LM 'Research and innovation in bio-technology: An analysis of the patents granted by Brazilian universities in the last decade' 05 July 2013 http://tha2013.org/index.php/tha/2013/paper/view/39 (accessed 13 October 2013)

Messer-Yaron, H 'Technology transfer in countries in transition: Policy and recommendations' 21 August 2012 http://www.wipo.int/export/sites/www/dcea/en/pdf/Technology_Transfer_in_Countries_in_Transition_FINAL-21.08.2012.pdf (accessed 28 May 2013)

Metrafaids 'Manufacturers study next phase of African anti-AIDS drug' 26 May 2003 http://www.panapress.com/Manufacturers-study-next-phase-of-African-anti-AiDS-drug--12-483106-66-lang2-index.html (accessed 24 May 2014)

Mimura, C 'Nuanced management of IP rights: Shaping industry-university relationship to promote social impact' 15 July 2009 http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1434545 (accessed 09 December 2014)

Mowery, DC 'The Bayh-Dole Act of 1980 and university-industry technology transfer: A policy model for other governments' nd https://projects.merid.org/SITECORE_DOCS/David%20Mowery%20Paper.pdf (accessed 17 April 2015 5-6)

Mowery, DC 'Universities in national innovation systems' nd http://webcache.googleusercontent.com/search?q=cache:Qed6NIQZ5XIJ:https://smartech.gatech.edu/bitstream/handle/1853/43390/L2_presentation.pps+&cd=5&hl=en&ct=clnk&gl=za (accessed 05 January 2014)

MSF 'As US FDA approves promising new HIV drug dolutegravir, MST asks when people in developing countries will have access' 13 August 2013

http://www.msfaccess.org/about-us/media-room/press-releases/us-fda-approves-promising-new-hiv-drug-dolutegravir-msf-asks-when (accessed 24 September 2013)

Nanayakkara, T 'Negotiating technology licensing agreements' International Trade Centre Trade Forum nd http://www.tradeforum.org/Negotiating-Technology-Licensing-Agreements/ (accessed 19 November 2014)

National Institute of Health 'Targeted research on oral microbial biofilms' 21 July 1998 http://grants.nih.gov/grants/guide/rfa-files/RFA-DE-98-006.html (accessed 22 February 2014)

National Institute of Health Office of the Director 'In the case of Novir® manufactured by Abbott Laboratories, Inc.' 25 May 2006 http://www.ott.nih.gov/policy/March-In-Norvir.pdf (accessed 16 March 2013)

Nelles, J & Vorley, T 'Entrepreneurship architecture in the UK Higher Education Institutions: Consolidating the third mission' 17 – 20 June 2008 http://www2.druid.dk/conferences/viewpaper.php?id=3275&cf=29 (accessed 18 December 2013)

Ngozwana, S 'The pharmaceutical manufacturing plan of Africa – pathway to local production of generic medicines in Africa?' 26 February 2013 www.thedti.gov.za/business_regulation/.../generic_medicines.pdf (accessed 01 September 2014)

Nixon, R 'Memorandum about government patent policy' 23 August 1971 http://www.presidency.ucsb.edu/ws/?pid=3130 (accessed 16 April 2015)

Noonan, KE 'NIH declines to exercise march-in rights over Abbott Laboratories' Novir®' 10 November 2013 http://www.patentdocs.org/2013/11/nih-declines-to-exercise-march-in-rights-over-abbott-laboratories-norvir.html (accessed 22 March 2014)

Obom-Egbulem, K 'Another look at African roots and herbs' 01 March 2006 http://www.nigeria-aids.org/news/content.cfm?184 (accessed 11 March 2013)

Ocampo, AR 'Health funding in Africa: How close is the AU to meeting Abuja targets?' 05 August 2013 https://www.devex.com/news/health-funding-in-africa-how-close-is-the-au-to-meeting-abuja-targets-81567 (accessed 24 February 2015)

Office of Intellectual Property and Industry Research Alliances 'Socially responsible licensing at U.C. Berkeley: An intellectual property management strategy to stimulate research support & maximise societal impact' nd http://www.ipadvocate.org/mission/pSociallyResponsibleLicensing_Berkeleydfs/.pdf (accessed 23 March 2914)

Pennsylvania State University News 'Land-grant universities celebrate Morrill Act sesquicentennial' 22 June 2012 http://news.psu.edu/story/148276/2012/06/22/land-grant-universities-celebrate-morrill-act-sesquicentennial (accessed 02 March 2013)

