

REGULATORY IMPACT ASSESSMENT INTELLECTUALL PROPERTY LAWS AMENDMENT BILL, 2009

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Intellectual Property Laws Amendment Bill, 2009

This document relates to the Regulatory Impact Assessment (RIA) on the Intellectual Property Laws Amendment Bill. In the application of the RIA instrument an assessment of the likely impacts, costs and benefits of the various policy proposals (options) has to be conducted in a systematic manner.

Furthermore, the inputs of stakeholders are recognized as a critical element of policy formulation and as a result a number of stakeholders from various communities, industry and other government departments were afforded the opportunity to contribute inputs into the process. The full list of the stakeholders is provided for at the end of the report.

The proposed solutions offered are open to further reviews and refinements mainly due to additional information gathered from wider stakeholder consultations.

1. Introduction.

The prevailing circumstances relating to insufficient protection of Intellectual Property Rights on Indigenous Knowledge (IK) necessitated the need for government to intervene in trying to remedy the situation. It should also be stated upfront that IP rights cut across various legislation and are enforced by different departments, thus necessitating the need for these departments to work in harmony.

In 1999 the then Department of Arts, Culture, Science and Technology approached Cabinet to formulate a policy on Indigenous Knowledge Systems (IKS). This gave birth to an interdepartmental task team that embarked on a process of consultations and research to create a guide for the recognition, understanding, integration and promotion of South Africa's indigenous knowledge, which took longer than anticipated. The resultant effect was a policy encompassing a wide scope of actions and recommendations pertaining to indigenous knowledge systems, including, inter alia, integration of IK into the research and development proposed education. systems, administration of IK systems, institutionalization, funding and legislative imperatives.

The Indigenous Knowledge Systems Policy was adopted by Cabinet in November 2004. Since then, various departments have been tasked with developing policies and legislative amendments that will support the objectives of the IKS Policy.

One of the areas identified as requiring urgent attention from this exercise, was the protection of indigenous knowledge and the holders of such knowledge against exploitation. It was agreed during the interdepartmental deliberations that this would be done by ensuring that individuals and communities receive fair and sustained recognition and, where appropriate, financial remuneration for the use of their indigenous knowledge.

Indigenous knowledge has always been and continues to be the primary factor in the survival and welfare of a number of communities in South Africa. In this light, **the dti** undertook a regulatory review intended at describing how the various forms of the South African Intellectual Property system – trademarks, geographical indications, patents, designs and copyright – could be used to protect indigenous knowledge systems.

The review therefore considered ways of how to confirm, promote and protect the holders and practitioners of indigenous knowledge and to enable them to benefit from the proceeds made out of commercialization of their indigenous knowledge. The need therefore arose to closely examine the challenges alluded to, with a view of improving the effectiveness and efficiency of the Intellectual Property Law System, especially when used with other mechanisms that are aimed at protecting indigenous knowledge.

2. Purpose and intended effect

2.1. Problem statement

There are essentially two main concerns with regard to the protection and commercialisation of traditional knowledge in South Africa using the intellectual property system.

The current intellectual property system allows individuals to protect their inventions and intellectual property rights, but does not allow communities to collectively protect their knowledge in all areas and in those areas where collective intellectual property registration is possible, communities are not exercising their rights.

As a result, in both South Africa and internationally, traditional knowledge is not generally protected using the intellectual property system. However, the intellectual property system has been protecting traditional knowledge using geographical indications in the area of wines and spirits exceedingly well.

Misappropriation of indigenous knowledge using the IP system

Even though the intellectual property system is limited, in the absence of its protection, other users are "poaching" or "misappropriating" indigenous or traditional knowledge under the auspices of intellectual property. In other words, they are using the IP system to register ownership of an idea without appreciating or benefiting the holders of any pertinent traditional knowledge.

The traditional knowledge holders are disadvantaged economically and socially without protection and the country is disadvantaged economically if no immediate protection is afforded. The pharmaceutical and agricultural industries are major contributors to the economy and if there is no protection of traditional knowledge, the locals and the country are the major losers.

