



aidslaw
project

Centre for Applied Legal Studies (CALs)
University of the Witwatersrand
Private Bag 3, Wits 2050, South Africa
C/o Docex 197 Johannesburg
Tel +27 11 717-8600 • Fax +27 11 403-2341
www.alp.org.za



NATIONAL: 34 Main Road Muizenberg 7945 Tel: 021-788 3507 Fax: 021-788 3726
EMAIL: info@tac.org.za **WEBSITE:** <http://www.tac.org.za>

**Joint submission:
Patents Amendment Bill [B 17—2005]**

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Drafted by:
Jonathan Berger
Head: Law and Treatment Access Unit
AIDS Law Project
University of the Witwatersrand

(011) 717-8627 (t)
(011) 403-2341 (f)
083.419-5779 (c)

bergerj@law.wits.ac.za

INTRODUCTION

The AIDS Law Project (ALP) and the Treatment Action Campaign (TAC) welcome this opportunity to make written submissions on the Patents Amendment Bill [B 17—2005] (“the Bill”). As two organisations that have consistently advocated for the development of our patent system into one that considers South Africa’s competitive advantage and takes into account the specific needs of its people, we support what the Bill aims to achieve and, in general terms, how it goes about accomplishing its stated objective. In our view, the Bill is a necessary and constitutionally required legislative measure that complements the National Environmental Management: Biodiversity Act, 10 of 2004 (“the Biodiversity Act”).

Over the past few years, the ALP and TAC have sought to use and develop the law to ensure that all people in South Africa have access to a sustainable supply of affordable medicines for preventing and treating HIV infection and AIDS-related illnesses. In particular, we have taken direct action to remove some of the many barriers that currently limit access to all essential medicines. Part of this work has included a focus on ensuring that the Patents Act, 57 of 1978, is amended to ensure a suitable balance between creating incentives for innovation and ensuring access to the benefits of scientific developments. This submission is made in furtherance of this body of work.

SUMMARY OF OUR SUBMISSIONS

We support the Bill in general and in principle. However, we submit that if it is to play its rightful role in striking a balance between incentives for innovation and access to the benefits of scientific developments, it needs to be strengthened by:

- Requiring the applicant for a patent to submit proof of his or her title or authority to make use of the identified indigenous biological resource, genetic resource, traditional knowledge and/or traditional use. In our view, the mandatory submission of proof is preferable to the current formulation in the Bill that simply empowers the registrar to request such proof. Without the obligation on the applicant to submit proof, a patent could be granted in the absence of title or authority, amounting to classic biopiracy.
- Introducing a system of pre-grant opposition by interested parties, which is especially relevant in a country that does require (and may not have the capacity to conduct) full patent examinations.
- Ensuring that applicants for patents take all reasonable steps to ensure that they have title or authority to engage in bioprospecting, being research and development (“R&D”) based on indigenous biological resource, genetic resource, traditional knowledge and/or traditional use. The Bill merely proposes that a patent can be revoked if the declaration regarding bioprospecting is materially false and the applicant had knowledge of the falseness. In our view, this should be expanded to include cases where the applicant ought reasonably to have known that the declaration was materially false and would have known had he or she taken reasonable steps.

- Expanding the grounds of patent revocation to include revocation on the basis of a lack of valid legal title or authority.

STRUCTURE OF THE SUBMISSION

To begin, we briefly consider the rationale behind patent protection and explore how the Bill is consistent with this rationale. Second, we highlight several examples of how other countries have developed their patent laws to respond to domestic needs and/or competitive advantage. Third, we set out the text of our proposed amendments to the Bill. Finally, we make some comments and recommendations regarding the need for further amendments to the Patents Act in a manner that complements the Bill and its objectives.

Rationale behind patent protection

The reason the state sponsors the guarantee of market exclusivity that lies at the heart of patent protection is the public interest. Professor Peter Drahos of the Australian National University explains:

“[T]he Western intellectual property tradition is rooted in the idea that intellectual property rights are property rights created by the state for the benefit of the commonwealth”.¹

In other words, the state creates private rights because the public is able to benefit from their grant.

South African patent law has a similar foundation. Our Patents Act is based in part on the recognition, the Supreme Court of Appeal has said, that “the limited statutory monopoly afforded a patentee is seen as a means of encouraging inventors to put their inventions into practice”.² An “essential quid pro quo of the theory” is that the grant of statutory exclusivity must be to the benefit of the public.³ This then begs the question: what is the public benefit that the Bill is seeking to achieve?

The Bill implicitly recognises the potential value of bioprospecting, which is defined in section 1 of the Biodiversity Act to include “research on, or development or application of, indigenous biological resources for commercial or industrial exploitation”. It further recognises that commercial entities require incentives, such as exclusive rights in patents, to engage in bioprospecting.