Pielke, R Jr 'In retrospect science - The endless frontier' 19 August 2010 http://sciencepolicy.colorado.edu/admin/publication_files/2010.24.pdf (accessed 27 January 2013)

Platt, JR 'Federally funded research: The key to unexpected (and valuable) discoveries' 13 November 2013 http://www.todaysengineer.org/2013/Nov/Federally-Funded-Research.asp (accessed 15 May 2014)

Pruitt, C 'NIH once again reject calls to exercise march-in rights' 19 December 2013 http://www.insidemedicaldevices.com/2013/12/19/nih-once-again-rejects-call-to-exercise-march-in-rights/ (accessed 22 March 2014)

Public Citizen 'Rebuttals to PhRMA responses to the public citizens report "RX R&D myths: The case against the drug industry's R&D "Scare Card""' 07 July 2001 http://www.citizen.org/congress/article_redirect.cfm?ID=6514 (accessed 10 April 2014)

Rai, AK 'Proprietary rights and collective action: The case of biotechnology research with low commercial value' 10 April 2004 http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1993&context=faculty_scholarship (accessed 17 September 2013)

Reinhardt, J 'Bill aims to provide taxpayers access to publicly funded research' 21 July 2009 http://ohmygov.com/blogs/general_news/archive/2009/07/21/bill-aims-to-provide-taxpayers-access-to-publicly-funded-research.aspx (accessed 25 October 2009)

Rosenberg, T 'In Rwanda, health care coverage that eludes the U.S.' 03 July 2012 http://opinionator.blogs.nytimes.com/2012/07/03/rwandas-health-care-miracle/?_r=0 (accessed 24 February 2015)

SciDevNet 'Integrating modern and traditional medicine: facts and figures' 30 June 2010 http://www.scidev.net/global/disease/feature/integrating-modern-and-traditional-medicine-facts-and-figures.html (accessed 06 September 2014)

Science Africa 'Kenya leads Africa with 2% of GDP for Research & Development' available at http://www.scienceafrica.co.ke/index.php?option=com_content&view=article&id=183:kenya-leads-africa-with-2-of-gdp-for-research-and-development&catid=87&Itemid=586 (accessed 23 December 2015)

Smith, SE 'Opening up to the world: Indian pharmaceutical companies prepare for 2005' 12 May 2000 http://fsi.stanford.edu/sites/default/files/Smith.pdf (accessed 28 May 2014)

Sotunde, O 'Over 44 million invested in Nigerian pharmaceutical industry - PGM-MAN Chairman' 10 October 2013 http://www.ventures-africa.com/2013/10/44m-investments-made-nigeria-pharmaceutical-industry-pmg-man-chairman/ (accessed 30 December 2013)

Spicy, IP 'Guest post on the Conference on Publicly Funded Patents and Technology Transfer: A review of the Indian "Bayh-Dole" Bill' 1 November 2009 http://spicyipindia.blogspot.com/2009/11/guest-post-on-conference-on-publicly.html (accessed 24 September 2013)

Spielman, DJ & Von Grebmer, K 'Public-private partnerships in international agricultural research' International Food Policy Research Institute 15 January 2004

http://www.ifpri.org/publication/public-private-partnerships-agricultural-research (accessed 15 August 2014)

Stanford University 'Technology licensing at Stanford University' nd http://otl.stanford.edu/about/resources/about_resources.html (accessed 24 September 2013)

Stanford University Office of Technology Licensing 'Why we do it' nd http://otl.stanford.edu/about/about_why.html?headerbar=0 (accessed 23 March 2014)

Thom, A 'African herbal medicine is beating AIDS' 16 July 2002 http://www.health-e.org.za/2002/07/16/african-herbal-medicine-is-beating-aids/ (accessed 24 May 2014)

Thifa, D 'India and Nigeria: Countries With The Fastest Growing Populations' available at http://www.mbctimes.com/english/india-and-nigeria-countries-with-the-fastest-growing-populations (accessed 18 December 2015)

Thurston, J 'Compulsory licenses: necessary or threat' 23 May 2013 http://www.rsc.org/chemistryworld/2013/05/compulsory-licence-license-patent-drugs-debate (accessed 13 October 2013)

Tomlinson, C & Louw, M 'Local production not a silver bullet' 10 June 2012 http://www.nspreview.org/2012/06/10/local-production-not-a-silver-bullet-2/ (accessed 07 August 2014)

Tottie, L 'The professor's privilege' Valea Technology & Law 1 nd http://valea.episerverhosting.com/Global/Dokument/Nyheter/Professors%20privilege.pdf (accessed 20 December 2013)