Whilst the largest threat in this regard is from foreign sources, unfortunately, "poaching" of traditional knowledge also takes place at national level by local companies and research institutions.

International resistance

Internationally, developing countries and least developed countries support the use of intellectual property to protect traditional or indigenous knowledge. Developed countries, however, are not in favour of this approach possibly due to the fact that multinational pharmaceutical companies from these countries are the greatest "poachers" of traditional knowledge from their developing counterparts. As already mentioned, many developed countries do not support treaties and debate which will lead to the protection of traditional knowledge at international forums such as WTO and WIPO. Some of them, including the United States are also not members of the Convention on Biological Biodiversity (CBD), which encourages the protection of traditional knowledge through the IP system.

A number of challenges face rights holders of indigenous knowledge in terms of the South African Intellectual Property Law as it stands, which include but are not limited to the following:

- 2.1 There are limitations in the current regulatory framework since it allows individuals to protect their inventions and intellectual property rights, but does not allow communities to collectively protect their knowledge in all areas.
- 2.2 The limited capacity of the Intellectual Property System, relating to indigenous knowledge, leads to poaching and misappropriation of indigenous knowledge using the intellectual property rights as pretence to register ownership of an idea, without acknowledging or benefiting holders of such knowledge.
- 2.3 International resistance by developed countries to support the use of intellectual property, as a means of protecting Indigenous knowledge.

3. Policy Objectives

The objectives to be achieved through the review of the policy and legislative framework are to:

- 3.1. Improve the livelihoods of indigenous knowledge holders and communities, by commercializing and protecting indigenous knowledge using Intellectual Property System.
- 3.2. Benefit the National Economies in ensuring that communities and holders of indigenous knowledge share in the proceeds derived from usage of such knowledge by various individuals and industries.

- 3.3. Conserve the Environment by promoting traditional farming methods which have been successfully used by communities over the years.
- 3.4. Prevent Bio-Piracy by putting measures in place to curtail unauthorized extraction of biological resources or associated indigenous knowledge.
- 3.5. Provide Legal Protection by instituting instruments aimed at providing protection and redress to owners of indigenous knowledge against exploitation of such knowledge.

Currently, there are challenges or problems relating to the protection of traditional or indigenous knowledge. These challenges go a long way in nullifying the objective of protecting and benefiting holders of indigenous knowledge, conserving the environment, preventing bio-piracy and so forth.

4. Methodology

The inputs into this report relied to some extent on World Intellectual Property Organisation (WIPO) commissioned research reports and the oral and/or written submissions from various industry stakeholder groups consulted with. All the stakeholders consulted were acknowledged in the list of stakeholders consulted at the end of the report.

Published industry based reports did not possess significant baseline information which could have enriched this process. The protection of IP rights span from sector to sector and is difficult to neither ascertain nor extrapolate exact data related to its use, by various departments. This shortcoming limits the statistical data's availability for any rigorous analysis.

We have therefore not placed significant emphasis on an assessment of the baseline situation. It is the view of the authors that a different exercise should be undertaken to establish baseline data sets that will assist in the future evaluation of the impacts of the policy proposals.

5. Risk assessment

To-date South Africa's IP Law system has not been used to protect indigenous knowledge but has in fact been used to usurp it, without any benefit to the holders of such knowledge.

As a result of this shortfall, individuals, communities and national economies continue to be disadvantaged and lose any benefits that could have accrued to them had there been adequate protection of traditional or indigenous knowledge rights. The revenue generated through the use of this knowledge, is not properly distributed amongst the designated beneficiaries nor are they afforded proper protection of their rights including protection of the environment.

Therefore, a need arises to closely examine these challenges with a view of improving the effectiveness and efficiency of the Intellectual Property Law, especially when used with other mechanisms aimed at protecting indigenous knowledge.

The risk associated with lack of action regarding the current situation, is that the rightful custodians of indigenous knowledge will continue to be disadvantaged in so far as being afforded proper recognition or entitlement of benefits generated as a result of the use of indigenous knowledge in their possession.