At the same time, however, the Bill recognises that the public benefit is not met by simply ensuring the commercial or industrial exploitation of indigenous biological resources. Instead, it sees the public benefit as including the protection of the interests of those who provide access to such resources, whose “traditional uses of the indigenous biological resources ... have initiated or will contribute to or form part

¹ Peter Drahos, “The Universality of Intellectual Property Rights: Origins and Development” in *Intellectual Property Rights and Human Rights* (World Intellectual Property Organisation in collaboration with the Office of the United Nations High Commissioner for Human Rights, November 1998) at 14.

² *Syntheta (Pty) Ltd (formerly Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another* 1999 (1) SA 85 (SCA) at 88l

³ *Ibid* at 88l-J

of the proposed bioprospecting” or “whose knowledge of or discoveries about ... indigenous biological resources ... are to be used for the proposed bioprospecting”.⁴

In other words, the Bill sees the need for creating incentives for persons and indigenous communities to provide access to indigenous biological and genetic resources and to share their traditional knowledge and use. By ensuring that such people are able to share directly in the benefits that may flow from bioprospecting, the Bill seeks to ensure that innovative products based on indigenous biological resources, genetic resources, traditional knowledge and/or traditional use come to market.

In general, a rational patent policy is in part based on a country’s comparative advantage, considering not only the interests of innovators, imitators and adaptors, but also the interests of consumers.⁵ In short, the Bill seeks to do just this – exploit South Africa’s comparative advantage in indigenous biological resources, genetic material, traditional knowledge and traditional use in a reasonable manner that is fair to all. Further, the Bill seeks to develop our law in a way that takes our specific needs into consideration, by ensuring that bioprospecting that leads to the market entry of innovative products also benefits the indigenous communities – who hold the key to accessing such resources or knowledge – through their economic development.

Amending patent laws in response to domestic need

In the 1970s, the United States (US) government owned intellectual property (IP) created by federally funded research but had failed to exploit it. So Congress passed the Bayh-Dole Act in 1980: it gave recipients of federal grants exclusive rights to the IP they had developed, with public money, in exchange for their undertaking to exploit those rights commercially.⁶ This included taking active steps to commercialise the IP in question.

In other words, the Bayh-Dole statute adapted the patent system by transferring ownership of federally funded research from the federal government to the innovators themselves. It did so to resolve a problem particular to the domestic United States. Without the context-specific adjustment it introduced, the commercialisation of important health products may not have occurred.

German patent law, on the other hand, expressly states that a “patent shall have no effect where the Federal Government orders that the invention be exploited in the interest of public welfare.” It further provides that the “effect of a patent [shall not] extend to any exploitation of the security of the Federal Republic by the appropriate supreme federal authority or, on the latter’s instructions, by a subordinate agency.”⁷ Public welfare and national security concerns in Germany have resulted in specific developments in the national patent law.

⁴ Section 82(1)(b) of the Biodiversity Act

⁵ Michael J. Trebilcock and Robert Howse, *The Regulation of International Trade*, 2nd ed. (London: Routledge, 1999) at 308

⁶ See ‘Chapter 18—Patent rights in inventions made with federal assistance’, 35 USC § 200 – 212.

⁷ Section 13-(1) of the Patent Law (Text of December 16, 1980, as last amended by the Laws of July 16 and August 6), as reported in Third World Network, *Manual on Good Practices in Public-Health-Sensitive Policy Measures and Patent Laws*, 2003. For more information on the publication, see <http://www.twinside.org.sg/title/manual2.htm>.

Other domestic situations have required equally specific adjustments. The examples are too numerous to mention.⁸

Proposed amendments to the Patents Amendment Bill

The following four categories of amendments are proposed:

- Submitting proof of title or authority to make use of indigenous biological resources, genetic resources, traditional knowledge and/or traditional use;
- Introducing a system of pre-grant opposition by interested parties;
- Ensuring that applicants for patents take all reasonable steps to ensure that they have title or authority to engage in bioprospecting; and
- Expanding the grounds for patent revocation.

In addition we propose the following minor amendment to subsection (3A)(b) so that it makes reference to the correct statement:

“(b) Despite subsection (6) an application contemplated in subsection (1) shall not be given a lodging date until the statement contemplated in subsection ~~[(1)]~~ (3A) has been lodged with the registrar.”

Submitting proof of title or authority

We propose that subsection (3B) be deleted and incorporated – in the form of a requirement on the part of the applicant – into a new subsection (3A)(c):

“(c) If the statement lodged in terms of subsection (3A) acknowledges that the invention is directly derived from an indigenous biological resource or a genetic resource, and/or that the invention is based on or derived from traditional knowledge or traditional use, the applicant shall lodge with the registrar proof in the prescribed manner as to his or her title or authority to make use of the indigenous biological resource or genetic resource or of the traditional knowledge or traditional use.”