University of California Berkeley 'Socially responsible licensing and IP management' nd http://ipira.berkeley.edu/socially-responsible-licensing-ip-management (accessed 23 March 2014)

University of Oxford 'Access to essential medicines in the developing world' 10 December 2010 http://www.admin.ox.ac.uk/researchsupport/integrity/access/ (accessed 27 September 2014)

Van der Wolf, M 'Africa's pharmaceutical industry faces numerous challenges' 10 May 2013 http://www.voanews.com/content/challenges-ahead-for-africas-phamaceutical-industry/1658686.html (accessed 27 December 2013)

Von Braun, J 'Use of compulsory licenses selected national experiences' nd http://unctad.org/Sections/dite_totip/docs/tot_ip_0018_en.pdf (accessed 13 October 2013)

Walsh, JP 'The patenting of research tools and biomedical innovations' prepared for the Science, Technology and Economic Policy Board of the National Academy of Sciences 09 October 2000 http://www.iatp.org/files/Patenting_of_Research_Tools_and_Biomedical_Inn.htm (accessed 17 March 2013)

Zhao, F 'Opportunities and challenges: African pharmaceutical sector' 25 December 2013 http://www.hha-online.org/hso/system/files/3zhao_pharmaceutical_sector__africa_value_for_money_tunis.pdf (accessed 01 August 2014)

Zuhn, D 'Senator Leahy urges NIH to use march-in rights on Myriad BRCA test' 17 July 2013 http://www.patentdocs.org/2013/07/senator-leahy-urges-nih-to-use-march-in-rights-on-myriad-brca-test.html (accessed 22 March 2024)

Newspapers

'African firms up for the fight' *African Business* 27 November 2012

'Border line drugs' *The Economist* 29 January 2004

Dell, S 'International collaboration in African research – who wins?' *University World News* 07 February 2014

Hermann, RM 'East African Community doubles efforts to boost local pharmaceutical manufacturing' *Intellectual Property Watch* 28 March 2013

‘Innovation’s golden goose’ *The Economist* 12 December 2002

J Whelan ‘Switzerland’s thriving pharmaceutical industry: high-altitude thinking’ *New Scientist* 6 May 2006

‘Local pharmaceutical companies need government support – Pharm. Ezekwesili’ *Pharmanews* 18 September 2013

Langlands, A ‘Research commercialisation is changing. Are you ready?’ *The Review* 2010 - 2011 7

Nagarajan, R ‘Scientists fume over new patent bill*’ Times of India* 22 January 2010 (accessed 04 July 2010)

Ramesh, R ‘NHS fares best on free access to healthcare’ *The Guardian* 19 November 2010

Rosenberg, T ‘Prizes with an eye towards the future’ *The New York Times* 29 February 2012

‘Swedish healthcare: all you need to know’ *The Local Sweden’s news in English* 27 March 2013

‘The trouble with cheap drugs’ *The Economist* 29 January 2004

Worstall, T ‘You can’t have free trade and price controls: Pharmaceutical Drugs Edition’ *Forbes* 23 June 2012

Presentations

Baker, B ‘Economics of the pharmaceutical industry’ paper presented during the 2011 IP and access to medicines short course at the University of KwaZulu-Natal

Barnett, J ‘Technology transfer license negotiation’ paper presented at the 2014 SARIMA Conference in Botswana 6 - 10 July 2014

Berry, RS ‘Is electronic publishing being used in the best interests of science? The scientist’s view’ paper presented at the Second Conference on Electronic Publishing

in Science held in UNESCO House Paris, France 19 - 23 February 2001 http://www.mdpi.org/ijms/htm/i2030133.htm (accessed 15 November 2014)

Dahlstrand, A 'Is the commercialisation of European R&D weak? A critical assessment of the dominant belief and associated policy responses' paper presented at the Birkbeck Workshop on 'Intellectual property and university entrepreneurship' 19 April 2013

Jennings, R 'Adventures in knowledge transfer' paper presented at PraxisUnico Annual Conference on Inspiring Futures in Nottingham 13 June 2013

Thesis

Harvey, K 'Managing the exploitation of intellectual property: An analysis of policy and practice in nine UK universities' unpublished PhD thesis, University of Sterling 1992 2 - 3

