Legal developments in the protection of plant-related traditional knowledge: An intellectual property lawyer’s perspective of the international and South African legal framework

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Abstract

The South African legal framework regulating the research and commercialisation of plant material, or bioprospecting, consists of the National Environmental Management: Biodiversity Act, 2004, and the Bioprospecting, Access and Benefit Sharing Regulations issued under that Act in 2008, and Section 30 of the Patents Act, 1978, as amended by the Patents Amendment Act, 2005. The international backdrop to this legislation is the Convention on Biological Diversity, which came into force in 1993.

In October 2010, the Convention on Biological Diversity adopted the Nagoya Protocol, which is intended to be a binding legal instrument on the subject of access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation. The underlying principles are that the prior informed consent of communities holding the traditional knowledge must be obtained and that benefits arising from utilisation of that knowledge must be shared, the arrangements being managed by the State.

This article is a broad discourse on the relevant legislation as seen from the perspective of an intellectual property lawyer, focusing on the most recent developments, and illustrating its application in cases which have been reported in the press.

Keywords: Benefit sharing agreements; Bioprospecting legislation; Nagoya Protocol; Patents; Traditional knowledge

1. Introduction

In recent years, the press has reported on cases where extracts from South African plant materials, which are used by indigenous communities as traditional remedies, have been patented or attempted to be patented (Business Day, 2010; Mail & Guardian 2010a, 2010b, 2010c). These press reports have brought to the public eye the tension between the commercialising and patenting of such extracts, as features of our formal economy, and the position of indigenous communities in relation to the commercialisation of the products derived from those extracts. In roughly the same time frame, South Africa has passed legislation regulating bioprospecting and patent applications for inventions derived from traditional knowledge with the object of strengthening the position of indigenous communities to negotiate commercial benefits arising from the commercialisation of these products (Biodiversity Act, 2004; Patents Amendment Act, 2005). In a parallel development, legislation to protect traditional works as copyright and other forms of intellectual property is being debated in Parliament (the Intellectual Property Laws Amendment Bill, No 8 of 2010). In this legislation, the procedures and flow of benefits are, or are to be, undertaken by the State or State-appointed bodies.

This legislation directly affects the patentability, in South Africa, of inventions which are derived from South Africa-sourced traditional knowledge. On the other hand, the internationally applied principles of patent law which require novelty and inventiveness of inventions to qualify for patentability, already serve to prevent the registration of patents on plant extracts which make claims derived from traditional knowledge relating to those plants.
2. The convention on biological diversity and the adoption of the Nagoya Protocol

Before dealing with the South African legislation, it is worth looking at the country’s international obligations which gave rise to it and the latest developments in international law.

The Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation to the convention on biological diversity (“Nagoya Protocol”) was adopted on 29 October 2010 by the contracting states to the United Nations Convention on Biological Diversity (“CBD”) (CBD, 1995; Nagoya Protocol, 2010). By the end of August 2011, it had been ratified by nearly the minimum number of fifty CBD contracting states needed before it comes into force, including by South Africa.

The backdrop to the Nagoya Protocol is found in one of the three main objects of the CBD, namely “fair and equitable sharing of the benefits arising out of the utilisation of genetic resources”, as well as in article 15 of the CBD, which recognises “the sovereign rights of States over their natural resources.” Article 8(j) of the CBD requires contracting states to “respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices”, subject to their national legislation (CBD, 1995).

The focus of the Nagoya Protocol is on fair and equitable sharing of the benefits arising from the utilisation of genetic resources between the member State providing the resources and the member State acquiring the resources for utilisation. Benefits arising from the utilisation of genetic resources that are recognised under local law as being held by indigenous and local communities, whether those benefits are monetary or non-monetary, must be shared by mutual agreement in a fair and equitable way. Under the term “utilisation” is understood the research of the genetic resources concerned and their application and commercialisation in technical applications and derivative products. The *quid pro quo* is that providing States have to give transparent, cost-effective and timely access to its genetic resources (Nagoya Protocol, 2010; Articles 5 and 6).