Introducing a system of pre-grant opposition by interested parties

Given the absence of detailed patent examinations, we proposed that a system of pre-grant opposition, similar to that found in the Indian Patents Act, 1970 (as amended), be incorporated through the amendment of section 34 of the Act:

“The registrar shall examine in the prescribed manner every application for a patent and every complete specification accompanying such application or lodged at the patent office in pursuance of such application and if it complies with the requirements of this Act, he or she shall accept it if the following steps have been completed:

- (1) He or she has caused notice of the application for the patent to be published in the *Government Gazette* not less than six months prior to the date upon which the application is accepted;
- (2) All interested parties, including those acting solely in the public interest, have been provided the opportunity to make written

⁸ For many relevant examples, see *ibid*.

- submissions setting out the manner in which the patent application does not comply with any provision of this Act; and
- (3) He or she has provided written reasons justifying the acceptance of the patent application, notwithstanding the submissions advanced in terms of subsection (2)."

Taking reasonable steps to ensure title or authority to engage in bioprospecting

It is important to demand of those seeking patents that they take all reasonable steps to determine whether the inventions in respect of which they seek patents have in any ways relied upon bioprospecting. Given the high number of licensing agreements between small biotechnology companies and university-based researchers on the one hand and multinational pharmaceutical companies on the other, patentees may indeed benefit from bioprospecting in the absence of any benefit sharing agreements having been concluded.

In the result, we propose the amendment of section 61(1)(g) in the following manner:

“(g) that the prescribed declaration lodged in respect of the application for the patent or the statement lodged in terms of section 30(3A) contains a false statement or representation which is material and which the patentee knew to be or ought reasonably to have known was false at the time when the statement or representation was made”.

Expanding the grounds for patent revocation

Similarly, we propose that section 61(1) be amended by the addition of a new paragraph (j) that ensures that title or authority to make use of the results of bioprospecting is in fact lawfully obtained:

“(j) that at the time of the lodging of the statement in terms of section 30(3A), the applicant for the patent did not have title or authority to make use of the indigenous biological resource or genetic resource or of the traditional knowledge or traditional use, and the relevant invention was directly derived from an indigenous biological resource or a genetic resource, and/or that the invention was based on or derived from traditional knowledge or traditional use.”

Necessity of further amendments to the Patents Act

In conclusion, we would like to draw to the Portfolio Committee’s attention that South Africa requires a comprehensive review of its patent legislation to enable the development of an appropriate patent regime within the bounds of both what is permitted in terms of international trade law and what is required by international human rights law and the Constitution. In many respects, the level of protection afforded to patentees in the Patents Act remains inappropriate for a country with our level of development, burden of disease and industrial strategy regarding the domestic generic pharmaceutical industry.

In our view, much of this can be corrected by amendments to the Patents Act that fully incorporate the public health safeguards and flexibilities permitted by the World Trade Organisation (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs), as clarified in the *Declaration on the TRIPS Agreement and*

*Public Health (the Doha Declaration)*⁹ and complemented by the WTO decision on *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (the Paragraph 6 decision)*.¹⁰

For South Africa to be able to make full use of the regulatory options permissible under international law, it needs – at minimum – to enact the following legislative amendments:

- Amend section 4 of the Patents Act to expand the category of state officials who may use an invention for public purposes (issue compulsory licences) and, to deal with those circumstances where there is an absence of agreement between the relevant state official and the patentee regarding the terms and conditions of such use, to put in place a default position in this regard;
- Insert a new section 4A into the Patents Act to permit the Minister of Health, the Minister of Trade and Industry or the member of the executive council responsible for health in a province, to issue compulsory licences to deal specifically with a health emergency;
- Amend section 25 of the Patents Act to limit the granting of patents in respect of new uses and new forms of known substances;
- Amend section 56 of the Patents Act, which allows private persons (including companies) to apply for compulsory licences, so that standing to apply for a compulsory licence is broadened, processes are streamlined and patent protection reduced so as only to provide that which is required by TRIPs and no more. As it currently reads, section 56 provides TRIPs-plus protections;
- Insert a new section 56A into the Patents Act to permit private persons (including companies) to apply for compulsory licences to deal with a public health emergency or situation of extreme urgency;
- Insert a new section 56B into the Patents Act to permit the issuing of compulsory licences for the local production of generic pharmaceutical products solely for export to countries with limited or no pharmaceutical manufacturing capacity, as permitted by the WTO's Paragraph 6 decision;
- Amend section 61 of the Patents Act to provide for the revocation of a patent when the grant of a licence in terms of section 4, 4A, 56 or 56A has not been sufficient to prevent abuse resulting from the exercise of the exclusive rights conferred by the patent, provided that at least two years have expired since the grant of such licence; and

⁹ *Declaration on the TRIPS Agreement and Public Health*, WTO Res. WT/MIN(01)/DEC/2, 4th Sess., Ministerial Conference, 20 November 2001. The *Doha Declaration* was adopted at the WTO Ministerial Conference in Doha, Qatar in November 2001.

¹⁰ WT/L/540, 1 September 2003, available online at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

- Insert various new definitions into the Patents Act to give proper effect to the additions and amendments proposed above.

Not only is this a desirable course of action to take, but in our view, it is also constitutionally mandated.

[ENDS]