Websites

http://bolarpharm.com/ (accessed 30 December 2013)

http://circ.ahajournals.org/content/99/1/168.full (accessed 11 December 2014)

http://essentialinventions.org/ (accessed 22 October 2013)

http://knowledgecommission.gov.in/ (accessed 24 August 2013)

http://quod.lib.umich.edu/l/lincoln/lincoln3/1:87?rgn=div1;view=fulltext (accessed 02 March 2013)

http://sparc.arl.org/advocacy/national/frpaa (accessed 22 September 2013)

http://sparc.arl.org/advocacy/national/frpaa (accessed 22 September 2013)

http://www.abrahamlincolnonline.org/lincoln/education/patent.htm (accessed 02 March 2013)

http://www.indexmundi.com/namibia/ (accessed 26 December 2015)

http://www.s-ge.com/global/invest/en/content/switzerland-pharmaceutical-hub-key-points-glance accessed (3 December 2015)

http://www.arc.agric.za/Agricultural%20Sector%20News/Groundbreaking%20drought-tolerant%20maize%20hybrids%20launched.pdf (accessed 14 December 2014)

http://www.century-of-flight.net/Aviation%20history/WW2/radar%20in%20world%20war%20two.htm (accessed 13 November 2012)

http://www.dndi.org/about-us/overview-dndi.html (accessed 22 February 2014)

http://www.dndi.org/about-us/overview-dndi/vision-mission.html (accessed 06 September 2014)

http://www.dndi.org/donors/donors.html#Private%20Foundations%20&%20Private%20Individual%20Donors (accessed 22 February 2014)

http://www.doug-long.com/bush.htm (accessed 13 August 2012)

http://www.emzorpharma.com/index.php/our-company (accessed 30 December 2013)

http://www.evansmedicalplc.com/ (accessed 30 December 2013)

http://www.gavi.org/ (accessed 06 September 2014)

http://www.healthinfonet.ecu.edu.au/uploads/funding/258_trf_application_pack.pdf (accessed 22 February 2014)

http://www.kemri-wellcome.org/index.php/en/about (accessed 21 May 2014)

http://www.life-enhancement.com/magazine/article/972-stifle-hunger-with-hoodia (accessed 29 September 2014)

http://www.malariavaccine.org/about-overview.php (accessed 20 August 2014)

http://www.nih.gov/about/budget.htm (accessed 07 January 2014)

http://www.nimr.mrc.ac.uk/about/funding/ (accessed 07 January 2014)

http://www.rcuk.ac.uk/research/Pages/outputs.aspx (accessed 18 December 2013)

http://worldpopulationreview.com/countries/kenya-population/ (accessed 23 December 2015)

http://www.worldbank.org/en/country/kenya (accessed 23 December 2015)

http://www.researchinfonet.org/publish/finch/ (accessed 18 December 2013)

http://www.shenlaw.com/en/pat_lic_impr.htm (accessed 10 August 2014)

http://www.taxpolicycenter.org/briefing-book/background/numbers/revenue.cfm (accessed 21 April 2013)

http://www.tballiance.org/ (accessed 06 September 2014)

http://www0.sun.ac.za/research/thrip (accessed 28 August 2014)

http://agro-hub.com/general/asserting-cameroon-as-africa-in-miniature/#.Vne57RXRKko (accessed 21 December 2015)

https://www.cia.gov/library/publications/the-world-factbook/geos/print_cm.html 9accessed 19 December 2015)

https://challenge.gov/p/about (accessed 10 July 2014)

https://ipo.llnl.gov/data/assets/docs/TechTransfer.pdf (accessed 10 August 2012)

https://www.thedti.gov.za/financial_assistance/financial_incentive.jsp?id=52&subthemeid=1 (accessed 28 August 2014)

www.sahealthinfo.co.za/traditionalmeds/traditionalpart2.pdf (accessed 06 September 2014)

www.wto.org/english/thewto_e/acc_e/members_brief_e.doc (accessed 28 May 2014)

Interviews and letters

Discussion between researcher and James Love, Director of Knowledge Ecology International

Interview between researcher and D Jungmann (Intellectual Property Programme Coordinator at the National Confederation of Industry in Brazil) held on 21 November 2013

Letter by E Guillen to Dr Boni Mehlomakulu, Deputy Director-General: Research, Development and Innovation, Department of Science and Technology on 11 August 2009

Letter by S Pitroda, Chairman of the National Knowledge Commission, to the Prime Minster 16 January 2007 http://knowledgecommissionarchive.nic.in/downloads/recommendations/LegislationPM.pdf (accessed 24 August 2013)

Skype communication between researcher and R Jennings on 23 September and 12 November 2013