Being an instrument which is supplementary to the CBD and therefore approaches the topic from the perspective of the conservation and sustainable use of biodiversity, the Nagoya Protocol does not require amendments to intellectual property legislation. An international position on intellectual property law relating to traditional knowledge and genetic resources is being negotiated in 2011 under the auspices of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of the World Intellectual Property Organisation (WIPO) (WIPO, 2011).

3. Postulating the case for legislative protection of traditional knowledge and its challenges

The simple argument in favour of legislative intervention is that communities which hold traditional knowledge in the use of plants need protection against the appropriation and use of their knowledge by outsiders, especially in the form of patenting and commercialisation of the results of that knowledge (Mukuka, 2010). The scenario which is invariably drawn, amongst others by a number of NGOs, is one where the community and the plant resource are from a developing country and an outsider from a developed country patents or commercialises a product derived from the plant and its associated traditional knowledge without the authorisation or even knowledge of the originating community. This kind of appropriation is then labelled “biopiracy” (Bavikatte et al., 2010; Mayet, 2010).

Traditional knowledge generally does not qualify for protection under existing intellectual property law legislation because it is mostly not new or original. By its very nature, traditional knowledge is knowledge which has been used by members of indigenous communities over time and in most cases will even be in the public domain. Therefore, an item of traditional knowledge will typically not meet the novelty requirements for patents and designs, just as a traditional work of an indigenous community (often referred to as “an expression of culture”) will not meet the originality requirements of copyright. The subject matter simply does not fit into intellectual property law systems (Harms, 2009).

If traditional knowledge needs to be protected or its existence recognised in commerce and in the intellectual property framework, specific legislation needs to be passed. This legislation will have to address complex legal challenges. An indigenous community is not recognised as a legal person in law. The absence of such recognition means that it is not an entity with which a contract can be concluded, and that it will be difficult, if not impossible, to identify any given community, its members and representatives. Even once these problems are addressed, it cannot be said that the traditional knowledge which it practises is something which is “held” by it, if “held” is used in the sense of “owned”, which means that a legal construct has to be devised by legislation under which a duty is established to seek consent from, and share benefits with, the community which practises the traditional knowledge. This problem is exacerbated when the same traditional knowledge is practised by different communities, as is so often the case. (Case studies of use of the same plant remedy by different communities for the same and for different purposes can be found in Van Wyk and Gericke (2000) and in Brendler and Van Wyk (2008)). Finally, such legislation will only truly be effective if
there is corresponding legislation in other countries under which these rights are recognised reciprocally.

4. Legislation: the Biodiversity Act

Legislation requiring prior informed consent from, and benefit sharing agreements with, communities which contribute to bioprospecting research already took effect in South Africa in 2006 in terms of the provisions of Chapter 6 of the National Environmental Management: Biodiversity Act, 2004 (the “Biodiversity Act”), although the regulations giving effect to them were only promulgated in 2008 (Biodiversity Act, 2004; Regulations on ABS, 2008). (For ease of reference, these legislative provisions are referred to together as the “bioprospecting provisions”). The bioprospecting provisions were implemented in compliance with South Africa’s obligations under the CBD and also anticipate the coming into effect of the Nagoya Protocol. Although the CBD was binding on South Africa since it became a party to it in 1995, in terms of the Constitution it only became law in South Africa when its terms were enacted by legislation passed by Parliament (Constitution, 1996; Section 231(4)). The bioprospecting legislation has already been the subject of detailed commentary (Crouch et al., 2008; Wynberg, 2009).

The original bioprospecting provisions were subject to much criticism, especially as they required a permit to research. At the time of initiating the research, the ultimate findings would be unknown, which in turn made it impossible to determine the terms of any benefit sharing agreement and therefore to apply for a permit (Crouch et al., 2008). The situation was eased by the amendment to the Biodiversity Act by the National Environmental Laws Amendment Act, 2009, which took effect from 1 April 2011, in which a distinction was made between the discovery phase of bioprospecting, which only requires notification to the Minister, and any resultant commercialisation phase, which requires a permit.

