

Pretoria

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South Africa

Recent developments in the patent field

Patents Amendment Bill 2004

Objectives of the Bill

The Amendment Bill (which at this stage has been published for public comment but is **not yet** before Parliament) seeks to introduce into the South African Patents Act provisions, in the first place, to compel applicants for patents in those cases where an invention entails the use of genetic or biological resources, or where an invention is based on indigenous or traditional knowledge, to disclose this fact in the patent application; and, in the second place, to compel applicants for patents in those cases where a patent aims to protect an element of indigenous or traditional knowledge or of 'heritage', to obtain the prior and informed consent of the owners of the traditional knowledge for the sharing of the ownership, control, use and benefits of such knowledge; and, in the third place, to provide for sanctions in cases of non-compliance with these provisions.

In the explanatory memorandum published with the Bill, the problem being addressed by the Bill is stated to be that genetic and biological resources are being patented without the knowledge or consent of the states to which these resources belong, and without the knowledge or consent of the indigenous peoples from whom the knowledge was derived and who, through their knowledge, have made a contribution to the invention.

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New legislative and regulatory framework for medicines

Amendments of Medicines Act put into operation

Section 15C of the Medicines and Related Substances Control Act no. 101 of 1965 gives the Minister (of Health) the power to 'prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public', inter alia by determining that patent rights would not extend to certain acts (eg importation) in respect of medicines which have been put onto the market by the owner of the medicine.

This section, the precise ambit and effect of which lack clarity and which gave rise to a spate of litigation when it was passed by Parliament as part of the Amendment Act no. 90 of 1997, was put into operation on 2 May 2003 together with a number of further amendments and a full set of regulations dealing not only with the registration of medicines for marketing purposes, but also with the importation of medicines (regulation 7) and international tender procedures (regulation 3). This was followed in June 2003 by comprehensive guidelines to the regulations, and in January 2004 by draft regulations (published for comment) relating to a transparent pricing system for medicines and scheduled substances.

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Adams & Adams

Patents Amendment Bill (cont)

Main provisions of the Bill

The Bill seeks to introduce into the South African Patents Act, 1978 (Act no. 57 of 1978) the following provisions:

- to require of an applicant for a patent to disclose in the patent application information regarding the origin of biological or genetic material 'used in the invention' (section 25(A)(2));
- to place an obligation on the registrar of patents to treat the 'non-disclosure or wrongful non-disclosure of the origin of genetic or biological resource or knowledge' in a patent application, and the 'non-disclosure or the wrongful non-disclosure of prior knowledge, traditional knowledge, oral or otherwise' as grounds for the rejection or revocation of the patent application (section 25(A)(1));
- to place an obligation on the registrar of patents to 'deny' an applicant the right to obtain patent protection for 'any element of indigenous/heritage' without adequate documentary proof of the prior and informed consent of the 'owners or holders' of traditional knowledge in regard to the 'sharing of ownership, control, use and benefits' (section 25(A)(3)); and
- to provide for any interested party to have the right to institute legal action with a view to 'rescinding the patent based on the above-mentioned grounds' (section 25(A)(4)).

Response to the Bill

It is our view that, on a legal technical level, the draft Bill as published has many defects and inconsistencies, and also lacks clarity on numerous points, such as whether or not the provisions will apply to genetic and biological material originating from countries outside South Africa; whether the provisions will apply retroactively; what the parameters would be of the obligation to disclose (ie only in respect of genetic or biological material directly used in the invention, or also in respect of such material where a derived product is used in the invention); etc.

Partners of Adams & Adams were instrumental in drafting comments on the Bill and co-ordinating the endorsement and support of the comments by various interested parties, including intellectual property law firms, professional intellectual property bodies, universities, pharmaceutical companies, etc. The main points were:

- that the duty to disclose should relate to indigenous biological resources and that this concept should be clearly defined;
- that the disclosure requirements should be structured as a formal requirement with the disclosure statements made on a prescribed form rather than in the specifications;
- that a false disclosure made knowingly would constitute a material misrepresentation and as such would provide a ground for revocation; and
- that the issue of consent by indigenous people in respect of traditional knowledge and the need for benefit-sharing agreements should be dealt with in other more appropriate legislation, such as in terms of the National Environmental Management: Biodiversity Bill which was recently passed by our Parliament.

