

A Barratt

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## Lessons from Bayh-Dole: Reflections on the *Intellectual Property Rights from Publicly Financed Research and Development Act*

### Summary

The *Intellectual Property Rights from Publicly Financed Research and Development Act* 51 of 2008 promotes patenting and commercialisation of state-funded science. The Act is similar in scope and objective to the American *Bayh-Dole Act*. This article explores some of the problems created or exacerbated by the *Bayh-Dole Act*. Traditionally, American innovation was based on a philosophy of open science. Universities conducted basic foundational research which was freely available to others who wanted to commercialise and build on it, or use it for further scientific research. The *Bayh-Dole Act* changed the model of science to a proprietary model. One of the problems this created was increased patenting of foundational research tools such as genes and cell-lines, which follow-on researchers require for their own research. Sometimes, research has been blocked or impeded by an inability to obtain research licences to patented research on reasonable terms. The Act has also had a negative effect on scientific collaboration and publishing. The article examines whether South Africa's *Intellectual Property Rights from Publicly Financed Research and Development Act* has been able to avoid the most serious of the Bayh-Dole pitfalls.

### Lesse uit Bayh-Dole: Gedagtes oor *Wet* 51 van 2008

*Wet* 51 van 2008 bevorder die patentering en kommersialisering van die wetenskap wat met publieke fondse bedryf word. Wat betref sy omvang en oogmerke lyk die *Wet* soortgelyk aan die Amerikaanse *Bayh-Dole Wet*. Hierdie bydrae verken sommige van die probleme wat geskep is of versterk word deur die *Bayh-Dole Wet*. In Amerika is innovering tradisioneel gebaseer op die sogenaamde 'open science'-filosofie. Die grondliggende navorsing wat by universiteite bedryf is, was vryelik beskikbaar vir diegene wat dit in die handelswese wou gebruik, of daarop wou voortbou, of dit wou gebruik vir verdere wetenskaplike navorsing. Die *Bayh-Dole Wet* omskep hierdie wetenskaplike model in 'n eiendomsregtelike model. Een van die probleme wat hierdeur veroorsaak is, is die toename in patentering van basiese navorsingsmiddels, soos gene en sellines. Navorsers in die navolging vereis sulke middels vir hul eie navorsing. Soms word sulke navorsing belemmer deur die onvermoë van die navorsers om lisensies te verkry om gepatenteerde navorsing op redelike terme te kan gebruik. Die *Wet* het ook 'n negatiewe impak op wetenskaplike samewerking en publikasie van navorsing gehad. Hierdie bydrae ondersoek of *Wet* 51 van 2008 die ernstigste van die Bayh-Dole valstrikke vermy.

## 1. Introduction

The *Intellectual Property Rights from Publicly Financed Research and Development Act*<sup>1</sup> (*IPR Act*) came into operation in August 2010.<sup>2</sup> The *Act* promotes patenting of scientific findings that result from publicly financed research at universities and other state-funded research institutions. The underlying motivations for the *Act* are to encourage commercialisation of university research, increase the overall number of patents awarded to South Africans, and in this way promote South Africa's innovation economy.<sup>3</sup>

These aspirations were set out by the Department of Science and Technology in several documents preceding the *Act*'s adoption.<sup>4</sup> For example, the Department's *Ten Year Plan for Innovation* envisages South Africa's transformation to a "knowledge-based economy".<sup>5</sup> It identifies sectors (such as the pharmaceutical and biotechnology sectors) as potential growth areas for South African research and development,<sup>6</sup> and envisages South Africa as a leading international player in these sectors by 2018.<sup>7</sup> At present, an impediment to achieving these goals is South Africa's failure to "convert ideas into economic growth",<sup>8</sup> and the *Plan* emphasises the need to identify scientific research that could be commercialised so as to ensure that South African scientific and technological innovation is used to acquire "a more competitive foothold in the global economy".<sup>9</sup>

The Department's 2006 *Intellectual Property Rights and Publicly Financed Research Policy Document*<sup>10</sup> (*Policy Document*) sets out a framework for achieving these aims in the context of publicly financed research. The *Policy Document* identifies intellectual property protection (primarily patent protection)<sup>11</sup> as an important "basis for competitiveness and economic growth".<sup>12</sup> At present, South Africa has a very low rate of patenting,<sup>13</sup> and is therefore "falling behind in this important aspect of the knowledge economy".<sup>14</sup> The *Policy Document* expresses particular concern with low patenting rates of publicly financed research conducted at universities and state research agencies.<sup>15</sup> Compared to their counterparts in developed countries, South African academic scientists have very low patenting rates relative to the

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1 Act 51/2008.

2 Proclamation 34, 2010 (*Government Gazette* 33422).

3 See Visser 2007:363-4; Geyer *et al.* 2008:621-622.

4 See, for example, South Africa. Department of Science and Technology 2007; 2006 and 2002.

5 Dept of Science and Technology 2007:4.

6 Dept of Science and Technology 2007:10.

7 Dept of Science and Technology 2007:4.

8 Dept of Science and Technology 2007:5.

9 Dept of Science and Technology 2007:21.

10 Dept of Science and Technology 2006.

11 Dept of Science and Technology 2006:9.

12 Dept of Science and Technology 2006:5.

13 Dept of Science and Technology 2006:11-16, comparing the number of patents awarded to South Africans compared to those awarded to leading patenting countries.

14 Dept of Science and Technology 2006:5.

15 Dept of Science and Technology 2006:17.

number of articles they publish in the open literature.<sup>16</sup> This implies that, while they are doing the research and making important discoveries,<sup>17</sup> they are failing to patent and commercialise their inventions.<sup>18</sup> This failure to patent “directly and negatively” impacts on South Africa’s ability to be “effective in key areas of the knowledge economy”.<sup>19</sup>

Having identified “failure to patent” as a problem, the *Policy Document* sets out a framework to promote “the protection and commercialisation of IP derived from publicly funded research”.<sup>20</sup> The framework is directed at making academic scientists (and their institutions) aware of the importance of patent protection,<sup>21</sup> and to incentivise patenting by ensuring that both inventors and their institutions receive some of economic returns on patents.<sup>22</sup> The *Policy Document* recommends that inventors and institutions be required to disclose all inventions that are potentially patentable,<sup>23</sup> and that institutions be required to establish institutional machinery to manage reporting of inventions and securing of patents.<sup>24</sup>

While the *Policy Document* is clearly motivated by the “imperative to secure patents arising from publicly funded research”,<sup>25</sup> the drafters appear to be mindful of some of the potential pitfalls associated with university patenting. For example, the drafters recognise that scientific invention is cumulative and that “new inventions are often based on substantial background intellectual property”.<sup>26</sup> Because university research is often basic and foundational,<sup>27</sup> patenting of university research may impede important follow-on research.<sup>28</sup> The *Policy Document* also recognises that patenting can sometimes have negative social consequences – for example, patenting of pharmaceuticals may make medicines less affordable,<sup>29</sup> which might impede state efforts to combat epidemics such as HIV-AIDS.<sup>30</sup> The *Policy Document* thus also suggests measures that could ameliorate some of the pitfalls of university

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16 South African academics secure patents at 25 per cent of the rate of their peers in developed countries (Dept of Science and Technology 2006:10).

17 See Kaplan 2009:6, noting that publication rates of South African university-based scientists have increased since 1994, but that South Africa’s global share of all academic publications in science dropped significantly during the period 1994-2001. Sibanda (2009:131) concludes that these statistics suggest a “stagnant research output” from South African institutions.

18 Dept of Science and Technology 2006:5.

19 Dept of Science and Technology 2006:10.

20 Dept of Science and Technology 2006:27.

21 Dept of Science and Technology 2006:8.

22 Dept of Science and Technology 2006:33.

23 Dept of Science and Technology 2006:32.

24 Dept of Science and Technology 2006:33, 39 and 44.

25 Dept of Science and Technology 2006:8.

26 Dept of Science and Technology 2006:68.

27 Dept of Science and Technology 2006:4.

28 See section 5 of this article.

29 See Gifford 2004:85.

30 See Dept of Science and Technology 2006:39.

patenting, such as government “walk-in rights”<sup>31</sup> and a preference for non-exclusive licensing.<sup>32</sup>

The *Policy Document* refers explicitly to the American *Bayh-Dole Act* 1980.<sup>33</sup> The South African intellectual property policy has clearly been inspired by the Bayh-Dole model,<sup>34</sup> and the new South African legislation is similar to the *Bayh-Dole Act* in its scope and objectives. It appears, however, that the framers of the *Act* have been mindful of some of the potential dangers of “proprietary science”<sup>35</sup> and have included some important safeguards against these.

The *Bayh-Dole Act* has now been in force for 30 years. The effects and consequences of the *Act* have been the focus of an enormous volume of academic research and commentary.<sup>36</sup> The *Bayh-Dole Act* is thus a very useful case study for examining potential dangers associated with patenting of university science and the problems created by ‘proprietary science’ more generally. This article presents an overview of the American experience and discusses some of the problems apparently caused or exacerbated by Bayh-Dole. It then considers whether the South African legislation contains strong enough safeguards to avoid similar problems when implementing the *IPR Act*.

## 2. *The Intellectual Property Rights from Publicly Financed Research and Development Act* 51 of 2008

The stated object of the *IPR Act* is:

[T]o make provision that intellectual property emanating from publicly financed research and development is identified, protected, utilised and commercialised for the benefit of the people of the Republic, whether it be for a social, economic, military or any other benefit.<sup>37</sup>

The *Act* provides legislative implementation of the policies set out in the Department of Science and Technology’s *Policy Document*.<sup>38</sup> The Regulations promulgated in terms of the *Act* in August 2010<sup>39</sup> provide more detail on methods of implementation, and are very useful for understanding both the practical implications and the underlying objectives of the *Act*.

31 Dept of Science and Technology 2006:38-39. For example, the Government can “use patents in the national interest” in times of “national emergency” (Dept of Science and Technology 2006:29).

32 Dept of Science and Technology 2006:35-36.

33 *University and Small Business Patent Procedure Act* of 1980 (codified as amended at 35 USC §§200-212 (2000)) [*Bayh-Dole Act*]. See Dept of Science and Technology 2006:26-28.

34 See Graff 2007:191, concluding that South Africa’s *IPR Act* is an attempt to “emulate Bayh-Dole”.

35 Proprietary science means that research is ‘owned’ through patenting, and use of patented research is restricted to patent-owners or licensees.

36 See, for example, the references in the section on the *Bayh-Dole Act* below.

37 Section 1.

38 Dept of Science and Technology 2006.

39 Dept of Science and Technology 2010.

## 2.1 The National Intellectual Property Management Office (NIMPO)

The *Act* establishes a new national agency, the National Intellectual Property Management Office<sup>40</sup> (NIMPO) to oversee intellectual property emanating from state-funded institutions and to “promote the objects” of the *IPR Act*.<sup>41</sup> Specific functions allocated to NIMPO will be discussed in context below.

## 2.2 Identification, disclosure, protection, and commercialisation

The *Act* has similar objectives to the *Bayh-Dole Act*: promoting patenting and commercialisation of state-funded research. Like Bayh-Dole, it promotes such patenting by providing that the scientists whose work led to creation of the intellectual property, as well as the institutions that employ them, should receive a portion of the financial benefits accruing from protected intellectual property.<sup>42</sup> The *Act* further promotes patenting and commercialisation by requiring institutions to identify and disclose potential intellectual property, and to patent and commercialise it unless alternative arrangements are made. But while the *Act* strongly encourages patenting and commercialisation, it also contains a number of provisions whereby institutions can avoid commercial patenting. Furthermore, it expressly retains state ‘walk-in rights’ to intellectual property developed by means of state funding. These provisions are described in the following paragraphs. The potential difficulties arising from patenting of state-funded science, as well as the importance of the opt-out provisions, will be discussed in the following sections of the article.

The *Act* requires South African universities and other ‘recipients’ of state funding (defined as any person, including a juristic person, which undertakes state-funded research)<sup>43</sup> to identify research outputs that are suitable for intellectual property protection, (particularly patent protection), and ensure that steps are taken for adequate protection.<sup>44</sup> “Intellectual property” is broadly defined in section 1 as:

[A]ny creation of the mind that is capable of being protected by law from use by any other person, whether in terms of South African law or foreign intellectual property law, and includes any rights in such creation, but excludes copyrighted works such as a thesis, dissertation, article, handbook or any other publication which, in the ordinary course of business, is associated with conventional academic work.<sup>45</sup>

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40 Section 8.