Under the bioprospecting provisions, prior informed consent and benefit sharing are regulated by a permit system. A permit system brings with it State regulation and criminal sanctions. State regulation may be felt to be appropriate to place an indigenous community in a better negotiating position vis-à-vis bioprospectors and also enables the problem of how to identify indigenous communities and their authorised representatives to be swept under the carpet. However, as appears below, the bioprospecting provisions also interfere with contractual freedom and the patent system. At this juncture, it should be pointed out that a permit system and the amendment of intellectual property legislation are not specific requirements of the CBD or the Nagoya Protocol - the latter only asks contracting states to take “legislative, administrative or policy measures, as appropriate” to achieve its aims (Nagoya Protocol, 2010; Article 5).

The bioprospecting regulations set out the detail needed for the application for bioprospecting and export permits and also contain wide-ranging conditions attaching to their issue. Some of the items which will cause practical difficulties or result in legal exposure for applicants are:

- Applications may only be submitted by South African persons or companies or by foreign entities jointly with South African persons or companies (Regulations on ABS, 2008; Regulation 9). Considering the obligations to which a permit holder, the South African party in a permit jointly held with a foreigner will, in reality, take on the brunt of the legal exposure, and it can be expected that bioprospecting transactions will be so structured that only the party in the field applies for the permit, as opposed to any of the parties higher up in the commercialisation chain.
- The issue of the permit is the function of the Minister of Environmental Affairs, who is required to be “satisfied” by various aspects of the application and is empowered to make further enquiries in response to an application (Regulations on ABS, 2008; Regulation 8). The Minister has to be satisfied with the underlying benefit sharing agreement where traditional knowledge is being used and may even interfere with the contractual terms if she considers them not to be fair and equitable, and intervene in the identification of stakeholders (Regulations on ABS, 2008; regulation 17). The benefit sharing agreement may also be published for public comment. These conditions, as well as the decision making process, can only result in an extended approval process.
- A benefit sharing agreement has to be in a prescribed form (Regulations on ABS, 2008; Annexure 8) and, even though deviations from the form are allowed, it still has to follow its “general format”, which no doubt includes the clause that it “constitutes the entire agreement between the parties.” Great care therefore has to be taken in negotiating and drawing up the benefit sharing agreement to ensure that all the commercial terms and contingencies are covered.
- A resolution of the indigenous community consenting to the benefit sharing agreement and authorising a representative to enter into it, must be attached to the benefit sharing agreement (Regulations on ABS, 2008; Annexure 8). Since an indigenous community is not a legal person, this resolution, at best, will only contractually bind the persons who voted in favour of it. It will not bind community members who were not at the meeting and those who voted against the resolution. A majority vote should, however, “satisfy” the Minister, so it would be prudent to attach an attendance list to the resolution in which is indicated which attendees voted in favour.
- The permit holder is “liable for the costs of mitigating or remedying the impact of the bioprospecting on the environment” (Regulations on ABS, 2008; Regulation 12(f)).
- The consideration due under the benefit sharing agreement is not paid to the indigenous community, but to the Bioprospecting Trust Fund for the benefit of the community (Regulations on ABS, 2008; Regulation 19; Biodiversity Act, 2004; Section 85(1)). Although the Fund is subject to the Public Finance Management Act, No 29 of 1999, no audit report had been issued in respect of it by the Auditor General up the 2009–10 financial year. The handling of money through this Fund will not only show whether or not indigenous communities will be satisfied with this arrangement, but will also indicate the real commercial value of traditional knowledge in bioprospecting.
5. Legislation: amendment to the Patents Act

The Biodiversity Act was followed by the 2005 amendment to the Patents Act, No 57 of 1978, by the Patents Amendment Act, No 20 of 2005, (the “Patents Act”) and accompanying regulations, which took effect from 14 December 2007. An applicant for a patent with a complete specification must lodge a statement stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource or genetic resource, as defined in the Biodiversity Act, or traditional knowledge or use. The purpose of the amendment, as stated in its preceding Bill, was to “benefit and empower mainly the holders and the practitioners of genetic or biological resources and indigenous knowledge systems” and to make it “possible to outlaw bio-piracy activities, i.e. trafficking in biological materials with a view to developing patent inventions without prior approval from the relevant authority.” In the case of a positive statement, a copy of the bioprospecting permit and other documentation indicating the relevant community’s prior informed consent or benefit sharing agreement, must also be lodged before the patent can be accepted. An incorrect statement could invalidate the patent (Patents Amendment Act, 2005).

