Q&A on ABS compliance in South Africa

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Introduction

There has been much debate in recent years as to the effectiveness of access and benefit sharing (ABS) provisions relating to indigenous biological and genetic resources (IBGRs) and traditional knowledge (TK) or indigenous knowledge (IK) as set out in the Convention on Biological Diversity and adapted into the local legislation of member countries. Unfortunately, the consensus across a number of developing countries, including India, Brazil, Columbia and South Africa, seems to be that the current systems are not providing fair and equitable benefits to local stakeholders of such resources. Further, it seems that the additional objectives of the Convention on Biological Diversity (including sustainable use and the conservation of IBGRs) has taken a back seat to the emotive issue of how to manage bioprospecting and share the benefits arising from commercialisation.

This article explores the situation in South Africa, one of the most megadiverse countries in the world with a wealth of IK relating to IBGRs.

Q&A

Is South Africa a member of any international treaties that deal with ABS of IBGRs?
Yes. South Africa has been a member of the Convention on Biological Diversity since November 1995 and became a member of the Nagoya Protocol in January 2013.

What national legislation is relevant to ABS from commercialisation of IBGRs and TK?
South Africa's legislative landscape is complex. National legislation is fragmented and managed by multiple government departments which have a degree of overlap. The National Environmental Management: Biodiversity Act (NEMBA) and its Bioprospecting, Access and Benefit Sharing (BABS) Regulations (2008, amended in 2015), administered by the Department of Environment, Forestry and Fisheries (DEFF), regulates ABS from the commercialisation of IBGRs and associated TK in the context of bioprospecting through a permit process. Further, NEMBA requires that material transfer and benefit sharing agreements are executed with local stakeholders for the commercialisation of IBGRs and associated TK.

Amendments to the Patents Act of 1978 were introduced in 2005 to provide for a statement to be filed at the Patent Office on the use of IBGRs and TK in the invention to be patented. If the statement contains a material falsehood or information that the applicant ought to have known was false, this is a ground for revocation of the granted patent. In addition, proof of authority from any indigenous community providing access or TK giving rise to the patent application must be filed at the Patent Office.

The Intellectual Property Laws Amendment Act (2013) administered by the Department of Trade and Industry has introduced amendments into existing IP legislation – including the Trademarks Act, the Performers Protection Act, the Copyrights Act and Designs Act – to make provision for specific protection of TK as a form of intellectual property.

Finally, the Protection, Promotion, Development and Management of Indigenous Knowledge Act 2019 (which is not yet implemented) administered by the Department of Science and Innovation is to provide for the protection, promotion, development and management of IK generally.

How are IBGRs and associated TK managed in terms of NEMBA?
NEMBA essentially distinguishes between three scenarios relating to IBGRs and TK.

First, where there is purely basic research without any bioprospecting involved, only a permit from

the DEFF for export of IBGRs from South Africa will be required.

Second, if there is early stage research to find out whether IBGRs and associated TK has any potential to be further developed into a commercial product, this is considered the 'discovery phase' and no permit is required. Instead, the researcher must complete a so-called 'notification' template and submit this to the minister of the DEFF.

Finally, a bioprospecting, biotrade or integrated biotrade and bioprospecting permit is required where there is either biotrade or commercialisation of IBGRs and associated TK for the application or development of drugs, complementary medicines, neutraceuticals, industry enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts or essential oils. Where IBGRs are to be exported in such circumstances, there is integration of an export permit in the bioprospecting or biotrade permit application.

'Commercialisation' is defined broadly and includes:

- filing patent applications, applications for plant breeder's rights or any other IP application;
- obtaining or transferring IP rights or other tangible or intangible rights; and
- commencing clinical trials and product development (eg, conducting market research and seeking pre-market approval and the multiplication of IBGRs through cultivation, propagation, cloning or other means for commercial or industrial exploitation purposes.

'Biotrade' means the buying and selling of milled, powdered, dried, sliced or extracts of IBGRs for further commercial exploitation.

NEMBA also requires that a permit is applied for only by a South African legal or natural person or jointly with a South African legal or natural person.

All of the required documentation is available on the DEFF website.

It is important to remember that additional permits from the DEFF may be required where IBGRs that are listed as threatened or protected species are harvested.

Are benefits required to be monetary and how is the fairness and equitability of benefits determined?