41 Section 8(1).

42 Sections 10(2)(a) and 10(2)(b).

43 Act 51/2008:section 1.

44 See the discussion on sections 5-7 below.

45 Section 1. For discussion on possible difficulties that arise from this definition, see section 6.

Section 5(1) sets out a number of obligations. Universities, and other recipients of state funding must set up appropriate mechanisms for “identification, protection, development, and management” of intellectual property and intellectual property transactions,<sup>46</sup> and must also establish mechanisms for commercialisation of this intellectual property where applicable.<sup>47</sup> They must provide “effective and practical” procedures for disclosure of inventions that might be suitable for intellectual property protection,<sup>48</sup> and ensure that researchers do indeed disclose inventions to their parent institutions within 90 days of identifying potential intellectual property.<sup>49</sup> Institutions should ensure that this intellectual property is adequately protected before the research is made public (for example, through publication in academic literature).<sup>50</sup>

Institutions are obliged to assess research to determine whether it merits intellectual property protection, and where appropriate, to apply for such protection.<sup>51</sup> If institutions decide not to obtain intellectual property protection, they must refer the matter to NIMPO within 30 days.<sup>52</sup> Institutions are obliged to report to NIMPO twice a year on “all matters pertaining to intellectual property contemplated in this Act”, including “the intellectual property for which it elects to obtain statutory protection and the state of commercialisation thereof”.<sup>53</sup> Where institutions have not commercialised the intellectual property, they must provide NIMPO with full reasons for this failure.<sup>54</sup>

It is clear that the *Act* places significant obligations on institutions to identify and disclose potential intellectual property arising from state-funded research. Furthermore, it appears that the ‘default position’ is that this intellectual property must be patented and commercialised. However, patenting and commercialisation are not necessarily absolutely compulsory. The *Act* also provides a very important “choice in respect of intellectual property”,<sup>55</sup> as discussed below.

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46 Section 5(1)(a).

47 Section 5(1)(a).

48 Section 5(1)(b).

49 Section 5(1)(c).

50 Sections 5(1)(c) and 5(1)(b). If research is published before inventions are protected, this might undermine the possibility of successfully obtaining patent protection (Sibanda 2007:i). The implications of the potentially ‘chilling effect’ that this rule might have on academic publication is discussed in more detail below.

51 Section 5(1)(d).

52 Section 5(1)(e).

53 Section 5(1)(h).

54 Section 5(1)(i). The processes of identification, disclosure, commercialisation and reporting by research institutions are to be performed and managed by “offices of technology transfer” at each institution (section 6(2); section 7). The *Act* obliges research institutions to establish offices of technology transfer (staffed by “appropriately qualified” personnel) within 12 months of the *Act*’s commencement (section 6(1)). Alternatively, two or more institution can establish regional offices of technology transfer, with the concurrence of NIMPO (section 6(3)). Offices will be expensive to staff and run, and regional offices might be a cost-effective option (see Sibanda 2009:138).

55 Section 4.

Section 4(2) provides that institutions may elect *not* to obtain patent protection for their discoveries and inventions.<sup>56</sup> Should they decide not to obtain such protection, they must notify NIMPO and provide reasons for their decision.<sup>57</sup> The Regulations made in terms of the *Act* suggest that acceptable reasons for deciding not to patent research might include the possibility that patent protection “is likely to undermine the socio-economic needs of the Republic”,<sup>58</sup> or that the institution “wishes to place such intellectual property in the public domain”.<sup>59</sup> Section 4(2) and the quoted regulations are very significant because they demonstrate an awareness of the potential dangers of proprietary science, and a desire to avoid them. The importance of this ‘opt-out’ provision is discussed in more detail in the following sections of the article.

Section 4(3) provides that where institutions elect not to obtain intellectual property protection, NIMPO can “acquire ownership in the intellectual property and, where applicable, obtain statutory protection for the intellectual property”.<sup>60</sup> Should NIMPO take assignment in terms of section 4(3), it must award the initial inventors “an irrevocable, non-transferrable, and royalty-free licence to use the intellectual property for research, development and educational purposes” and may also grant such licences to other publicly funded South African research institutions.<sup>61</sup> These regulations are interesting both because they clearly try to ensure that follow-on research is not impeded by NIMPO’s intellectual property rights in the research, but also because they suggest that follow-on research by publicly funded research institutions requires a licence where the research has been patented.<sup>62</sup>

The *Act* provides that private entities can become “exclusive licensees” of patents emanating from publicly funded research provided that they have “the capacity to manage and commercialise the intellectual property in a manner that benefits the Republic”.<sup>63</sup> As a rule, however, patent-holders under the *Act* must give preference to non-exclusive licensing.<sup>64</sup> Furthermore, every licence must provide the State with “an irrevocable and royalty-free licence authorising the State to use ... the intellectual property ... for the health, security and emergency needs of the Republic” or to authorise others in such use.<sup>65</sup> This provision is particularly important in the context of pharmacological research and the microbiological research which supports it. Successful development

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56 Section 4(2).

57 Section 4(2)(b).

58 Regulation 2(1)(c). See discussion below on how patenting of research tools might impede research into essential medicines.

59 Regulation 2(4)(c). The ‘public domain’ comprises the knowledge, inventions and products of creation that are free from intellectual property protection and thus open and available for other potential innovators and creators to use. See discussions of the concept ‘public domain’ by contributors to Boyle 2003.

60 Section 4(3).

61 Regulations 2(12)(b) and 2(12)(c).

62 This is discussed in more detail in the following sections of the article.

63 Section 15(1).

64 Section 11(1)(a).

65 Section 11(1)(e).

of new drugs is notoriously expensive<sup>66</sup> and commercial companies might be reluctant to do this without an exclusive licence. In this situation, the possibility of patenting and licensing of state-funded research has obvious advantages – it promotes the technological development of essential medicines. Under these circumstances, the government walk-in rights will make it possible for the state to authorise manufacture of generic versions of essential medicines for distribution to the poor.<sup>67</sup>

### 2.3 Costs of intellectual property protection and other assistance from the state

The state is to assist institutions to implement the *Act* and obtain the necessary patents by providing financial support where this is necessary to obtain and maintain statutory protection.<sup>68</sup> Through NIMPO, the state must assist and advise institutions in implementing the *Act*<sup>69</sup> and particularly in establishing offices of technology transfer,<sup>70</sup> intellectual property transactions,<sup>71</sup> and commercialisation of intellectual property.<sup>72</sup>

## 3. Before Bayh-Dole: The United States as an example of an open-science model for university research

United States policy following World War II was heavily influenced by a policy document drawn up by Prof. Vannevar Bush. According to Bush, university-based scientists engaged in pursuit of scientific knowledge and understanding for its own sake are often motivated by sheer curiosity.<sup>73</sup> They were primarily interested in furthering the boundaries of knowledge rather than practical applications of this knowledge.<sup>74</sup> Sometimes this pursuit of “pure knowledge” resulted in “practical payoffs”, but these practical applications

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66 In the United States, for example, it has been estimated that it costs about US\$800 million to bring a new drug on to the market (Barratt 2010:9).

67 See the discussion on the importance of compulsory licensing and generic drugs in the context of state provision of essential medicines in Barratt 2010:5-6. The Dept of Science and Technology's *Policy Document* suggests that where government-funded health care inventions have been patented, licensees should be required to identify generic manufacturers to produce reasonably priced medicines for a segment of the market (Dept of Science and Technology 2006:39).

68 Section 13(2)(a).

69 Section 9(4)(c).

70 Section 9(4)(c)(i).

71 Section 9(4)(c)(ii).

72 Section 9(4)(c)(iii).

73 “Basic research is performed without thought of practical ends” (Bush 1945:13).

74 However, basic scientific research is often conducted in “Pasteur’s Quadrant” (Stokes 1997:73). “Pasteur’s Quadrant” is defined as “use-inspired basic research” which involves both a “quest for fundamental understanding” and “considerations of [practical] use” (Stokes 1997:73).



were unpredictable and serendipitous, and this made pure scientific inquiry too risky as a commercial venture.<sup>75</sup>

Foundational scientific research, or “pure science”, was regarded as having very little direct commercial potential but as indispensable for follow-on research in applied science and technological development.<sup>76</sup> However, because technological advancement is based on pure and fundamental science, Bush concluded that pure science should be given generous state funding,<sup>77</sup> and that results of research conducted at universities should be freely available to other scientists. Indeed, Bush stressed that scientific findings should be disseminated as widely as possible so that other scientists and potential technological innovators could draw upon it freely.<sup>78</sup>

Bush’s policy document shaped the model of United States research and development for more than 30 years: university science was state-funded and openly available to all. This was a major contributor to American technological progress.<sup>79</sup>

This open-science model has many advantages. Scientific knowledge and technological progress is always cumulative and evolutionary.<sup>80</sup> The process of scientific discovery works best when many scientists are working in a field, evaluating, testing and critiquing one another’s work and results, building on one another’s research, and furthering the boundaries of reliable knowledge.<sup>81</sup> The scientific process is thus most efficient and effective when scientists have unfettered access to one another’s work: “keeping science open is the most effective policy for enabling the public to draw practical benefits from it”.<sup>82</sup>

As publicly supported institutions of higher learning, universities have traditionally been core to fostering “pure” research and disseminating new knowledge to the broader scientific and technological community.<sup>83</sup> Even when university scientists developed applied technologies or engaged in basic research with potential technological application, university research was freely available to others so as to ensure maximum participation in research and development by as many scientists as possible.<sup>84</sup>

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75 Bush 1945:9-10.

76 See, for example, Bush 1945:10; Geuna & Nesta 2006:790; Mukherjee & Stern 2009:449.

77 Bush 1945:10-11. The continuing importance of state funding for basic foundational research has been confirmed by recent studies such as Cockburn & Stern 2010.

78 Bush 1945:24.

79 See Stokes 1997 generally.

80 Merges & Nelson 1990:872; Mukherjee & Stern 2009:449. See also Nelson 2004:458 for an overview of “empirically orientated scholarly accounts” of technological progress.

81 Nelson 2004:456; Cockburn & Stern 2010:32.

82 Nelson 2004:456.

83 Heller & Eisenberg 1998:698.

84 Nelson 2004:456. In practice, South African university scientists have tended not to patent their research (see statistics in Sibanda 2009:116-126; Sibanda 2007:6-35; Dept of Science and Technology 2006:11-18). As the Dept of Science and Technology *Policy Document* points out, as a result, this knowledge is “made available to the whole world in the form of publication ...” (Dept of Science and

Since the early 1980s, however, there has been a trend to privatise this “scientific commons”.<sup>85</sup> This could have negative effects on both pure science itself and on the technological innovation which draws upon it.<sup>86</sup>

#### 4. The *Bayh-Dole Act*

In 1980, the United States Congress passed the *Bayh-Dole Act*,<sup>87</sup> which encouraged universities to take out patents on their research results even if research had been supported by government funding.<sup>88</sup> The *Act* was motivated by the belief that universities should be sources of innovation that would contribute to the growth of the American economy and enhance America’s global competitiveness.<sup>89</sup> The rationale behind the *Act* was that private-sector commercial companies were more likely than universities to develop pure research into practical and commercially viable products but, given the risks and expense involved, they were likely to do this only if they had exclusive licences.<sup>90</sup> Universities would be able to award such licences if they could control access to their research through patents.<sup>91</sup>

It appears that the *Act* has encouraged disclosure of potentially patentable research as well as actual patenting by university scientists. Between 1991 and 2000, leading American research universities reported an 84 per cent increase in research disclosures of this kind.<sup>92</sup> Universities also reported a 238 per cent rise in patent applications during this ten-year period, a 161 per cent increase in licence agreements, and a 520 per cent increase in royalties from university-held patents.<sup>93</sup> In the 30 years since the *Bayh-Dole Act* was passed, the number of patents filed by American universities has increased a hundredfold. The apparent success of the *Bayh-Dole Act* has inspired similar

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Technology 2006:31). See also Sibanda 2009:136, noting that knowledge and technologies developed at universities are transferred to the private sector in a number of ways that do not involve patenting. These include “training of graduates and students, publications, consulting and contract research”.

85 The scientific commons is the scientific knowledge that is free from intellectual property or other restrictions and is open and available for other scientists and innovators to use (see Nelson 2004:455). The terms “commons” and “public domain” can be used interchangeably (see Boyle 2003).

86 Nelson 2004:455.

87 *University and Small Business Patent Procedure Act* of 1980 [codified as amended at 35 USC §§ 200-212 (2000)] (*Bayh-Dole Act*).

88 Eisenberg 2001:226; Mowery & Sampat 2005:228.

89 Kenny & Patton 2009:1408.

90 United Kingdom. Commission on Intellectual Property Rights 2002:123; Garde 2005:254-255. As noted above, the *IPR Act* favours non-exclusive licensing (section 11(1)(a)), but the regulations also make provision for exclusive licensing (regulations 2(12)(b) & 2(12)(c)).