Whilst, IP rights continue to be less enforced and upheld, manufactures and big companies will continue to thrive at the expense of vulnerable individuals and communities.

6. Options for consideration

Governments regulate due to imperfect market conditions and mainly for public interest purposes when market forces have failed to allocate resources efficiently or were not able to control the behaviour of the market participants.

An assessment of the current regulatory instruments that protects IP rights, makes it necessary to identify strengths and weaknesses and the extent to which protection of this rights have been satisfactorily carried out or not and if not, for a consideration of necessary reviews to accommodate protection of indigenous knowledge.

Given the challenges identified with respect to the weaknesses in the current regulatory framework, ineffective enforcement of the law, the lack of clear regulatory measures, procedures and remedies available to individuals or communities in the face of transgression by other parties, it is necessary for government to intervene so as to afford greater protection to holders of indigenous knowledge.

Of outmost importance is to distinguish IP protection from concepts such as "preservation" and "safeguarding". The goals of protection are largely to promote further creativity, encourage public dissemination and enable the holder to control commercial exploitation of the work. Preservation and safeguarding in the context of cultural heritage refer to the identification, documentation, transmission, revitalization and promotion of tangible or intangible cultural heritage in order to ensure its maintenance and viability¹.

The way in which a protection system is shaped and defined will depend to a large extent on the objectives it is intended to serve. Protection of TK, like protection of IP in general, is not undertaken as an end in itself, but as a means to broader policy goals. The kinds of objectives that TK protection is intended to serve include²:

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¹ Intergovernmental committee on IP and Genetic Resources, Traditional Knowledge and Folklore-WIPO, 2003

² Intellectual Property and Indigenous Knowledge, Booklet no2

- Recognition of value and promotion of respect for traditional knowledge systems
- Responsiveness to the actual needs of holders of TK
- Repression of misappropriation of TK and other unfair and inequitable uses
- Protection of tradition-based creativity and innovation
- Support of TK systems and empowerment of TK holders
- Promotion of equitable benefit-sharing from use of TK
- Promotion of the use of TK for a bottom-up approach to development

In addressing the current problems facing the protection of Indigenous Knowledge using Intellectual Property Rights, a number of solutions have been considered in the analysis. They include *Use of Existing Intellectual Property Laws*, *Sui Generis* and the "*Do Nothing*" option.

Below is a brief analysis of the different options available for application

6.1 Do Nothing

Little evidence exists to suggest that the current regulatory regime is able to address the limitations facing protection of indigenous knowledge, nor does it provide benefit sharing mechanism on behalf of communities, whose indigenous knowledge have been utilized in one way or the other.

Moreover no bases can be formulated to support the argument that the current Intellectual Property Law System as it stands, has matured to the extent to which one can safely submit that it can sufficiently address the identified market imperfections.

Submissions received from comments tendered to **the dti** and the consultation process, attest to the fact that there is an urgent need to review or amend existing IP regime in order to address the current regulatory gaps, due to lack of protection of IK.

Based on literature review and common knowledge spanning over the years, either national or international, a 'do nothing solution' would only aggravate the current problems being experienced and furthermore communities will continue to be denied the protection of law and forego any form of benefits to which they are legally entitled.

We equally share the view expressed in a number of WIPO reports, that legislative amendments aimed at strengthening the existing IP regime to adequately protect communities and ensure that they benefit from commercialisation of their indigenous knowledge, is an option for consideration.

6.1.1 Benefits

- Most people are familiar with the current system
- It will be business as usual no additional compliance costs
- No additional administration costs to the state

6.1.2 Costs

- Commercialisation of indigenous knowledge without the knowledge of communities will continue
- Communities will not have any financial gain i.e. losses in revenue which could have been generated amounting to over R180 million
- Past cases of exploited indigenous knowledge suggest that there may be a loss of more than US\$ 1 billion a year in lost intellectual property rights that have been registered unduly in other jurisdictions. Moreover, the sale of drugs based on traditional medicines alone amounts to over US\$ 32 billion a year³.