Turning first to the basic principles relating to the patentability of inventions, Section 25 of the Patents Act states that a patent may be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture (Patents Act, 1978). The novelty and inventiveness of an invention are adjudicated against the “state of the art” existing on the date of filing the patent. It comprises anything which has been made available to the public, such as existing products, processes or information about them, and whether it has been made available in South Africa or anywhere else. The standard of novelty is absolute, which means that if the invention has been used or published anywhere in the world before the filing date of the patent, the invention will be unpatentable for lack of novelty. The requirement of an inventive step is met if the invention is not obvious to a person skilled in the art, having regard to the state of the art at the time. These principles are universal and are applied in the patent laws of all industrialised countries.

In many industrialised countries, the substance of patent applications is examined for compliance with the requirements of novelty and inventive step. On the other hand, patent applications in South Africa are not substantively examined. Therefore, if a South African patent does not meet these requirements, it could still be registered, but it is then up to third parties to apply for expungement of the patent by bringing proceedings before the High Court or the Commissioner of Patents. Needless to say, this is a very expensive and time-consuming procedure.

However, if a South African patentee wishes to extend his patent to other countries in terms of the international Patent Cooperation Treaty (“PCT”), of which South Africa is a member, the patent application will be examined by an accredited international searching authority (PCT, 1970). A finding of lack of novelty and inventiveness made through the PCT process will result in the patent application being withdrawn.

It is notable that the South African legislation imposes these strict requirements on inventions based on indigenous, South African, sources, but it does not require disclosure of non-South African sources. On the other hand, Switzerland, Norway and China have introduced disclosure requirements relating to genetic resource or traditional knowledge, irrespective of its origin. Germany has the disclosure requirement for the origin of genetic resources only (Swiss Patents Act of 25 June 1954, as amended in 2007 — Section 49a; Norwegian Patents Act, Act 1967-12-15 no 09, as last amended in 2009 — Section 8b; Chinese Patent Law, as amended in 2009 - Section 25(5); German Patents Act — Section 34a). It is notable that a failure to disclose does not lead to the invalidity of the patent.

6. The outcome of some patent cases involving South African traditional knowledge

The case of the CSIR’s patent on the P57 extract from *Hoodia gordonii* has already been reported and commented upon often, and it is not intended to repeat the details here. The history of this case is set out, amongst others, in Indigenous Peoples, Consent and Benefit Sharing, by Rachel Wynberg and well-known human rights lawyer Roger Chennells (Wynberg and Chennells, 2009). Chennells was the attorney representing the San community.

Questioning the validity of the CSIR patent placed the community before a dilemma, as recounted by Wynberg and Chennells (2009): “Early on in the negotiations, the San faced a difficult choice. Should they oppose or even challenge the patent, based on ethical considerations and lack of novelty ... or should they adopt a more practical approach and actively negotiate a share of the royalties? This was a critical moral dilemma.”

They refer to a moral dilemma of the San people, for whom “the sharing of knowledge is a culture-defining attribute ... and basic to their way of life. Traditional knowledge of plants is viewed as collective and the idea of ‘owning’ life is abhorrent.” Yet the dilemma in the intellectual property dimension can be described in the same terms — should the San have negotiated royalties from the commercialising of a patent which may have been invalid in the light of the absolute standard of novelty or the requirement of an inventive step?

The benefit sharing agreement between the CSIR and representatives of the San communities was concluded in March 2003, before the bioprospecting provisions of the Biodiversity Act came into force, therefore entirely on a voluntary basis. In 2006 and 2007, two further benefit sharing agreements were signed with distributors of *Hoodia* products. However, the commercial partners to the P57 project withdrew and, to all accounts, these agreements have not yet produced significant financial returns for the San (Wynberg and Chennells, 2009).

Patents filed under the European Patent Convention for extracts from *Pelargonium sidoides*, amongst others to treat acute and inflammatory diseases and infections, and from rooibos, *Aspalathus linearis*, and honeybush, *Cyclopia intermedia*, for a variety of cosmetic and therapeutic applications and filed
were refused by the examining authorities for lack of novelty and inventiveness. (Unlike in South Africa, patents filed under the European Patent Convention are examined).