91 Arnold & Ogielska-Zei 2002:429.

92 Thursby & Thursby 2003:1052.

93 Thursby & Thursby 2003:1052; Williamson 2001:672; Jaffe 2000:540.

legislation in many other countries, including Japan,<sup>94</sup> China,<sup>95</sup> India,<sup>96</sup> Brazil,<sup>97</sup> all European countries except Ireland,<sup>98</sup> and now South Africa.<sup>99</sup>

Many economists and scientists, however, have expressed concern about some of the unintended consequences of the *Bayh-Dole Act*.<sup>100</sup> Economist Richard Nelson, for example, has concluded that patenting of university science has sometimes impeded follow-on research and might have constrained rather than promoted scientific progress and economic development.<sup>101</sup> Nelson is not opposed to university patenting where commercialisation is necessary to promote technological development.<sup>102</sup> However, he warns against potential negative effects that university patents may have on traditional models of scientific progress.<sup>103</sup> Some of the dangers of proprietary science are discussed in the next section.

## 5. Problems arising from the proprietary science model in the United States

The *Bayh-Dole Act* changed the model of science in the United States. Rather than the 'open science' model proposed by Vannevar Bush (and followed in the United States for many years), there is now an assumption of 'proprietary science' – that is, a model characterised by ownership and restriction of scientific findings through patents and commercialisation.

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94 Loewenberg 2009:91.

95 United Kingdom. Commission on Intellectual Property Rights 2002:123.

96 United Kingdom. Commission on Intellectual Property Rights 2002:123. A 2008 Bill (Protection and Utilization of Publicly Funded Intellectual Property Bill, 2008) is modelled very closely on the *Bayh-Dole Act*. (Financial Express (India) Staff Writer 2010:2; Sampat 2009:1). The Bill is still "pending" according to India Parliament, <http://www.parliamentofindia.nic.in/> (accessed in February 2011).

97 Ryan 2010:1990.

98 Dept of Science and Technology 2006:26. See Geuna & Nesta 2006 for a discussion of the situation in Europe generally. For discussions on specific European countries, see for France (Forero-Pineda 2006:817); for Germany (Loewenberg 2009:91), and for Italy (Baldini 2009:1218).

99 The number of patents filed by universities and other publicly funded research institutions has also increased dramatically in other countries following the passage of Bayh-Dole-type legislation (Geuna & Nesta 2006:792-793, examining the European context). In developing countries, this increase in university patenting has sometimes dramatically increased the total number of patents awarded in the countries concerned (United Kingdom. Commission on Intellectual Property Rights 2002:123).

100 See, in particular, Eisenberg 2001; Kapczynski *et al.* 2005.

101 Nelson 2004:455.

102 Nelson 2004:468. Nelson and other writers point out, however, that university research has often been developed by the private sector even when it was freely available in the public domain and there was no possibility of exclusive licensing. See Nelson 2004:467-468; Kenny & Patton 2009:1409; Sampat 2009:4.

103 Nelson 2004:468. See discussion below.

University patenting has increased dramatically since the *Bayh-Dole Act* came into operation.<sup>104</sup> Previously, the majority of the inventions, methodologies, tools, and materials produced at universities and similar research institutions would have been made available without patent restrictions.<sup>105</sup>

The paradox of patenting is that patents both stimulate and deter innovation.<sup>106</sup> Because of the evolutionary nature of scientific and technological progress,<sup>107</sup> all patents have an inherent tendency to slow follow-on research and development. As explained by Maskin, strengthening intellectual property protection has two important impacts. As a direct effect it will encourage more innovation: “If I am going to be rewarded with a longer or broader patent whenever I discover something, I will have correspondingly more incentive to try to make such a discovery”.<sup>108</sup> However, there is also an indirect effect: to deter innovation by others:<sup>109</sup>

If the property right you have to your invention is strengthened, you will then have more monopoly power over me if I try to use your invention to make one of my own. In other words, it will now be more expensive for me to innovate, and so I have less incentive to do it.<sup>110</sup>

Some of the problems arising from the proprietary science model based on patenting are discussed below.

## 5.1 Rise in patenting of basic research tools

Intellectual property protection of ‘upstream’ research may make it more difficult for follow-on researchers to improve and build on patented science and technology.<sup>111</sup> For example, ‘downstream’ researchers may require licenses from those holding patents to existing research, and this might make follow-on research prohibitively expensive – or even impossible, if necessary licences are withheld.<sup>112</sup>

Traditionally, universities did not patent their research, and thus university research findings were freely available to all follow-on researchers. This was particularly important in light of the traditional nature of university research – traditionally, much university research focused on basic foundational science.

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104 Williamson 2001:672; Jaffe 2000:540; Thursby & Thursby 2003:1052.

105 Nelson 2004:468; Eisenberg 2001:226; Mowery & Sampat 2005:228; Dreyfuss 2006:1566.

106 Gervais 1998:65.

107 Scotchmer 1991.

108 Maskin 2005:139.

109 Maskin 2005:139.

110 Maskin 2005:139. See also Kaplan 2009:3, commenting that the large number of patents filed by commercial companies at the South African Companies and Intellectual Property Registration Office (CIPRO) “could serve to discourage innovators”.

111 See, for example, Scotchmer 1991. For an empirical study concluding that patents impede follow-on innovation, see O’Donoghue *et al.* 1998 generally.

112 Encaoua *et al.* 2006:1429, noting that patents can sometimes completely block certain avenues of research.

Good examples of foundational science needed by those conducting follow-on research and technological application is genetics research such as gene sequencing, identification of gene mutations, and isolation of particular genes and gene fragments. Modern biomedical and pharmaceutical research relies on the use of genes, proteins and fragments. For example, understanding genes and gene fragments helps pharmacological researchers to identify the most promising targets at a cellular level,<sup>113</sup> to identify compounds for use in new pharmaceutical remedies, and to tinker with the structures of the most promising compounds to make them optimally effective.<sup>114</sup>

One problem with encouraging patents for university research is an increasing tendency to patent the foundational science that comprises the “research tools” which others need for their own research. Important examples of such research tools include genetic and proteomic materials and the tools used to isolate, manipulate and replicate these materials.<sup>115</sup> Genetic research tools are widely used in the pharmaceutical and biotechnical sectors, where sophisticated research tools have enabled scientists to make important breakthroughs.<sup>116</sup>

Traditionally, it was not possible to patent natural phenomena.<sup>117</sup> However, it is not always easy to distinguish between naturally occurring substances and those which have been invented by humans (and are thus potentially patentable). In a landmark 1911 case, the New York Supreme Court recognised a patent for purified human adrenalin as a “man-made substance”, holding that even though adrenalin occurs in the human body, it is never pure or distilled in its natural state; therefore, the distilled purified substance should be regarded as the result of human intervention, and patentable.<sup>118</sup>

This line of thinking has persisted in modern patent practice where patents have been granted on an increasingly wide range of biological materials, including isolated genes, receptors, and purified proteins on the grounds that since genes, receptors and proteins do not occur naturally in pure or isolated forms, modified genes, receptors or proteins are thus human-made

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113 For example, the BRCA genes linked to breast cancer (Kane 2007:329). See discussion below.

114 Berman & Dreyfuss 2006:885; Garde 2005.

115 Berman & Dreyfuss 2006:887. Internationally, the sectors with the highest concentration of university patents are the biotechnology and pharmacology sectors (Sibanda 2009:131). This is also true in South Africa (Sibanda 2009:131). During the period 1991-2005, at least 27 per cent of university patent applications were in the biotechnology sector (Sibanda 2007:30).

116 Arnold & Ogielska-Zei 2002:415. In South Africa, the Dept of Science and Technology has earmarked the biotechnology sector as an area of strength and has prioritised the sector in terms of funding (Dept of Science and Technology 2007:4 and 10).

117 See, for example, *Funk Brothers Seed Co v Kalo Inoculant Co* 333 US:442 (1948) where the United States Supreme Court held that a new combination of bacteria was “no more than a discovery of some of the handiwork of nature and hence ... not patentable”.

118 *Parke-Davis & Co v H K Mulford & Co* 189 F.95 (SDNY 1911).

and patentable.<sup>119</sup> In *Diamond v Chakrabarty*,<sup>120</sup> the United States Supreme Court held that, although it was not possible to patent “laws of nature, physical phenomena, and abstract ideas”, genetically engineered bacteria could be patented because they were the product of human ingenuity, and indeed the Court interpreted the term “patentable subject matter” to cover “everything under the sun made by man”.<sup>121</sup>

Since *Chakrabarty*, the United States Court of Appeals for the Federal Circuit (the special United States patent court) has demonstrated an “increasingly expansive (and controversial) interpretation of patentable subject matter ...”.<sup>122</sup> As a result, many essential research tools such as genes, proteins, or gene fragments have been successfully patented.<sup>123</sup>

## 5.2 Potential problems arising from research-tool patenting

Proprietary science might impede research by restricting access to necessary research tools and published information. The terms of licence agreements to patented research tools can significantly curtail scientists’ freedom to conduct research and share it with peers in the ways envisaged by Vannevar Bush in his *Endless Frontier* of science. This curtailment of the “public domain of science” presents significant obstacles to scientific progress, since “open

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119 See, for example, *Amgen Inc v Chugai Pharmaceutical Co Ltd* 927 F.2d 1200 (Fed Cir 1991).

120 *Diamond v Chakrabarty* 447 US 303 (1980).

121 *Diamond v Chakrabarty*:309-310.

122 Chin 2001:868. Recently, however, the USPTO has begun to reverse this trend by insisting on higher standards of utility and novelty. See the discussion on the University of Wisconsin patents on human embryonic cell-lines below. See also the discussion below on the BRCA patents, which have recently been overturned by the United States District Court.

123 Arnold & Ogielska-Zei 2002:420; Berman & Dreyfuss 2006:890. Note, however, the discussion on *Association for Molecular Pathology v US Patent and Trademark* 702 F.Supp 2d 181 (2010) (below) where the New York District Court rejects reasoning followed in *Diamond v Chakrabarty* and similar cases. TRIPS [Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, adopted on 15 December 1993 (1994) 33 *International Legal Materials* 81] was intended to oblige all WTO member states to adopt similarly high standards of intellectual protection to those used in the United States (for history of the TRIPS agreement, see Drahos & Braithwaite 2002; Sell 2003). Article 27(1) provides that “patents shall be available for any inventions, whether products or processes in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application ...”. Under pressure from the European states, TRIPS included an exception to this broad requirement in article 27(3)(b) which provides that states can exclude from patentability “plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes”. While the precise ambit of this exception has been controversial, it appears that WTO member states will be obliged to recognise United States patents of micro-organisms (such as gene sequences). See Correa 2008:233.

science” has traditionally been perceived as the most efficient and powerful model to generate progress in both the pure and applied sciences.<sup>124</sup>

Patent protection may end up stifling innovation rather than encouraging it.<sup>125</sup> Some commentators have concluded that the overall effect of gene patenting, for example, is a tendency “to retard, rather than to stimulate, both scientific and economic progress”.<sup>126</sup> The consequences of research-tool patenting are most severe where patents affect tools needed for a wide range of research projects.<sup>127</sup> Ultimately, patents granted over research tools often hinder “the ability of the scientific community, both that part interested in advancing the science further, and that part interested in trying to use knowledge in the search for useful product, to work freely with and from new scientific findings”.<sup>128</sup>

Examples of some specific problems and impediments are discussed below.

### 5.2.1 Refusal to issue licences for patented research

Sometimes patent-holders refuse to issue licences to other researchers who wish to use patented materials in their own research – typically if they want to prevent competitors from using the technology to develop rival commercial products.<sup>129</sup> This can be especially problematic when human genes are patented, because there might be no alternative research tools to the patented genes.<sup>130</sup>

The problems created by refusal to grant research licences are well illustrated by the case *Association for Molecular Pathology v US Patent and Trademark Office*<sup>131</sup> decided by the New York District Court in March 2010. This case concerned patents to genetic research that had been funded by the United States Government and was primarily conducted at a public university.<sup>132</sup>

In the early 1990s, scientists discovered correlations between two human genes and breast cancer.<sup>133</sup> These so-called ‘breast cancer genes’ were given the names BRCA1 and BRCA2. Scientists discovered that women with certain mutations of these genes have a significantly higher incidence of breast and ovarian cancer.<sup>134</sup> BRCA-based products are thus extremely valuable as diagnostic tools.<sup>135</sup>

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124 Nelson 2004; Cook-Deegan & Dedeurwaerdere 2006:309.

125 Many scholars have made this point. See, for example, Rai 2001:193; Berman & Dreyfuss 2006:887-888.

126 Williamson 2001:670.

127 Barton 2002:822; Nelson 2004:463; Dreyfuss 2004:460; Kane 2007:329.

128 Nelson 2004:463; Malinowski & Rao 2006:49.

129 Thumm 2005:1414; Eisenberg 2001:230.

130 Paradise *et al.* 2005:1566.

131 *Association for Molecular Pathology v US Patent and Trademark Office* [Association for Molecular Pathology v USPTO] 702 F.Supp 2d 181 (2010).