6.2 "Sui Generis" (i.e. Law of a Special Nature)

"Sui generic" is a Latin term meaning "of its own kind; unique", it is used to define or describe something that is unique or different from what is already known. The expression was effectively created by scholastic philosophy to indicate an idea, an entity or a reality that cannot be included in a wider concept.

There are a number of meanings attached to "sui generis". In terms of WIPO, what makes an IP system a "sui generis" one, is the modification of some of its features so as to properly accommodate the special characteristics of its subject matter, and the specific policy needs which led to the establishment of a distinct system. In various WIPO meetings it was outlined that "sui generis" relates to the establishment of new, specific measures and or statutory systems necessary to either complement the existing IP rights system or to act as a substitute for them, since they are regarded as inadequate and/or inappropriate.

When policymakers seek to develop a "sui generis" system for the protection of TK, they generally need to consider the following key issues:

- what is the (policy) objective of the protection?
- what subject matter should be protected?
- what criteria should this subject matter meet to be protected?
- who are the beneficiaries of protection?
- what are the rights?
- how are the rights acquired?
- how are the rights administered and enforced?

6.2.1 Benefits

- Traditional/Indigenous knowledge will have some level of protection.
- Separate from current IP rules, which may be less confusing.
- Easier to draft a new set of rules.

³ http://www.wipo.int/edocs/mdocs/tk/en/wipo grtkf ic 9/wipo grtkf ic 9 11.doc

6.2.2 Costs

- Use of instruments such as databases results in loopholes which might promote misappropriation of the stored IK in such databases due to insufficient protection.
- Owner of Indigenous knowledge will continue losing revenue estimated at more than R180 million annually.

6.3 Use of existing Intellectual Property Laws

The policy debate about TK and the IP system has underlined the limitations of existing IP laws in meeting all the needs and expectations of TK holders. Even so, existing IP laws have been successfully used to protect against some forms of misuse and misappropriation of TK, including through the laws of patents, trademarks, geographical indications, industrial designs, and trade secrets.

However certain adaptations or modifications to IP law may be needed to make it work better. For example, TK is often held collectively by communities, rather than by individual owners – this is often cited as a drawback in protecting TK. Yet it is possible for communities to form associations, community corporations or similar legal bodies to act on their behalf in IK related matters.

6.3.1 Benefits

- IK in the possession of individuals or various communities will be afforded better protection, thus reducing the current rate of IK misappropriation.
- Socio-economic status of the IK holders and the economy in general stand a good chance of improving, due to the requirement for recognition of IK holders and the signing of benefit-sharing agreements with users of IK in their possession.

6.3.2 Costs

- Minimal cost of implementation will be incurred by government, since there is currently a unit tasked with enforcement, Office of Consumer and Intellectual Property Enforcement (OCIPE), and only minor additional resources might be necessary to improve its capacity, when it is incorporated into the proposed Companies Commission as result of the enactment of the Companies Act.
- Institutions or individuals who were used to acquiring IK, without recognising or benefiting IK holders, might incur costs due to the new benefit sharing requirements or arrangements. This might require them to hire attorneys to draft benefits sharing contracts which may amount from R300 to R700 and above depending on thee hours spend to draft the contract.

7. Analysis of the proposed option

It is a standard practice for RIA to consider and assess the feasible solution/s to the respective policy options linked to the identified problems and recommend the most feasible solution to address each problem. This section is devoted to the analyses of the regulatory option that has been selected and approved by **the dti**.

The emphasis of this approach to regulatory solutions stem from the peculiar nature of the problems faced by the IP law framework. Elsewhere, in this document, an elaborate picture was painted about lack of protection of indigenous knowledge using the current IP system. Even though IP laws are there to protect rights of individuals and communities, they are insufficient in as far as protecting those rights as they relate to indigenous knowledge. This therefore requires a critical analysis of the regulatory landscape to identify and address respective gaps.

This section of the report integrates the option analysis into the cost benefit analysis. The short title of the problem is stated and its most feasible solution is given, followed by a brief analysis of the costs and benefits of the proposed solutions.