An important component of NEMBA's regulation of ABS is that in order to be provided with a permit, the biotrader or bioprospector must obtain a signed material transfer agreement (MTA) and benefit sharing agreement (BSA) from the relevant stakeholder(s) or must file a request for intervention by the issuing authority to assist with negotiations if no BSA has been signed. This provides the DEFF with an opportunity to review these agreements and ensure that they provide for fair and equitable sharing of benefits with the stakeholders. Benefits may be either monetary or non-monetary benefits – for example, monetary benefits might include royalty payments, access fees or joint ownership of relevant IP rights, while non-monetary benefits could include capacity-building, training and education, sharing of R&D results or the transfer of technology.

On the other hand, in the case of TK governed by the new Protection, Promotion, Development and Management of Indigenous Knowledge Act, a National Indigenous Knowledge Systems Office (NIKSO) is to be established, which will be tasked with determining the criteria for issuing licences for the use of TK, including benefit sharing in terms of such licences, and assist with the negotiation of these licences. Details will likely be provided in the regulations, once promulgated.

What issues relating to benefit sharing have been experienced?

Some of the biggest issues relating to benefit sharing include how to identify who the stakeholders for ABS are and how to quantify what are fair and equitable benefits during early stage commercialisation of IGBRs and associated TK and the actual negotiation process relating to ABS.

For example, one major problem experienced by biotraders is that each biotrade permit applicant was expected to negotiate ABS separately with each relevant indigenous stakeholder community. This has proved to be unworkable. In an attempt to alleviate this burden, the DEFF has proposed that a rate per crop is calculated, where there is a single broad-based negotiation with the relevant stakeholder communities where a rate will be set, starting with prominent crops.

The first such negotiation has been concluded, giving rise to the Rooibos Benefit Sharing Agreement which provides for the San and Khoi communities to receive 1.5% of the 'farm gate price' (ie, the price that agribusinesses pay for unprocessed rooibos, which was estimated to be approximately $680,000 for 2019). This has been heralded as a success, but unfortunately the solution is not so simple. There are communities outside of the San and Khoi that have been farming and using rooibos for generations and which feel that they have TK relating to rooibos and are providing access. They are now excluded from receiving benefits and may even be required to pay royalties to the San and

Khoi communities. It is likely that similar issues may arise in respect to other IGBRs such as Honeybush.

With respect to the Intellectual Property Laws Amendment Act, it has been difficult to reconcile conventional 'Western' IP rights with TK systems, which has in practice resulted in the limited adoption of the amended IP legislation for protection of TK. This is one reason for the enactment of the new Protection, Promotion, Development and Management of Indigenous Knowledge Act, which provides for a *sui generis* form of protection. It remains to be seen whether and how this act will be implemented with success to provide for effective protection of TK and the sharing of benefits relating thereto.

Are there any penalties for non-compliance with the abovementioned legislation?
Yes. NEMBA provides for criminal penalties, in that any person who contravenes or fails to comply with a provision of the regulations relating to ABS is guilty of an offence and liable on conviction to (either or both):

- up to 10 years' imprisonment, and
- a fine of up to R10 million.

Further, if a person is convicted of an offence involving bioprospecting or biotrading activities without a permit issued by NEMBA, a fine of up to R10 million or equal to three times the commercial value of the activity in respect of which the offence was committed, whichever is the greater, is payable on conviction.

To date there have been 105 bioprospecting and biotrade permits issued, but no penalties have been ordered against any non-compliant entity.

The Protection, Promotion, Development and Management of Indigenous Knowledge Act provides for a dispute resolution committee that may:

- issue a written warning to the licence holder;
- issue a notice prohibiting the unauthorised use of IK by the licence holder; and
- recommend to NIKSO the cancelling, suspending or revoking the licence holder's rights.

In addition, criminal penalties in the form of a fine on conviction are provided for any third party that:

- knowingly makes commercial use of IK in a manner which contravenes an agreement entered into with an indigenous community; or
- infringes the rights of that indigenous community.

As the regulations remain unpromulgated, details regarding these penalties are not yet available.

Comment

The rationale for providing fair and equitable ABS is understandable and justifiable, particularly in developing countries where the benefits that might be received could ostensibly contribute greatly to social and economic upliftment of the local communities that have contributed access or knowledge to the commercialisation of IBGRs and TK. However, this must be balanced with sustainable access to and conservation of IBGRs, which can be a difficult task to achieve. Moreover, practically speaking, it seems that the social and economic upliftment expected from the implementation of ABS policies in South Africa has not yet materialised, more than 20 years from the accession of South Africa to the Convention on Biological Diversity. It is time to start exploring new paradigms to achieve the objectives of ABS.

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