132 *Association for Molecular Pathology v USPTO*:202.

133 Hall *et al.* 1990:1684-1689; Miki *et al.* 1994:66.

134 *Association for Molecular Pathology v USPTO*:203.

135 *Association for Molecular Pathology v USPTO*:203.

Scientists working in the field also want to use the genes as research tools. For example, they want to investigate whether BRCA gene mutations are linked to other cancers; develop more sophisticated diagnostic tools, and explore the genes' potential as therapeutic tools for those who have already developed cancer.<sup>136</sup>

The initial identification and localisation of the BRCA genes and their mutations, as well as the links to breast and ovarian cancer, were achieved by collaborating teams of university scientists based at institutions in the United Kingdom, the United States and Canada,<sup>137</sup> while some early follow-on research was performed at Myriad Genetics, a private company established at the University of Utah Science Park in 1991.<sup>138</sup>

Much of the research was conducted at the University of Utah,<sup>139</sup> which had received significant state funding for its BRCA research.<sup>140</sup> Following successful sequencing of the genes at the University of Utah, the university obtained several patents to both of the BRCA genes. Although the patents were owned by the University of Utah, they were exclusively licensed to Myriad genetics, which also owned several BRCA patents in its own right.<sup>141</sup> By 2009, Myriad genetics had exclusive control of the BRCA genes, their corresponding proteins, and all their known mutations. The patents held by (or exclusively licensed to) Myriad were extremely broad, and included "all imaginable" diagnostic and therapeutic uses of the genes.<sup>142</sup>

In May 2009, the American Association for Molecular Pathology, along with several other plaintiffs, brought a class action against the United States Patent and Trademark Office, challenging the validity of the BRCA patents.<sup>143</sup> In part, their action was a response to Myriad's monopoly over BRCA screening and diagnosis. The Myriad tests were very expensive, and the Myriad patents prevented other laboratories from performing screening and diagnostic tests based on the BRCA genes.<sup>144</sup>

However, the action was also a response to the ways in which the Myriad patents prevented other university scientists from conducting any kind of research using the BRCA genes. Over the previous 15 years, Myriad had sent cease-and-desist letters to research scientists based at several American universities (including Columbia University, New York University, Emory University, Yale University and the University of Pennsylvania)<sup>145</sup> when scientists embarked on research projects which Myriad viewed as

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136 These and similar research objectives were listed by the plaintiffs in *Association for Molecular Pathology v USPTO*.

137 *Association for Molecular Pathology v USPTO*:201-202.

138 <http://www.myriad.com/about/> (accessed in July 2009).

139 Miki *et al.* 1994. Authors of this study were based at the University of Utah.

140 *Association for Molecular Pathology v USPTO*:201-202.

141 See *Association for Association for Molecular Pathology v USPTO*:202-203 for details and chronology of the BRCA patenting.

142 Thumm 2005:1414.

143 *Association for Molecular Pathology v USPTO*.

144 *Association for Molecular Pathology v USPTO*:188-189.

145 *Association for Molecular Pathology v USPTO*:187-188.



infringements of its BRCA patents.<sup>146</sup> Scientists complained that the Myriad patents prevented critically important research into breast cancer (the leading cause of cancer death among women in the United States), as well as cancers of other types.<sup>147</sup>

The case had a positive outcome for those opposing the Myriad patents. The court overturned the kind of reasoning used in *Diamond v Chakrabarty*<sup>148</sup> and similar cases. It held that isolating DNA or gene sequences did not change their “essential character” as a product of nature that occur naturally in the human body.<sup>149</sup> The court followed the reasoning of cases such as *Funk Brothers Seed Co v Kalo Inoculant Co*,<sup>150</sup> and concluded that the BRCA patents should be disallowed on the grounds that the genes were “unpatentable products of nature”.<sup>151</sup> It is clear, however, that the BRCA patents had impeded follow-on research for nearly 20 years. While the BRCA genes are now available to research scientists, there are still other essential genetic tools which remain locked up behind exclusive patents.<sup>152</sup>

### 5.2.2 Restrictions on use of research tools

Even when patent-holders do issue licences, they often place significant restrictions on how research tools may be used.<sup>153</sup> Typical restrictions include that research tools must not be shared with other institutions (and sometimes even with colleagues at the same institution);<sup>154</sup> used for commercial purposes, or used for research sponsored by other commercial companies.<sup>155</sup> Some licences provide that tools may be used only for the particular research project described in the user agreement.<sup>156</sup> These restrictions may impede collegial co-operation (traditionally, an important form of scientific advancement).

### 5.2.3 Prohibitive licence fees and ‘reach through’ agreements

Licences can also be very expensive.<sup>157</sup> Sometimes patent-holders demand exorbitant up-front fees.<sup>158</sup> Very often, instead of charging fees up front, patent-holders insist on ‘reach-through’ or ‘grant-back’ licences. These govern rights to potential future inventions that are developed using a research tool owned

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146 *Association for Molecular Pathology v USPTO*:187-188.

147 *Association for Molecular Pathology v USPTO*:187-188.

148 *Diamond v Chakrabarty* 447 US 303 (1980). See the more detailed discussion above.

149 *Association for Molecular Pathology v USPTO*:231.

150 333 US (1948). See the discussion above.

151 *Association for Molecular Pathology v USPTO*:229.

152 See examples in Kapczynski *et al.* 2005.

153 Eisenberg 2001:225.

154 Marshall 2000:257.

155 United States. National Institutes of Health. Working Groups on Research Tools 1998.

156 United States. National Institutes of Health. Working Groups on Research Tools 1998.

157 Thumm 2005:1414.

158 United States. National Institutes of Health. Working Groups on Research Tools 1998.

by someone else.<sup>159</sup> Some agreements require that research-tool owners be given outright ownership of discoveries made using the tool.<sup>160</sup> Short of outright ownership, suppliers of research tools might require an automatic licence to the product of the research.<sup>161</sup> The research-tool technology might itself be very expensive. For example, GenPharm charged US\$80 to US\$150 for a single genetically engineered mouse in 1997, with a stipulation forbidding further breeding of mice sold.<sup>162</sup>

Research may be restricted or prevented altogether if research institutions cannot afford to pay the licence fees or pay for expensive research tools.<sup>163</sup> Typically, a research project will require use of research tools patented to different patent-holders. This can create a negotiation nightmare if the patent-holders have conflicting reach-through demands. It might even prevent the research altogether if it is not possible to reach a compromise between the research-tool patent-holders.<sup>164</sup>

Recent examples of foundational university science restricted by expensive patents are the human embryonic stem (hES) cell patents held by the University of Wisconsin Alumni Research Foundation. The patents were based on cell-lines developed at the University of Wisconsin in 1998.<sup>165</sup> University scientists obtained patents to three human embryonic stem cell-lines, and assigned them to the University of Wisconsin Alumni Research Foundation (WARF).<sup>166</sup> WARF, in turn, awarded exclusive licences to a commercial company, Geron, to “develop therapeutic and diagnostic products from hES cell-derived neural, pancreatic, and cardiac cells”.<sup>167</sup> The stem cell-lines are fundamental research tools required by scientists in a wide range of biomedical and pharmacological fields, but WARF and Geron controlled the patents very aggressively. Their stance made it extremely difficult for other university scientists to use hES technology in follow-on research in key areas such as Parkinson’s disease, heart disease and diabetes.<sup>168</sup> Initially, the patents were extremely broad, and covered not only the three cell-lines actually developed at Wisconsin, but also prohibited the development or use of any other hES cell-lines unless scientists negotiated fees and royalties with the patent-holders.<sup>169</sup>

The hES patents have been challenged on several occasions. In the most recent legal action, two non-profit organisations, Consumer Watchdog and the Public Patent Foundation, successfully challenged the validity of the

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159 Runge & DeFrancesco 2006:1720; Eisenberg 2001:230.

160 Eisenberg 2001:230.

161 Eisenberg 2001:230.

162 Marshall 2000:255-256.

163 Heller & Eisenberg 1998:700. This problem is exacerbated for developing countries; usually, the cost of research tools and materials in developing countries represents a far higher percentage of total research budgets than in the developed world (see Forero-Pineda 2006:818).

164 See the discussion in Heller & Eisenberg 1998:700.

165 Thomson *et al.* 1998.

166 Plomer *et al.* 2008:13.

167 Plomer *et al.* 2008:13.

168 Schlaeger *et al.* 2007:270.

169 Plomer *et al.* 2008:13.

hES patents on the grounds that development of the stem cell-lines was not non-obvious (a requirement for patenting).<sup>170</sup> In May 2010, the United States Patent and Trademark Office withdrew the hES patents, a step which the Consumer Watchdog's Stem Cell Project Director described as "a major victory for unfettered scientific research that could lead to cures for some of the most debilitating diseases".<sup>171</sup>

#### 5.2.4 Logistical problems created by 'patent thickets'

The sheer number of patents needing negotiation prior to research ("patent thickets"<sup>172</sup>) can itself impede research, regardless of the terms on which various tools are subsequently offered.<sup>173</sup>

Heller and Eisenberg discuss the "tragedy of the anti-commons", which arises when a large number of patent-owners hold patents to research tools and materials required for a research project.<sup>174</sup> Under these conditions, transaction costs of performing research may become prohibitive, resulting in under-research in heavily patented areas,<sup>175</sup> for example, the merozoite surface protein 1 (MSP-1) of plasmodium shows promise for development of a malaria vaccine. Use of this protein, however, is covered by no less than 39 patents belonging to different patent-holders.<sup>176</sup> "This complex landscape requires the lengthy negotiation of multiple licenses, at an unpredictable cost."<sup>177</sup>

The need to negotiate multiple reach-through licences might also result in "royalty stacking" against any potential inventions arising from the research<sup>178</sup> – research may appear unattractively unprofitable where researchers must pay royalties to multiple prior patent-owners.<sup>179</sup>

#### 5.2.5 Research tools and 'neglected diseases'

Research-tool patents may hamper research into profitable areas, but they seldom prevent it altogether.<sup>180</sup> Where profits are more doubtful, however, patent thickets may make research almost impossible.<sup>181</sup> The non-profit Malaria Vaccine Institute, for example, has cited upstream research patents as an important barrier to its research;<sup>182</sup> researchers looking at HIV-1 subtypes

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170 *Biotech Business Week* 2010:2375.

171 *Biotech Business Week* 2010:2375.

172 Patent thickets can be defined as "multiple and overlapping patent rights that require those seeking to commercialize new technology to obtain licences from multiple patent-holders" (May & Sell 2006:26).

173 Huang & Murray 2009:1213.

174 Heller & Eisenberg 1998:698.

175 Heller & Eisenberg 1998:698.

176 Correa & Musungu 2002:20.

177 Correa & Musungu 2002:20.

178 Heller & Eisenberg 1998:698; Thumm 2005:1411.

179 Heller & Eisenberg 1998:699; Thumm 2005:1411.

180 Rai 2005:289.

181 Rai 2005:289.

182 Rai 2005:285.

C and A (the types prevalent in developing countries) have experienced similar problems; most research has been conducted into subtype B, which is prevalent in North America and Europe.<sup>183</sup>

Research-tool barriers also impede research into dosage formats best suited for use in developing countries: for example, fixed-dose combination pills; special paediatric formulations; heat-stable formulation of drugs such as insulin (essential where it is almost impossible to refrigerate medication),<sup>184</sup> or anti-retroviral drugs suitable for patients who are also infected with malaria or tuberculosis – a large percentage of patients in developing-countries.<sup>185</sup>

### 5.2.6 Restrictions on publication and other forms of sharing of research findings

Some licence agreements have confidentiality clauses which limit researchers' freedom to publish research results or to have their findings validated through the peer-review process.<sup>186</sup> Some agreements require delayed publication of research findings, or pre-publication approval by research-tool owner,<sup>187</sup> thus restricting flow of information about new discoveries and their potential applications.<sup>188</sup> There may also be restrictions on collaboration, particularly with competitor private companies, or with university-based scientists funded by competitors.<sup>189</sup> Some scientific researchers have significantly reduced normal academic collaboration, due in part to fears that such collaboration will infringe research-tool licences.<sup>190</sup>

Patenting restrictions (or secrecy in hope of patenting research) have undermined relationships and collaborations between American and European universities.<sup>191</sup> Confidentiality restrictions have also affected potential collaborative projects between universities in both developing and developed countries.<sup>192</sup>

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183 Rai 2005:303.

184 Kapczynski *et al.* 2008:1051-1052.

185 Médecins sans Frontières 2008:6.

186 Eisenberg 2001:230; Geuna & Nesta 2006:797.

187 DuPont, for example, demanded that scientists using its Cre-loxP mice sign agreements allowing the company pre-publication review of any articles based on research using the patented animals (Marshall 2000:257). It also demanded that researchers consult with the company before sharing information about any new discoveries found by using the mice (Heller & Eisenberg 1998:699).