7.1 Detailed discussion of the Identified Problems (Costs & Benefits)

Problem: Limitations of the IP System

The current IP system does not enable communities to collectively protect their indigenous knowledge in all areas, but only affords this opportunity to individuals to protect their inventions and intellectual property rights. In areas where collective intellectual property registration is possible, communities are not exercising this right.

Proposed solution:

To amend the Intellectual Property Law System so as to incorporate mechanisms aimed at protecting Indigenous Knowledge in the possession of communities.

Expected Benefits:

The proposed law review, would benefit various sectors, i.e.-

Cultural Sector

Indigenous culture would be protected for future generations, by using different laws such as copyright, designs, trade mark and geographical indications.

Pharmaceutical and chemical sectors

Since these sectors work closely with genetic, chemical and biotechnological resources in formulating inventions, the involvement of local communities, in terms of sharing their knowledge, will be protected and the sharing of benefits could be agreed to in terms of the Patents Amendment Act, 2005.

Agricultural Sector

Geographical indications may be utilized to protect and commercialize names of plants and animals which are peculiar to geographic areas, e.g. Nguni cattle, which are known for their hardiness and for their genetic adaptation to harsh and extreme climatic conditions in various Southern African regions.

In this instance indigenous knowledge system may be used to secure patents and protect local communities by employing Patent laws.

Medical or Health Sector

Traditional healers may use laws of trade secrets or patents to protect and commercialize indigenous knowledge. Moreover, this is relevant based on the notion that traditional medicines are being used as complementary medicines by various role players in the health sector.

Furthermore, the trade in traditional medicines in South Africa is estimated to be worth R2.9 billion per year, representing 5.6 of the National Health Budget, with 27 million consumers and employment for 133 000 people⁴.

Expected Costs:

Cost of compliance would be borne by various industry players who would be expected to register and comply with various clauses introduced by the Bill. These costs are estimated to be minimal since the total cost for registration would be R 60,00 (US\$8) for a provisional patent application; R590,00 (US\$79) for a full patent application and annual renewal fees of R130,00 (US\$17).

Whereas, the registration of a trademark is R590,00 (US\$79); a new copyright application for films and videos made for commercial use is R510, 00 (US\$68), these scales are relatively low by international standards⁵.

Problem: Misappropriation of Indigenous knowledge using the IP system Due to the limited nature of protection afforded in the existing IP system, other users continue to poach or misappropriate IK under the auspice of IP.

Proposed solutions:

To make it a requirement for a registrant to acknowledge the holders of indigenous knowledge and to also enter into a benefiting agreement with them in terms of the Patents Amendment Act, before any registration of ownership can be approved.

Expected Benefits:

Holders of traditional or indigenous knowledge will benefit from being acknowledged and would also be entitled to benefit from proceeds made due to usage of such knowledge.

Expected Costs:

No costs can be associated with complying with the proposed requirements except that registrants would avoid paying hefty penalties associated with non-disclosure of holders/owners, of indigenous knowledge.

⁴ Economics of the Traditional Medicine Trade in South Africa

⁵ CIPRO, 2008: (The Economics of Intellectual Property in SA, p2)

Problem: International resistance

Many developed countries do not support the inclusion of treaties and debates which will lead to the protection of IK, at international forums such as WTO and WIPO.

Proposed solution:

To incorporate indigenous knowledge into the existing IP system to protect collective ownership of such knowledge nationally, against exploitation and to afford legal redress to owners of indigenous knowledge, in the event of an infringement, by multinationals.

Expected Benefits:

Any extrusions of resources would be curtailed by ensuring that upon registration, registrants would be required to declare ownership of indigenous knowledge, for example as required by section 3 (3A) of the Patents Amendment Act, 2005 and furnish proof entitling use of such knowledge.

Holders/owners of indigenous knowledge will also benefit by signing benefiting agreements with parties wishing to use their knowledge and share in the proceeds made. These agreements will be in line with international treaties (Berne Convention; Paris Convention and TRIPS) and be afforded the same rights in other countries as they would have been in South Africa.

Expected Costs:

Costs will be minimal, as it will entail the normal travelling costs for officials on assignments or official missions abroad, to present South Africa's position on protection of IK.