The *P. sidoides*-based patent filed by German phytopharmaceutical company, Dr. Willmar Schwabe GmbH & Co. KG (“Schwabe”), was the subject of a judgment by the European Patent Office’s Opposition Division in January 2010, in which the patent was held to be invalid due to a lack of an inventive step when compared to prior art in percolation and maceration techniques identified by one of the three commercial objectors. However, the objection on the ground of illegality for failure to comply with the disclosure requirements of the CBD to state the origin of an invention, was rejected because such a disclosure was not a ground for the invalidity of a patent (European Patent Office Opposition Division, 2010; Myburgh, 2010).

Similar results were achieved in other attacks on patents for extracts from plant material where traditional knowledge was involved (Robinson, 2010). In the writer’s opinion, this demonstrates that the patent system can deal with those cases where an outsider attempts to patent plant-based traditional knowledge. The true problem is one of access to justice. As mentioned earlier, patent cases are expensive and complex, and these cases have often been brought for indigenous communities by non-governmental organisations, such as the Declaration of Berne and Biosafety Africa in the *P. sidoides* case (Mayet, 2010).

Some developing countries have been more pro-active than South Africa in defending their plant-based traditional knowledge. The Indian Government has made its Traditional Knowledge Digital Library, which documents Indian traditional medicine treatments, accessible to various examining patent offices around the world (TKDL, 2011). Peru’s National Commission against Biopiracy has taken this a step further by using its database records to actively oppose the grant of patents containing Peruvian traditional knowledge (WIPO, 2007).

7. Developments in the ministerial approval of benefit sharing agreements under the bioprospecting regulations

In October 2010, HGH Pharmaceuticals (Pty) Ltd announced the approval by the Minister of Environmental Affairs of a bioprospecting and export permit and its underlying benefit sharing agreement with the San concerning a dietary supplement derived from *Sceletium tortuosum* under its trade mark Zembrin™. The product is the subject of a patent application filed in 2009 by another company (South African patent application 2009/02001, PCT application no PCT/IB2010/051133), which was still pending at the time of writing.

Also in October 2010, Schwabe announced that its South African supplier, Parceval, had entered into a benefit sharing agreement with Chief Mavuso representing the Alice community in the Xhosa Rharhabe Kingdom, to support a bioprospecting and export permit for *Pelargonium* (Schwabe 2010).

However, by as late as February 2011, out of 58 bioprospecting projects, only two permits had been issued (DEA, 2011). One of them was for Zembrin™ (Engineering News, 2010). Approval of the San’s benefit sharing agreements for *Hoodia* and Parceval’s agreement for *Pelargonium* were still outstanding.

8. Conclusions

Ultimately, the greatest criticism of the legislation is that it stifles innovation and commercialisation of South African-sourced indigenous plant material, whilst creating unrealistic expectations about the benefits and causing the indigenous communities to change the way they organise themselves in order to obtain and distribute these benefits (Dewan, 2010; Wynberg and Chennells, 2009).

It is discouraging that, out of 58 bioprospecting projects over the period from April 2008 to February 2011, only two permits have been issued. These delays, as well as the burdensome procedures involving the exercise by the Minister of her discretion, bring into question whether the procedure is certain, clear and transparent, and whether it can be implemented in a cost effective manner within a reasonable period of time, as required by article 6 of the Nagoya Protocol.

A long outstanding permit application places the patent applicant in an invidious position, because he cannot have his patent issued until such time as the relative benefit sharing agreement is approved and the permit is issued. The access provisions of the bioprospecting legislation must therefore be improved by lowering the bureaucratic burdens in a way which will be compliant with the Nagoya Protocol, once it comes into force.

The provisions of the Patents Act relating to inventions based on traditional knowledge affect South African and non-South African inventors alike, but South African inventors are at a greater disadvantage if they wish to extend their patents internationally. They will only discourage patenting of inventions arising from bioprospecting in South Africa, and not internationally, since the South African legislation does not have extra-territorial effect and no other industrialised country has benefit sharing as a condition for a the validity of a patent. In the writer’s opinion, access and benefit sharing legislation should complement a process which records South Africa’s traditional knowledge and encourages home-grown innovation from that base.

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