188 Williamson 2001:672. The *IPR Act* has several provisions which could result in publication delays. Section 5(1)(b): Institutions must ensure that potential intellectual property resulting from publicly-funded research must be kept secret until it has been "appropriately protected". This confidentiality applies throughout the period during which the institution reports the intellectual property to NIMPO, even if the institution elects not to patent the invention in terms of section 4(2), regulation 2(5).

189 Thursby & Thursby 2002:93.

190 González 2005:11.

191 Litan *et al.* 2007:59.

192 Forero-Pineda 2006:809.

Deterring publication and information collaboration among peers are particularly damaging side-effects of research-tool patenting because publication and collaboration are usually key factors driving scientific progress and advancement.<sup>193</sup>

### 5.2.7 Universities as commercial competitors

The bulk of scientific research is performed at universities.<sup>194</sup> Traditionally, the majority of their research was open, with the result that most science was in the public domain.<sup>195</sup> But universities are now charging for access to their research findings and tools.<sup>196</sup>

This has impacted on how university research is perceived, because universities and university-based researchers are now potentially in a position to profit substantially through scientific research conducted at universities. This has made it more difficult for universities to argue that 'pure science' should be granted some kind of research exemption from paying licence fees when using patented research tools and techniques.<sup>197</sup>

Commercial companies have thus begun to view universities as direct competitors in the search for patentable products of research rather than collaborators, and relationships between universities and the private sector have sometimes become very strained.<sup>198</sup>

### 5.2.8 Empirical findings

The first large-scale investigation of potential problems created by university patenting was conducted by the American National Institutes of Health (NIH) in 1997. At that time, scientists complained about restrictions on the kinds of research they could conduct, licence fees, reach-through licences, restrictions

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193 Nelson 2004:456. South Africa's 'top five' academic inventors (ranked by number of PCT (Patent Co-operation Treaty applications filed at WIPO)) reported that patenting activities had an "adverse effect" on publication. They were obliged to delay publication in order to avoid undermining the novelty requirements for patentability. Some papers were delayed for so long that they had to be abandoned because results had become obsolete or overtaken by better data (Sibanda 2009:134).

194 In South Africa, "publicly financed research institutions form the largest concentration of skills and personnel in the area of science and technology" (Sibanda 2009:113).

195 Nelson 2004:467. Nelson points out that even before Bayh-Dole a great deal of university research was directed towards practical application and economic development. He cites several examples from agricultural technology, chemical and electrical engineering, and medicine. Patents were not unknown, but until the 1980s, they were rare (Nelson 2004:467-468).

196 Nelson 2004:462.

197 Nelson 2004:466; Dreyfuss 2006:1566. See discussion on *Madey v Duke University* 307 F.3d 1351 (Fed Cir 2002) and research exemptions generally below.

198 Litan *et al.* 2007:59; Sampat 2010:756.

on collaboration with peers, and restrictions on publication of research.<sup>199</sup> They reported that these restrictions sometimes made it impossible for them to proceed with research, either because of an absolute refusal to licence necessary research tools, or because royalties demanded were too expensive or offered on unreasonable terms.<sup>200</sup> Similar problems have also been reported in European countries.<sup>201</sup>

However, some empirical studies have suggested that, in practice, scientists have been less impeded by research-tool patenting than might have been anticipated by the NIH findings. For example, Walsh *et al.* interviewed American biomedical scientists, and discovered that those working on important projects were usually able to work around the patent problem by licensing, inventing around the patent,<sup>202</sup> moving their research offshore, developing their own research tools, or using patented technology in secret without paying licence fees.<sup>203</sup> Commercial enterprises have tended to pay, even excessive, licence fees, passing costs on to consumers.<sup>204</sup>

However, many recent studies have documented specific projects that were abandoned because access to necessary research tools or information was either impossible, or too difficult or expensive.<sup>205</sup> In a study conducted in 2000, for example, Campbell *et al.* reported that over 20 per cent of university-based geneticists had been unable to continue with promising lines of research because of contractual prohibitions in research-tool agreements preventing collegial data-sharing and collaboration with peers, while nearly 50 per cent were unable to acquire data required for their research from their colleagues during the previous three years.<sup>206</sup> A 2006 study by Zheng, Juneja and Wright reported that one third of scientists interviewed had struggled to obtain necessary research materials, and that one quarter of these projects had to be abandoned.<sup>207</sup> A 2005 survey conducted by the American Association for the Advancement of Science found that 58 per cent of bioscientists had experienced delays in their research because of patent issues; 50 per cent of bioscience projects had to be changed, and 28 per cent of bioscience projects had to be abandoned.<sup>208</sup> A 2009 study by Huang and Murray examined use of 2637 human gene sequences in published scientific papers, and by modelling relationships between patents and published research concluded that gene-

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199 United States. National Institutes of Health. Working Groups on Research Tools 1998.

200 Eisenberg 2001:230.

201 See, for example, the 2003 study conducted by the Swiss Federal Institute of Intellectual Property, which canvassed 53 Swiss biotech companies (Thumm 2005:1411); and the 2006 survey of several European countries by Geuna and Nesta (Geuna & Nesta 2006).

202 Berman & Dreyfuss (2006:900) report that some researchers change a non-material part of a sequence, and then use it claiming not to have infringed the patent.

203 Walsh *et al.* 2003:1021.

204 Rai 2005:293.

205 See, for example, studies discussed by Runge & Defrancesco 2006:1721ff and by Thomas 2005:718.

206 Campbell *et al.* 2000.

207 Runge & Defrancesco 2006:1721.

208 Runge & Defrancesco 2006:1721.

patenting and patent thickets have a significant and negative impact on follow-on innovation and production of public knowledge.<sup>209</sup> Negative impact is most severe with genes that are closely relevant to human diseases. These genes have the greatest commercial potential and are therefore most likely to be tightly controlled by patenting.<sup>210</sup>

## 6. Will patenting university science in South Africa create similar problems?

This article focuses on the problems associated with upstream patenting in the United States. Many countries have now imitated the United States in enacting Bayh-Dole-type legislation.<sup>211</sup> Similar statutes have been enacted in Japan,<sup>212</sup> China,<sup>213</sup> India,<sup>214</sup> Brazil,<sup>215</sup> the Philippines,<sup>216</sup> and all European countries except Ireland.<sup>217</sup> Similar kinds of problems to those experienced in the United States have arisen in developed countries which have implemented Bayh-Dole-type legislation.<sup>218</sup> Commentators who observe developing countries such as India and Brazil recognise that the research environments and economic contexts differ from those in the United States and other developed economies,<sup>219</sup> but many of the commentators anticipate that patenting of university science in developing countries will create similar kinds of problems to those experienced in the United States and elsewhere.<sup>220</sup>

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209 Huang & Murray 2009:1213-1214.

210 Huang & Murray 2009:1214.

211 See Graff 2007:171, noting the influence of Bayh-Dole on developing country legislation.

212 Loewenberg 2009:91.

213 United Kingdom. Commission on Intellectual Property Rights 2002:123.

214 United Kingdom. Commission on Intellectual Property Rights 2002:123. A 2008 Bill (Protection and Utilization of Publicly Funded Intellectual Property Bill, 2008) is modelled very closely on Bayh-Dole. [Financial Express (India) Staff Writer 2010:2; Sampat 2009:1]. The Bill is still 'pending' according to the Indian Parliament's website, <http://www.parliamentofindia.nic.in/> (accessed in February 2011).

215 Ryan 2010:1090.

216 Sampat 2010:755.

217 Dept of Science and Technology 2006:26. See Geuna & Nesta 2006 for a discussion of the situation in Europe generally. For discussions on specific European countries, see for France (Forero-Pineda 2006:817); for Germany (Loewenberg 2009:91), and for Italy (Baldini 2009:1218).

218 See, for example, the 2003 study conducted by the Swiss Federal Institute of Intellectual Property, which canvassed 53 Swiss biotech companies (Thumm 2005:1411), and the 2006 survey of several European countries by Geuna and Nesta (Geuna & Nesta 2006). See also the Australian government's conclusions on potential negative effects of patenting in Australia (Department for Innovation, Industry, Science and Research 2009:56).

219 See, for example, Sampat 2009:1, examining India specifically.

220 See Sampat 2009 generally, examining India, and Sampat 2010:755-756, examining developing countries more broadly. See also So *et al.* 2009:2082, recommending that developing states that implement Bayh-Dole-type legislation ensure that their legislation includes safeguards to prevent similar problems to those experienced in the United States.

There is some empirical evidence to support this,<sup>221</sup> and the dynamics of the research processes in developing countries are similar to those of developed states to make similar consequences likely. However, it is still too early to draw more definitive conclusions from the early evidence.<sup>222</sup>

The impact of South Africa's intellectual property regime on innovation and follow-on research has received virtually no scholarly attention.<sup>223</sup> It is clear that the South African scientific research environment is much smaller than that in the United States,<sup>224</sup> and South African scientists generate far less scientific research or potentially patentable upstream research tools.<sup>225</sup> However, even though the scale of research is far smaller, South African scientists working at state-funded institutions often perform similar kinds of research to their American counterparts. For example, the discussion above focused on potential problems associated with the patenting of upstream research in genetics, microbiology and pharmacology. These are important research sectors for scientists at South African research institutions,<sup>226</sup> and have been flagged as priority sectors for expansion by the Department of Science and Technology.<sup>227</sup> The Department of Science and Technology recognises that the kind of research performed at state-funded research institutions is often "closer to basic research".<sup>228</sup> Research of this kind is foundational for follow-on researchers.

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221 Even before it became compulsory to patent state-funded research (Sampat 2009:6) Indian scientists complained that their research had been impeded by voluntary patents on upstream research (Thomas 2005:728). See Forero-Pineda 2006:818, discussing the negative impact of upstream patents on researchers in developing countries; Maskus & Reichman 2005:7, discussing potentially negative impacts of upstream patents on developing countries more generally; Runge & Defrancesco 2006:1722, critiquing the impact of proprietary science models and concluding that developing countries have even more to lose through adoption of such policies than researchers in developed economies; Evans 2005:93, arguing that developing countries are better served by open-science models than by proprietary science. See also Taylor & Cayford 2005:344-345, discussing the negative impact of patents on upstream research in the agricultural biotechnology sector and the particular problems that this creates for developing country researchers and farmers.

222 Sampat 2009:5.

223 In 2009, Kaplan (2009:1) bemoaned "the absence of any study" on these issues. The edited volume in which this article appeared was intended to provide some "initial research" of this kind (Kaplan 2009:15).

224 South Africa has 23 higher education institutions and five publicly funded science institutions (Sibanda 2009:113). The United States has hundreds of universities conducting scientific research (see, for example, those discussed in the Times Higher Education World University Rankings, <http://www.timeshighereducation.co.uk/> (accessed in March 2011)), as well as national publicly funded science institutions such as the National Institutes of Health, which describes itself as "one of the world's foremost medical research centers", <http://www.nih.gov/> (accessed in March 2011).

225 Kaplan 2009:6; Sibanda 2009:131; Dept of Science and Technology 2006:5.

226 Internationally, the sectors with the highest concentration of university patents are the biotechnology and pharmacology sectors (Sibanda 2009:131). This is also true in South Africa (Sibanda 2009:131).

227 Dept of Science and Technology 2007:4 and 10.

228 Dept of Science and Technology 2006:4.



Potentially, increased patenting by South African universities could create similar difficulties for follow-on researchers to those created in the United States. As discussed below, however, it appears that the drafters of the new legislation have taken steps to ameliorate this.

The broad definition of 'intellectual property' in section 1 of the *Act* is potentially problematic in its own right. The definition includes "any creation of the mind which is capable of being protected in law ... whether in terms of South African law or *foreign intellectual property law ...*"<sup>229</sup> This reference to foreign intellectual property laws could create problems. Countries do not have identical patenting standards, and national patenting standards can change. For example, the United States has permitted patenting of isolated genetic materials in the past, but courts now seem to be rejecting such patents on the grounds that human biology, whether isolated or not, is a "product of nature" and unpatentable.<sup>230</sup> Thus one problem that the definition creates for South African researchers and institutions is uncertainty about what is 'capable of being protected' in terms of foreign intellectual property law. Another problem is the possibility that foreign countries might have very low patentability thresholds that are unsuitable for the South African economy. South Africa has been an active member of the Group of Friends of Development at WIPO which has resisted the international harmonization of patenting standards (for example through WIPO's proposed Substantive Patent Law Treaty) on the grounds that patenting standards appropriate in developed country contexts might not be appropriate for developing countries.<sup>231</sup> The definition of intellectual property in the *IPR Act* has the effect that foreign patenting standards have been incorporated into South African law in a different way.