Bursary scheme

Adams & Adams has for many years, from as early as 1981, been making available study bursaries to South African universities for law students. At the beginning of this year the firm embarked on an improved scheme to provide bursaries to deserving students from previously disadvantaged communities. The bursary scheme is aimed at supporting the bursary holders during their third and fourth year LLB studies, covering class and registration fees, whilst at the same time providing a small annual allowance towards study material, travel etc. Upon completion of the LLB degree, the firm may provide the bursary holders with a two-year contract of articles.

Shadow programme & involvement in the Integrated Bar Project

At the beginning of this year, we also implemented a shadow programme for third and fourth year LLB students. This programme runs for a duration of two weeks, during the June / July university vacation period and provides the students with exposure to the law and the practice of law.

Regulatory framework (cont)

Importation permits

Regulation 7 of the 2003 regulations, which bears the heading 'Importation of medicines in terms of section 15C', provides that a medicine referred to in section 15C(b) - ie a medicine which is identical in composition to another medicine already registered (with the Medicines Control Council (MCC) for marketing purposes) in South Africa, meets the same quality standard and is intended to have the same proprietary name - may be sold in South Africa if -

- the medicine is being sold outside South Africa with the consent of the patent holder;
- the medicine is imported from a person licensed by a recognised regulatory authority;
- the medicine is imported by a person with a permit issued in terms of the regulation; and
- the medicine is registered in terms of the South African Medicines Act.

Guidelines: parallel importation

It is not clear from its wording whether this regulation is intended to apply to parallel importation of medicines. However, the guidelines pertaining to regulation 7 expressly refer to the parallel importation of medicines, and state that the holder of a MCC registration certificate in South Africa in respect of a medicine will not be entitled to prevent its importation nor its sale on account of such registration or on account of the existence of a patent on such medicine. No express reference is made to the position of the patentee, ie whether the patentee would likewise not be entitled to prevent the importation.

It seems, however, that a patented medicine could be imported into South Africa by a third party on the strength of a permit issued by the Minister of Health and probably without the need to obtain a licence (either voluntary or compulsory) under the patent in terms of the Patents Act.

International tendering

The regulations also provide (regulation 3) for an international tendering procedure to enable the State to obtain a medicine internationally if such medicine can be obtained at a lower price outside the Republic, or it is, in the opinion of the Minister (of Health) essential for national health. It is not clear from the formulation of regulation 3 whether the international tendering will be limited to authentic medicines under patents, or whether generic equivalents or off-patent branded products would also be included.

So far there has been no attempt by government to introduce into the Patents Act a compulsory licence provision in accordance with the model published by the WTO/TRIPS Council on 30 August 2003 pursuant to the Doha Declaration.

Draft regulations: pricing system

In terms of these regulations (at present still in draft form and published for comment) the manufacturers or importers of medicines and scheduled substances will be required to publish certain prescribed information in respect of such medicines or substances, including the single exit price which shall not be higher than 50% of the manufacturer nett price as at the date of publication of the regulations (ie 16 January 2004). The single exit price may only be increased once annually by the Minister after consultation with a pricing committee, taking into account the Consumer Price Index, the Production Price Index, foreign exchange rates and the need to ensure the availability, affordability and quality of medicines and scheduled substances.

Furthermore, the Director-General of Health may determine that the price of a medicine or scheduled substance is unreasonable, taking into account inter alia the seriousness of the obstacle, represented by the price to access to medicines when compared to the interest of the public in having access to that medicine.

Recent awards

MIP - World IP Survey - 2003

Adams & Adams once again received, for the third year running, the top rating for the categories patents and trade marks in South Africa in the annual Managing Intellectual Property World IP survey.

PMR - SA Business Leaders' Survey - 2003

A national survey was again conducted within South Africa by the business magazine Professional Management Review (PMR) among 200 of the top South African companies. The survey covered legal services in various fields, and Adams & Adams was rated, for the third year running, the top firm specialising in patents and trade marks.