## 7. Avoiding and minimising problems associated with proprietary science

As discussed in the previous section, the *Bayh-Dole Act* (and proprietary science more generally) has created problems for follow-on researchers in the United States where attempts have been made to ameliorate these problems through mechanisms that try to improve access to patented research tools. Other states which have adopted Bayh-Dole-type legislation have also tried to avoid some of the potential problems caused by proprietary science.

Some of the most important access measures are research and experimental use exemptions for scientific researchers; compulsory licensing provisions, and open-access patenting. These are discussed in the following section which also examines the extent to which South African law provides similar mechanisms.

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229 Section 1. Emphasis added.

230 See for example, *Association for Molecular Pathology v US Patent and Trademark* 702 F.Supp 2d 181 (2010) and discussion above.

231 See Barratt 2010:20-24 for discussion on the Group of Friends of Development. See Reichman 2006:3-4, discussing potential dangers for developing countries of the "deep harmonization" of patenting standards which would arise from the proposed Substantive Patent Law Treaty.

## 7.1 Research and experimental use exemptions

Patents on research conducted at universities can potentially impede follow-on research, particularly in view of the kinds of research conducted at universities. One way to ameliorate the chilling effect of research-tool patents is to make legal provision for research and experimental use exemptions for those who use patented tools in their own research but do not envisage direct commercial competition with the patent-holder.

Some patent systems provide for ‘experimental use exemptions’ which permit researchers to use patented products for research purposes without paying licence fees. The *Japanese Patent Act*, for example, provides that “the effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research”.<sup>232</sup> The patent statutes of the majority of European countries have experimental use exemptions modelled on article 27(b) of the European Community Patent Convention (CPC). This article provides that “The right conferred by the Community patent does not cover acts done for experimental purposes relating to the subject matter of the patented invention.”<sup>233 234</sup> Other countries with statutory research exemptions include Canada<sup>235</sup> and India.<sup>236</sup>

United States courts have created a common law research exemption for “pure research” (that is, “non-commercial” research).<sup>237</sup> However, the court interpreted “non-commercial” research very narrowly in *Madey v Duke University*, and held that it should apply only to research conducted “solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry”.<sup>238</sup> The Court held that this excluded university research, even if the research concerned had no direct commercial application, because the research would nevertheless further the university’s “legitimate business objective” by raising its profile and status, thus attracting staff, students, and funding.<sup>239</sup>

The *Madey* case illustrates the dangers associated with recognising exemptions for certain types of research, since it is often very difficult to

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232 Berman & Dreyfuss 2006:905, citing the *Japanese Patent Act*, Law 121/1959, ch. 4, no. 69(1).

233 Voelker 2000:68.

234 Thumm 2005:1413; Garde 2005:280.

235 *Patent Act*:section 71(e)(1).

236 Helm 2006:197; Thomas 2005:714.

237 Malinowski & Rao 2006:49, citing as examples *Whittemore v Cutter* 21 Fed Cas 554, No 12, 391 (CCD Mass, 1813) and *Sawin v Guild* 29 Fed Cas 1120, No 17, 600 (CCD Mass, 1813). In addition to this common-law exemption, there is also a narrow statutory exemption provided in the *Drug Price Competition and Patent Term Restoration Act* of 1984 [codified as amended at 35 U.S.C. § 271 (2000)] [*Hatch Waxman Act*], for research conducted on pharmaceutical products for the purpose of obtaining FDA approval (Dreyfuss 2004:459).

238 *Madey v Duke University* 307 F.3d 1351 (Fed Cir 2002):1362.

239 *Madey v Duke University* 307 F.3d 1351 (Fed Cir 2002):1362. Following the *Madey* decision, the United States Supreme Court delivered a reasonably broad interpretation of the provisions in the *Hatch-Waxman Act* in *Merck KGaA v Integra Lifesciences I, Ltd.* 545 US 193 (2005). Garde 2005:266.

decide what should be regarded as 'non-profit' research, and what should be regarded as 'commercial'.<sup>240</sup> Unclear definitions could have a chilling effect on research.<sup>241</sup>

The question of research exemptions has received very little legislative or judicial attention in South Africa. Section 45(1) of the *Patent Act*<sup>242</sup> gives patent-holders exclusive rights to make, use, exercise, dispose of and import patented inventions. It has no provisions dealing specifically with use for experimental purposes and provides no explicit research exemption. Burrell has concluded that 'use' in terms of section 45(1) does not include experimental use in the course of research. He states that "*bona fide* experiment does not amount to use and does not constitute an act of infringement".<sup>243</sup>

The only reported South African case examining experimental use is *Stauffer Chemicals Chemical Products Division of Chesebrough Ponds (Pty) Ltd v Monsanto Company*,<sup>244</sup> where Judge Harms interpreted 'use' to include experimental use and held that "experimental use of an invention amounts to an infringement if the experimenter uses the invention".<sup>245</sup> In this case, the experimenter was a rival commercial company using a patented Monsanto herbicide to test a competing product.

Referring to Burrell and the *Stauffer* case, Alberts concludes that:

With regard to 'using', it can be noted that *bona fide* experimental use does not amount to use and, thus, infringement. On the other hand, use by way of demonstration, but for *commercial purposes* would not be covered by this exclusion.<sup>246</sup>

According to the Department of Science and Technology *Policy Document*, South African legislation "does not preclude research being conducted by a non-patent holder ...".<sup>247</sup> (Experimental or research 'use' of the patented materials is implied by the context). On the other hand, the Department's regulations made in terms of the *IPR Act* provide that where NIMPO takes assignment of intellectual property in terms of section 4(3), it must award the initial inventors "an irrevocable, non-transferrable, and royalty-free licence to use the intellectual property for research, development and educational purposes" and may also grant such licences to other publicly funded South African research institutions.<sup>248</sup> This regulation suggests that publicly funded research institutions might indeed require licences to conduct follow-on research under some circumstances.

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240 Thumm 2005:1413.

241 Thumm 2005:1413.

242 Act 57/1978.

243 Burrell 1999:section 5.7.

244 *Stauffer Chemicals Chemical Products Division of Chesebrough Ponds (Pty) Ltd v Monsanto Company* 1988 (1) SA 805.

245 809A.

246 Alberts 2008:70.

247 Dept of Science and Technology 2006:36.

248 Regulations 2(12)(b) and 2(12)(c).

At present, South African law regarding experimental use for research purposes seems rather uncertain. It appears that ‘non-commercial research’ might qualify for an experimental use exemption. However, the ‘non-commercial’ status of university research is undermined where the results of the research are patented and commercialised. Universities and other research institutions would be able to maintain the ‘non-commercial’ status of a particular research project if they decided not to patent their research results using the *IPR Act* section 4(2) procedures. It would be useful for South African law to offer clearer guidance on whether experimental use in the course of non-commercial research infringes the *Patent Act*, particularly in light of legislation which encourages patenting of upstream research by South African universities and state-funded research institutions.

## 7.2 Compulsory licensing

Some scholars advocate using certain types of compulsory licences for research purposes, rather than the more general research exemptions discussed in the previous section.<sup>249</sup> In Germany, such licences are available where researchers need to use inventions in the public interest, cannot obtain licences from the patentees in reasonable terms, and there are no reasonable alternatives to using the patenting invention.<sup>250</sup>

The South African *Patent Act*<sup>251</sup> makes provision for compulsory licensing on two grounds: section 55 provides for compulsory licences in respect of dependent patents and section 56 provides for compulsory licences “in cases of abuse of patent rights”. In specifying the meaning of “abuse of patent rights”, the *Act* lists activities that appear similar to those in the German statute. Section 56(c) provides that the patent will be deemed to have been abused if “the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms”, while section 56(d) provides that the patent will be deemed to have been abused if the patentee refuses to grant licences on reasonable terms, and as a result:

[T]he trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new trade or industry in the Republic, is being prejudiced, and it is in the public interest that a licence or licences should be granted.

These sections were promulgated long before patenting of gene fragments and cell-lines became possible, but they might nevertheless be broad enough to cover refusal to permit experimental use of patented research tools in science.

Private companies might also be ordered to award licences on reasonable terms under the *Competition Act* 89 of 1998. The *Act* forbids dominant firms from charging excessive prices to the detriment of consumers;<sup>252</sup> refusing to

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249 Garde 2005:272ff, arguing for “license of right” to NIH-funded research.

250 Berman & Dreyfuss 2006:906.

251 Act 57/1978.

252 Section 8(a).

give competitors access to essential facilities,<sup>253</sup> and exclusionary acts that have an anticompetitive effect that outweighs technological, efficiency or other pro-competitive gains.<sup>254</sup> In 2003, the Competition Commission found that pharmaceutical companies GlaxoSmithKline and Boehringer Ingelheim had abused their dominant positions in the anti-retroviral drug market through excessive pricing and failure to grant licences to generic drug manufactures on reasonable terms.<sup>255</sup>

In addition to the *Patent Act* and *Competition Act* provisions, the *IPR Act* itself gives the government fairly extensive powers to regulate terms of the patents envisaged by the *Act*. For example, section 2(g) provides that “where necessary, the State may use the results of publicly financed research and development and the attendant intellectual property in the interest of the people of the Republic”, and subsection 11(1)(e) provides that:

[E]ach intellectual property transaction must provide the State with an irrevocable and royalty-free licence authorising the State to use or have the intellectual property used throughout the world for the health, security and emergency needs of the Republic.

In certain circumstances, these sections might cover experimental use situations, particularly if the follow-on research is directed to research in health, pharmacology or the upstream microbiological and genetic research that supports these sectors.

A very important implication of the compulsory licensing provisions is that they can ensure that, even if pharmacological innovations are patented in an effort to promote technological development,<sup>256</sup> the government will retain walk-in rights to privately developed technology. This has important implications for the ability of the state to obtain affordable generic medicines for distribution to the poor.

### 7.3 The public domain and open-access patents

Many scientists, concerned about patenting of upstream research such as genes and cell-lines, have collaborated in releasing important discoveries directly into the public domain, free from all patent and licensing restrictions. The most famous example of this is the Human Genome Project, which released their genome data into the public domain within 24 hours, thus preventing anyone else from establishing intellectual property rights over released data.<sup>257</sup>

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253 Section 8(b).

254 Section 8(c).

255 See the press release from the Competition Commission, 16 October 2003, <http://www.cptech.org/ip/health/sa/cc10162003.html> (accessed in March 2011). The text of the complaint *Hazel Tau and Others v GlaxosmithKline and Others*, <http://www.section27.org.za/wp-content/uploads/2010/10/TauvGSKEvidenceAndLegalSubmissions.pdf> (accessed in March 2011).

256 See discussion above.

257 González 2005:10; Chin 2005:863.

Similarly, the private sector-led SNP Consortium<sup>258</sup> has placed a number of SNPs<sup>259</sup> in the public domain to make them freely available for scientific research.<sup>260</sup> In 1995, over 100 American universities voluntarily entered into Uniform Biological Materials Transfer Agreement, aimed at ensuring that upstream patented biological materials were freely shared among universities for research purposes.<sup>261</sup> Both public and private research institutions have tried to collaborate in making more upstream research tools freely available in the public domain, particularly for research purposes, or particularly to non-profit research institutions. Merck, for example, recently invested millions in an open-access genomics database because it “sees gene sequences as inputs, rather than as products”.<sup>262</sup>

Many economists and scientists continue to believe that open science models offer many advantages over proprietary models. For example, the Declaration of the World Congress for Freedom of Scientific Research stresses that free and open science is “one of the main guarantors of human health and welfare”.<sup>263</sup> In 2008, the World Health Assembly adopted the *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*<sup>264</sup> which endorses a co-operative approach to development of new essential medicines, and emphasises the need to encourage “needs-driven research rather than purely market-driven research to target diseases which disproportionately affect people in developing countries”. In the past, the World Health Organisation has expressed concern about patenting of research tools and its negative effects on the development of medicines, particularly those intended primarily for the poor.<sup>265</sup> Eve Gray notes that, as a member of the World Health Organisation, the South African Government is obliged to implement the WHO Global Strategy, including provisions concerning use of “open-source development, open access to research publications and data, voluntary provision of access to drug leads, open licensing, and voluntary patent pools”.<sup>266</sup> She points out that the almost simultaneous adoption of the

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258 This is the official name of the Consortium.

259 Single nucleotide polymorphisms (SNPs) are ‘single base-pair variations’ in the human genome. Most humans have identical DNA sequences, with our genetic differences located in these SNPs. These occur, on average, about once in 1000 base pairs. Identifying and locating these SNPs is useful for understanding disease and, possibly, for predicting which people might be prone to developing particular diseases (Campbell & Reece 2005:402).

260 Barton 2002:823; Cook-Deegan & Dedeurwaerdere 2006:306. For more examples of similar projects, see Cook-Deegan & Dedeurwaerdere 2006:302 and 306; Runge & DeFrancesco 2006:1721.

261 Rai 2005:299.

262 Kapczynski *et al.* 2005:1067-1068.

263 Declaration of the First Meeting of the World Congress for Freedom of Scientific Research, Campidoglio, Rome 16-18 February 2006, <http://www.freedomofresearch.org/node/82> (accessed in November 2010).

264 [http://www.who.int/phi/implementation/phi\\_globstat\\_action/en/print.html](http://www.who.int/phi/implementation/phi_globstat_action/en/print.html) (accessed in November 2010).

265 See, for example, World Health Organisation 2003:paragraph 3.

266 Gray 2009:7.

*IPR Act* (with its emphasis on proprietary and commercialised science) seems to run contrary to these international obligations.<sup>267</sup>

However, section 4(2) of the *IPR Act* gives state-funded research institutions a choice as to whether or not to patent their research. The Regulations recognise a desire to release research into the public domain as a legitimate reason for refusing to patent. Section 4(3) of the *Act* allows NIMPO itself to patent (or not patent) the research under these circumstances. It is to be hoped that in exercising its powers in terms of section 4(3), NIMPO is mindful of the important role that open-access patenting can play in promoting essential research.<sup>268</sup>

Some institutions patent their research tools, but make them available under 'open-access patents'. Open-access patents allow researchers to use tools without charge, but typically require that researchers agree not to patent research resulting from this use.<sup>269</sup> South African scientists who wish to use these tools will need to elect not to patent their research [using the section 4(2) mechanisms] so that they can agree to the terms of these open-access licences. The Regulations in terms of the *IPR Act* explicitly note that a possible reason for choosing not to patent research is a desire on the part of the researchers to release their data to the public domain.<sup>270</sup> Presumably, holders of open-access patents will require similar 'no-patent' undertakings from NIMPO (it would defeat the object of the open-access licence if the product of the research was merely patented by NIMPO instead of the institution that actually used the research tool). NIMPO can elect not to patent in terms of section 4(3).

## 8. Conclusion

This article has discussed some of the potential dangers of Bayh-Dole-type legislation by examining some of the negative consequences of the American *Bayh-Dole Act* in the United States. Among the most serious consequences are the potential barriers to follow-on research caused by the patenting of upstream research tools. Other dangers include publishing delays and disincentives to collegial collaboration in the scientific community.

The South African *IPR Act* has similar aims to the *Bayh-Dole Act*. Its objective is to increase the extent of patenting by state-funded institutions, and the *Act* strongly encourages patenting. It requires the disclosure of all potentially patentable inventions, and the establishment of machinery to oversee patenting and commercialisation of university science. However, it appears that the framers of the *IPR Act* and its Regulations have taken steps

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267 Gray 2009:7.

268 See Sampat 2010:755-756, pointing out that in some sectors successful development of technology is enhanced by open-access patents.

269 Excellent examples of open-access patents which may be used free of charge provided that users make their discoveries available on similar terms are the CAMBIA and BIOS licences, <http://www.cambia.org> and <http://www.bios.net> (accessed in November 2010).

270 Regulation 2(1)(g).

to avoid some of the dangers and pitfalls experienced in the United States as a result of the Bayh-Dole policies. Among the most significant of these is recognition of the importance of the public domain, and the section 4(2) mechanisms that allow state-funded inventors to choose not to patent their research, thus leaving it freely available for follow-on researchers.<sup>271</sup> While NIMPO is permitted to patent and commercialise the research under these circumstances, NIMPO can also elect not to patent.<sup>272</sup> Even if NIMPO does patent the research, potential barriers to follow-on researchers at South African state-funded institutions may be minimized by rules permitting NIMPO to award royalty-free licences to researchers who wish to use the patented materials in research and teaching.<sup>273</sup> Appropriate use of sections 4(2) and 4(3) will ensure that South Africa is also able to meet its commitments to the World Health Assembly to ensure that the development of new medicines (and the development of the science on which their development is based) is not unduly impeded by intellectual property barriers. Sections 4(2) and 4(3) could also be used to ensure that South African scientists are able to use open-access licences that have 'no-patent' conditions.

The state 'walk-in rights' created by sections 2(g) and 11(1)(e) are extremely important. The State can use any intellectual property resulting from state-funded research (or authorise someone else to use it) in the interests of the people of South Africa. Compulsory licensing provisions of this kind ensure that patenting of new medicines, for example, will not impede state efforts to provide essential medicines to the poor.

However, the *IPR Act* does not avoid all the Bayh-Dole-type problems. Some provisions of the *Act* could potentially have an adverse effect on publishing. In terms of section 5(1)(b) institutions must ensure that potential intellectual property resulting from publicly funded research must be kept secret until it has been 'appropriately protected'. This confidentiality restriction applies throughout the period during which the institution reports the intellectual property to NIMPO, even if the institution elects not to patent the invention in terms of section 4(2).<sup>274</sup> Should NIMPO elect to patent the invention in terms of section 4(3), researchers will not be able to publish their research results until NIMPO's protection is in place. South African researchers have found that publishing delays of this kind might make it impossible to publish their research results where it becomes obsolete or overtaken by better data.<sup>275</sup> The *Act* and Regulations attempt to ameliorate this by providing time limits to ensure that decisions are taken as quickly as possible and publishing is not unduly delayed.<sup>276</sup>

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271 Section 4(2) read with regulations 2(1)(g) and 2(4)(c).

272 Section 4(3).

273 Regulations 2(12)(b) and 2(12)(c).

274 Regulation 2(5).

275 South Africa's 'top five' academic inventors [ranked by number of PCT (Patent Cooperation Treaty applications filed at WIPO)] reported that patenting activities had an "adverse effect" on publication (Sibanda 2009:134).

276 For example, if an institution makes a referral to NIMPO in terms of section 4(2), NIMPO must inform the institution of its 4(3) decision within 60 days of referral [regulation 2(7)].



Section 5(1)(b) not only forbids publication. It forbids publicly disclosing the research result by any means. It is not clear whether sharing the results with colleagues at other institutions would be regarded as a public 'disclosure'. However, disclosures of this kind might undermine the novelty requirements for patenting in a similar way to publication, and uncertainty about the precise meaning of 'public disclosure' might have a chilling effect on collegial data sharing and co-operation.

Commentators who have considered the benefits and risks of Bayh-Dole-type policies for developing countries have concluded that states implementing such legislation should learn from the United States experience and include safeguards to avoid the most serious pitfalls.<sup>277</sup> It appears that the *IPR Act* and Regulations contain several important provisions of this kind. Researchers, their institutions and NIMPO should bear these safeguards in mind and use them wherever appropriate to ensure that South African research is not hobbled by the new legislation.

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<sup>277</sup> See, for example, So *et al.* 2008:2081.

## Bibliography

- ALBERTS W  
2008. Patent infringement. *De Rebus* (Jan/Feb):70-71.
- ARNOLD BE AND OGIELSKA-ZEI E  
2002. Patenting genes and genetic research tools: Good or bad for innovation? *Annual Review of Genomics and Human Genetics* 3:415-432.
- AUSTRALIA. DEPARTMENT FOR INNOVATION, INDUSTRY, SCIENCE AND RESEARCH  
2009. *Powering ideas: An innovation agenda for the 21st century*. Canberra: Dept for Innovation, Industry, Science and Research.
- BALDINI N  
2009. Implementing Bayh-Dole-like laws: Faculty problems and their impact on university patenting activity. *Research Policy* 38(8):1217-1224.
- BARRATT A  
2010. The curious absence of human rights: Can the WIPO Development Agenda transform intellectual property negotiation? *Law, Democracy and Development* 14(3):1-42.
- BARTON JH  
2006. Research-tool patents: Issues for health in the developing world. *Bulletin of the World Health Organization* 80(2):121.
- BERMAN HM AND DREYFUSS RC  
2006. Reflections on the science and law of structural biology, genomics, and drug development. *UCLA Law Review* 53(4):871-908.
- BIOS  
<http://www.bios.net/daisy/bios/home.html> (accessed in November 2011).
- BIOTECH BUSINESS WEEK STAFF WRITER  
2010. *Biotech Business Week*. May 17, 2010:2375.
- BOYLE J (ED)  
2003. *The public domain. Law and Contemporary Problems* 66(1-2):1-483.
- BURRELL TD  
1999. *Burrells South African patent and design law*. 3<sup>rd</sup> ed. Durban:Butterworths.
- BUSH V  
1945. *Science, the endless frontier: A report to the President*. Washington DC: Government Printing Office.
- CAMPBELL NA AND REECE JB  
2005. *Biology*. 7<sup>th</sup> ed. San Francisco: Pearson.
- CAMPBELL EG, WEISSMAN JS, CAUSINO N AND BLUMENTHAL D  
2000. Data withholding in academic medicine: Characteristics of faculty denied access to research results and biomaterials. *Research Policy* 29(2):303-312.
- CHIN A  
2005. Research in the shadow of DNA patents. *Journal of the Patent and Trademark Office Society* 87(11):846-906.
- COCKBURN IM AND STERN S  
2010. Finding the endless frontier: Lessons from the Life Sciences Innovation System for technology policy. *Capitalism and Society* 5(1):1-48.
- COOK-DEEGAN R AND DEDEURWAERDERE T  
2006. The science commons in life science research: Structure, function, and value of access to genetic diversity. *International Social Science Journal* 58(188):299-317.
- CORREA CM  
2008. Patent rights. Correa and Yusuf (eds) 2008:227-258.
- CORREA CM AND MUSUNGU SF  
2002. The WIPO patent agenda: The risks for developing countries. *TRADE Working Paper 12*. Geneva: South Centre.
- CORREA CM AND YUSUF AA (EDS)  
2008. *Intellectual property and international trade: The TRIPS Agreement*. 2<sup>nd</sup> ed. Netherlands:Wolters-Kluwer.

- DECLARATION OF THE FIRST MEETING OF THE WORLD CONGRESS FOR FREEDOM OF SCIENTIFIC RESEARCH  
2006. <http://www.freedomofresearch.org/node/82> (accessed in November 2010).
- DRAHOS P AND BRAITHWAITE J  
2002. *Information feudalism: Who owns the knowledge economy?* London: Earthscan.
- DREYFUSS RC  
2004. Protecting the public domain of science: Has the time for an experimental use defense arrived? *Arizona Law Review* 46(3):457-72.  
2006. Pathological patenting: The PTO as cause or cure? *Michigan Law Review* 104(6):1559-1578.
- DREYFUSS RC, ZIMMERMAN DL AND FIRST H (EDS)  
2001. *Expanding the boundaries of intellectual property law: Innovation policy for the knowledge society*. Oxford: Oxford University Press.
- EISENBERG RS  
2001. Bargaining over the transfer of proprietary research tools: Is the market failing or emerging? Dreyfuss, Zimmerman and First (eds) 2001:223-251.
- ENCAOUA D, GUELLEC D AND MARTÍNEZ C  
2006. Patent systems for encouraging innovation: Lessons from economic analysis. *Research Policy* 35(9):1423-1440.
- EVANS P  
2005. The new commons versus the second enclosure movement: Comments on an emerging agenda for development research. *Studies in Comparative International Development* 40(2):85-94.
- FAGERBERG J, MOWERY DC AND NELSON RR (EDS)  
2005. *The Oxford Handbook of Innovation*. Oxford: Oxford University Press.
- FINANCIAL EXPRESS (INDIA) STAFF WRITER  
2010. Govt expands royalty share in IP Bill to deflect criticism. *Financial Express* 6 July. <http://www.financialexpress.com/news/Govt-expands-royalty-share-in-IP-Bill-to-deflect-criticism/642651/> (accessed on 8 April 2011).
- FORERO-PINEDA C  
2006. The impact of stronger intellectual property rights on science and technology in developing countries. *Research Policy* 35(6):808-824.
- GARDE TV  
2005. Supporting innovation in targeted treatments: Licenses of right to NIH-funded research tools. *Michigan Telecommunications and Technology Law Review* 11(2):249-284.
- GERVAIS D  
1998. *The TRIPS agreement: Drafting history and analysis*. London: Sweet & Maxwell.
- GEUNA A AND NESTA LJ  
2006. University patenting and its effects on academic research: The emerging European evidence. *Research Policy* 35(6):790-807.
- GEYER S, KEBRINK R AND VISSER C  
2008. Intellectual property law. *Annual Survey of South African Law*:621-638.
- GIFFORD DJ  
2004. How do the social benefits and costs of the patent system stack up in pharmaceuticals? *Journal of Intellectual Property Law* 12(1):75-124.
- GONZÁLEZ AG  
2005. Open science: Open source licences in scientific research. Paper available from [ssrn.com](http://ssrn.com) [SSRN-id 764064].
- GRAFF GD  
2007. Echoes of Bayh-Dole: A survey of IP and technology transfer policies in emerging and developing economies. Mahoney, Krattiger and Nelson (eds) 2007:169-196.