Recent trade mark decisions

Registration of colours



Cadbury Limited applied to register the colour purple as a trade mark in relation to 'chocolate confectionery' and its application was opposed by Beacon Sweets

and Chocolates (Pty) Ltd. Originally, the trade mark was simply depicted by a square showing the colour that constituted the mark.

During the opposition proceedings, Cadbury restricted its application to indicate that the mark was only to be registered in respect of 'Chocolate confectionery in moulded slab form' and that the mark consisted of the colour purple 'applied to the whole visible surface or being the predominant colour applied to the whole visible surface of the packaging of the goods'.

Although the Trade Marks Act expressly indicates that a mark includes a colour, Judge Spoelstra, sitting as the Registrar of Trade Marks, relied on European case law in order to determine registrability. He took the view that a colour, in isolation and without being used in a distinct fashion, does not constitute a registrable trade mark. He indicated that, to be registered as a mark, a colour must be represented visually in an application, particularly by means of images, lines or characters, so that the nature of the mark can be precisely identified. In short, there should be a visual representation showing the manner in which the mark is to be used on goods.

Although there was evidence to show that the colour purple does not serve a descriptive purpose when used in relation to chocolate, that it is not normally associated with chocolate (except that of the applicant) and that it had been used on a massive scale by the applicant, the Judge was not prepared to accept there was good cause for the registration of the colour alone. The application therefore did not proceed.

Wrongly issued registration certificates

Judges McCreath and Spoelstra, each sitting as the Registrar of Trade Marks, were required to consider the implications when the registrar wrongly issued registration certificates. In *Home Hyper City (Pty) Ltd v Home Mark (Pty) Ltd*, Judge McCreath indicated that when a trade mark application is under opposition and the registrar improperly issues the registration certificate, the registrar is not able to withdraw the registration certificate. The aggrieved party may bring a formal application to set aside the granting of a registration certificate but, until it does so, the trade mark must be considered as having been properly registered.

In the matter of *Neville Dorrington v Hugo Boss AG*, Judge Spoelstra was faced with a similar situation but, in that case, the registrar simply cancelled the entry in the register in respect of the issue of the registration certificate, taking the view that the amended register correctly reflected the factual situation. The judge held that the registrar did not have the power to cancel the register entry even though the certificate may have been wrongly issued. A formal review or an appeal is needed to set aside the error. The opposition of Hugo Boss AG was, therefore, effectively brought to an end by the inadvertent issuing of the registration certificate.

These cases have serious implications for both opponents and applicants as they mean that, in the event of the registrar inadvertently issuing a registration certificate, the opponent will be obliged to bring a formal application to set aside the certificate before continuing with any opposition, and the applicant may have what is possibly a voidable registration. Requests have been made for the legislation to be revised to eliminate the problem.

Impact of abbreviations



In an appeal to the High Court against the decision of the Registrar of Trade Marks, Budejovicke Budvar Narodni Podnik (BB) asked the court to allow its trade mark application for the mark BUDEJOVICKE BUDVAR in script form to proceed to registration in the face of earlier registrations of Anheuser-Busch Incorporated (AB) for the marks BUDWEISER and BUD. Although BB had applied for registration in several classes, it was common cause that, unless it could obtain registration in class 32, the mark in its other applications would not be used and therefore they should also be refused.

The basis of AB's argument was that any reasonable consumer would not, in the normal course of trade, use the full mark BUDEJOVICKE BUDVAR to order a beer. The evidence showed that the word BUD was the most likely abbreviation. This was apparent from the fact that BB had itself used the abbreviation BUD in various countries of the world.

Taking into account the various places in which the mark BUDEJOVICKE BUDVAR is likely to be used, the nature of consumers and the likelihood of the mark being abbreviated, the court decided that the product was likely to be called BUD in the normal course of trade. The mark BUD is a strong prefix in both BUDEJOVICKE and BUDVAR and the court could not discount the probability that typical consumers would identify the BUDEJOVICKE BUDVAR product with that identified by the mark BUD.

In the circumstances, the court upheld the decision of the registrar and refused to allow the application to proceed to registration.