- GRAY E  
2009. Clash gets to heart of how to build "a better life for all". *Business Day* 13 July:7.
- HALL JM, LEE MK, NEWMAN B,  
MORROW JE, ANDERSON LA, HUEY B,  
KING MC  
1990. Linkage of early-onset familial breast cancer to chromosome 17q21. *Science* 250(4988):1684-89.
- HAZEL TAU AND OTHERS V  
GLAXOSMITHKLINE AND OTHERS  
Complaint submitted to the South African Competitions Commission. <http://www.section27.org.za/wp-content/uploads/2010/10/TauvGSKEvidence-AndLegalSubmissions.pdf> (accessed in March 2011).
- HELLER MA AND EISENBERG R  
1998. Can patents deter innovation? The anticommens in biomedical research. *Science* 280(5364):698-701.
- HELM KA  
2006. Outsourcing the fire of genius: The effects of patent infringement jurisprudence on pharmaceutical drug development. *Fordham Intellectual Property, Media and Entertainment Law Journal* 17(6):153-206.
- HUANG K AND MURRAY FE  
2009. Does patent strategy shape the long-run supply of public knowledge? Evidence from human genetics. *Academy of Management Journal* 52(6):1193-1221.
- INDIA PARLIAMENT  
<http://www.parliamentofindia.nic.in> (accessed in February 2011).
- JAFFE AB  
2000. The US patent system in transition: Policy innovation and the innovation process. *Research Policy* 29(4-5):531-557.
- JAFFE AB AND JOSH LERNER J  
2004. *Innovation and its discontents: How our broken patent system is endangering innovation and what to do about it*. Princeton: Princeton University Press.
- KANE EM  
2007. Molecules and conflict: Cancer, patents, and women's health. *American University Journal of Gender, Social Policy and the Law* 15(2):305-336.
- KAPLAN D  
2009. Intellectual property rights and innovation in South Africa: A framework. Kaplan (ed) 2009:1-17.
- KAPLAN D (Ed)  
2009. *The economics of intellectual property in South Africa*. Geneva: World Intellectual Property Organization.
- KAPCZYNSKI A, CHAIFETZ S, KATZ Z AND BENKLER Y  
2005. Addressing global health inequalities: An open licensing approach for university innovations. *Berkeley Technology Law Journal* 20(2):1031-1114.
- KENNY M AND PATTON D  
2009. Reconsidering the Bayh-Dole Act and the current university invention model. *Research Policy* 38(9):1407-1422.
- LITAN RE, MITCHELL L AND REEDY EJ  
2007. The university as innovator: Bumps in the road. *Issues in Science & Technology* 23(4):57-66.
- LOEWENBERG S  
2009. The Bayh-Dole Act: A model for promoting research translation? *Molecular Oncology* 3(2):91-92.
- MAHONEY A, KRATTIGER L AND NELSON L (Eds)  
2007. *Intellectual property management in health and agricultural innovation: A handbook of best practices*. Oxford: MIHR. [www.iphandbook.org](http://www.iphandbook.org). (accessed in March 2011).
- MALINOWSKI MJ AND RAO R  
2006. Legal limitations on genetic research and the commercialization of its results. *American Journal of Comparative Law* 54(4):45-65.

- MARSHALL E**  
2000. A deluge of patents creates legal hassles for research. *Science* 288(5464):255-257.
- MASKIN E**  
2005. Public goods and public science. Maskus and Reichman (eds) 2005:139-141.
- MASKUS E AND REICHMAN J (Eds)**  
2005. *International public goods and transfer of technology under a globalized intellectual property regime*. Cambridge: Cambridge University Press.
- MAY C AND SELL SK**  
2006. *Intellectual property rights: A critical history*. Boulder: Lynne Rienner.
- MÉDECINS SANS FRONTIÈRES**  
2008. *Untangling the web of price reductions: A pricing guide for the purchase of ARVs for developing countries*. 11<sup>th</sup> ed. Paris: Médecins sans Frontières.
- MERGES RP AND NELSON RR**  
1990. On the complex economics of patent scope. *Columbia Law Review* 90(4):839-916.
- MIKI Y, SWENSEN J, SHATTUCK-EIDENS D, FUTREAL PA, HARSHMAN K, TAVTIGIAN S, LIU Q, COCHRAN C, BENNETT LM, DING W, BELL R, ROSENTHAL J, HUSSEY C, TRAN T, McCLURE M, FRYE C, HATTIER T, PHELPS R, HAUGEN-STRANO A, KATCHER H, YAKUMO K, GHOLAMI Z, SHAFFER D, STONE S, BAYER S, WRAY C, BOGDEN R, DAYANANTH P, WARD J, TONIN P, NAROD S, BRISTOW PK, NORRIS FH, HELVERING L, MORRISON P, ROSTECK P, LAI M, BARRETT JC, LEWIS C, NEUHAUSEN S, CANNON-ALBRIGHT L, GOLDGAR D, WISEMAN R, KAMB A AND SKOLNICK MH**  
1994. A strong candidate for the breast and ovarian cancer susceptibility gene BRCA1. *Science* 266 (5172):66-71.
- MOWERY DC AND SAMPAT BN**  
2005. Universities in national innovation systems. Fagerberg J, Mowery DC and Nelson RR (eds) 2005:209-239.
- MUKHERJEE A AND SCOTT S**  
2009. Disclosure or secrecy? The dynamics of open science. *Journal of Industrial Organization* 27(3):449-462.
- MUSUNGU SF**  
2008. The TRIPS agreement and public health provision. Correa and Yusuf (eds) 2008:421-422.
- NELSEN RR**  
2004. The market economy, and the scientific commons. *Research Policy* 33(3):455-471.
- O'DONOGHUE T, SCOTCHMER S AND THISSE J-F**  
1998. Patent breadth, patent life, and the pace of technological progress. *Journal of Economics and Management Strategy* 7(1):1-32.
- PARADISE J, ANDREWS L AND HOLBROOK T**  
2005. Patents on human genes: An analysis of scope and claims. *Science* 307(5715):1566-1567.
- PLOMER A, TAYMOR KS AND SCOTT CT**  
2008. Challenges to human embryonic stem cell patents. *Cell Stem Cell* 2(1):13-17.
- RAI AK**  
2005. Proprietary rights and collective action: The case of biotechnology research with low commercial value. Maskus and Reichman (eds) 2005:288-306.
- REICHMAN JH**  
2006. Patent law harmonization and the draft SPLT. Paper presented to the WIPO Open Forum on the SPLT, Geneva, Switzerland, 1-3 March 2006. [www.wipo.int](http://www.wipo.int) (accessed in November 2007).

- RUNGE CF AND DEFRANCESCO E  
2006. Exclusion, inclusion, and enclosure: Historical commons and modern intellectual property. *World Development* 34(10):1713-1727.
- RYAN MP  
2010. Patent incentives, technology markets and public-private bio-medical innovation networks in Brazil. *World Development* 38(8):1082-1093.
- SAMPAT BN  
2009. *The Bayh-Dole model in developing countries: Reflections on the Indian Bill on Publicly Funded Intellectual Property*. Geneva: International Centre for Trade and Sustainable Development.  
2010. Lessons from Bayh-Dole. *Nature* 468(7325):755-756.
- SCHLAEGER TM, LENSCH W AND TAYLOR PL  
2007. Editorial. *Drug Discovery Today* 12 (7/8):269-271.
- SCOTCHMER S  
1991. Standing on the shoulders of giants: Cumulative research and the patent. *Journal of Economic Perspectives* 5(1):29-41.
- SELL SK  
2003. *Private power, public law: The globalization of intellectual property rights*. Cambridge: Cambridge University Press.
- SIBANDA M  
2007. *The state of patenting in South Africa: Special report 2007*. Pretoria: Dept of Science and Technology. Innovation Fund.  
2009. Intellectual property, commercialization and institutional arrangements at South African publicly financed research institutions. Kaplan 2009:113-145.
- SO A, SAMPAT BN, RAI AK, COOK-DEEGANN R, REICHMAN J, WEISSMAN R AND KAPCZYNSKI A  
2009. Is Bayh-Dole good for developing countries? Lessons from the US experience. *PLoS Biology* 10(6) (e262):2078-2084.
- SOUTH AFRICA. COMPETITION COMMISSION  
2003. Competition Commission finds pharmaceutical firms in contravention of the Competition Act. Pretoria: Competition Commission. <http://www.cptech.org/ip/health/sa/cc10162003.html> (accessed in March 2011).
- SOUTH AFRICA. DEPARTMENT OF SCIENCE AND TECHNOLOGY  
2002. *National research and development strategy*. Pretoria: Dept of Science and Technology. <http://www.dst.gov.za/> (accessed in June 2010).  
2006. *Intellectual property rights and publicly financed research policy document*. Pretoria: Dept of Science and Technology. <http://www.dst.gov.za/> (accessed in June 2010).  
2007. *Ten year innovation plan*. Pretoria: Dept of Science and Technology. <http://www.dst.gov.za/> (accessed in June 2010).  
2010. Regulations made in terms of Section 17 of the Intellectual Property Rights from Publicly Financed Research and Development Act, 2008 (Act no 51 of 2008). Government Notice No R.675, 2 August 2010 (*Government Gazette* No. 33433).
- STOKES DE  
1997. *Pasteur's Quadrant: Basic science and technological innovation*. Washington DC: Brookings Institution Press.
- TAYLOR MR AND CAYFORD J  
2004. American patent policy, biotechnology, and African agriculture: The case for policy change. *Harvard Journal of Law and Technology* 17(2):321-408.

THOMAS Z

2005. Agricultural biotechnology and proprietary rights: Challenges and policy options. *Journal of World Intellectual Property* 8(6):711-734.

THOMSON JA, ITS KOVITZ-ELDOR J, SHAPIRO SS, WAKNITZ MA, SWIERGIEL JJ, VIVIENNE S, MARSHALL VS AND JONES JM

1998. Embryonic stem cell lines derived from human blastocysts. *Science* 282(5391):1145-1147.

THUMM N

2005. Patents for genetic inventions: A tool to promote technological advance or a limitation for upstream inventions? *Technovation* 25(12):1410-1417.

THURSBY JG AND THURSBY MC

2002. Who is selling the ivory tower? Sources of growth in university licensing. *Management Science* 48(1) 90-104.

2003. University licensing and the Bayh-Dole Act. *Science* 301(5636):1052.

TIMES HIGHER EDUCATION

2010. *Times Higher Education World University Rankings*. London: Times Higher Education. <http://www.timeshighereducation.co.uk> (accessed in March 2011).

UNITED KINGDOM. COMMISSION ON INTELLECTUAL PROPERTY RIGHTS

2002. *Integrating intellectual property rights and development policy: Report of the Commission on Intellectual Property Rights*. London: United Kingdom. <http://www.iprcommission.org> (accessed in November 2010).

UNITED STATES. NATIONAL INSTITUTES OF HEALTH

Website for the National Institutes of Health. <http://www.nih.gov/> (accessed in March 2011).

UNITED STATES. NATIONAL INSTITUTES OF HEALTH. WORKING GROUPS ON RESEARCH TOOLS.

1998. *Report of the National Institutes of Health (NIH) Working Group on Research Tools. Presented to the Advisory Committee to the Director*. June 4, 1998. Washington DC: National Institutes of Health. <http://www.nih.gov/news/researchtools/> (accessed in November 2009).

VISSER C

2007. Intellectual property rights from publicly financed research: The way to research hell is paved with good intentions. *South African Mercantile Law Journal* 19(3):363-371.

VOELKER I

2000. Protecting research methods and tools. *Managing Intellectual Property* 95:68-69.

WALSH JP, ARORA A AND COHEN WM

2003. Working through the patent problem. *Science* 299(5609):1021-1022.

WILLIAMSON AR

2001. Gene patents: Socially acceptable monopolies or an unnecessary hindrance to research? *Trends in Genetics* 17(11):670-673.

WORLD CONGRESS FOR FREEDOM OF SCIENTIFIC RESEARCH

2006. Declaration of the First Meeting of the World Congress for Freedom of Scientific Research, Campidoglio, Rome 16-18 February 2006. <http://www.freedomofresearch.org/node/82> (accessed in November 2010).

WORLD HEALTH ORGANISATION

2003. *Intellectual property rights, innovation and public health: Report by the Secretariat 12 May 2003 (A56/17)*. [www.who.int](http://www.who.int) (accessed in November 2010).

WORLD HEALTH ORGANISATION. WORLD  
HEALTH ASSEMBLY

2008. *Global strategy and plan of action on public health, innovation and intellectual property*. [http://www.who.int/phi/implementation/phi\\_globstat\\_action/en/print.html](http://www.who.int/phi/implementation/phi_globstat_action/en/print.html) (accessed in November 2010).