7.2 Implementation Costs

Implementation costs are categorized into two i.e. administration costs and compliance costs. Administration costs are borne by government whilst compliance costs are borne by the regulated (private sector). Below is a brief discussion on these costs as outlined.

7.2.1 Costs of administration

This section of the report reflects the cost of implementing the proposed amendments to the state, i.e. commonly known as the costs of administration. In particular, the costs relate to the introduction of new institutions as proposed by the Bill, namely the National Council; National Database and the National Trust Fund, which will operate across the regulatory framework in respect of the Copyright Act, Performer's Act, Designs Act and Trade Marks Act.

7.2.1.1 National Council for Traditional Intellectual Property

The National Council for Traditional Intellectual Property (council) will be responsible for the protection and promotion of IK, advising the minister on IK

related matters including the Registrars of patents, copy right, trade marks traditional terms and expressions on registration of IP related to IK.

The council will consist of experts on IK who will be responsible for advising the Minister and Registrars of IK, on all matters mentioned before. The council may also appoint a person or a committee to assist with its tasks and the Minister may in consultation with the Minister of Finance, prescribe the tariff of fees payable for any work performed or services rendered by any person at the specific request or instruction of the Council.

Furthermore, Alternative Dispute Resolution (ADR) mechanism as an alternative to applying for relief to a court of law will reside with the National Council. The ADR mechanisms will address the challenges of accessibility and affordability on behalf of communities whenever they lodge complaints against any form of infringement.

Verification of ownership of IK where there are disputes will also be carried out by the council and the licensing of the agreement between two parties who enter into a benefit-sharing arrangement will be licensed by the proposed Commission.

Costs

Costs associated with the creation of the council will be minimal, since it will be composed of part time individuals who will meet at least four to ten times per year or whenever circumstances dictate.

Members of the Council will be paid remuneration and allowances determined by the Minister of Trade and Industry, in consultation with the Minister of Finance. In comparing to the remuneration of part-time members of other regulatory bodies such as:

- Medical Research Council Fees for the board and board sub-committee meetings for the period 1 April 2008 to 31 March 2009⁶ amounted to R459.707
- National Energy Regulator of South Africa (NERSA) the cost is estimated to be between R876 000 to R1, 4m (a comparison to NERSA spending-March 2008)⁷ a year.

Within **the dti** itself there are various committees whose work could be equaled to that of the envisaged council, even though the functions might differ, the following are costs estimates associated with the functioning and administration of such committees:

- Gambling Commission (Appointed by the dti) compensation of employees on a part time basis was budgeted for R1 million annually. This cover the cost of meetings held and any associated functions.
- Standing Advisory Committee on Intellectual Property (SACIP) Compensation for employees is determined or based on the scale approved by the National Treasury. Remuneration has been provided for under the

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⁶ http://www.mrc.ac.za/annualreport/annual2009/ar09 finance stats.pdf

⁷ RIA Report on the IP Bill, 2009 (SBP Consultant Services)

Standing Advisory Committee Regulations, read with section 20.2 and 20.3 of the PFMA: Treasury Regulations

Furthermore, National Treasury determines the remuneration of members of various councils, i.e. government wide, based on category, sub-category & official designation in terms of the Remuneration Levels Guidelines as reflected in Annexure A. In terms of these guidelines the remuneration are structured as follows:

- <u>Chairperson</u> range from a high of R942 759 p.a; R3 742 p.d or R468 p.h. to a low of R 274 212 p.a; R1 089 p.h or R 137 p.d
- <u>Vice chairperson</u> range from a high of R801 039 p.a; R2 909 p.d or R364 p.h. to a low of R 247 815 p.a; R948 p.h or R 123 p.d
- Ordinary member range from a high of R732 987 p.a; R2 909 p.d or R364 p.h. to a low of R 220 279 p.a; R875 p.h or R 110 p.d

Should the council consist of twelve members as contained in the Bill, the estimated cost of maintaining a council will range from a high of **R 9 073 668** and a low of **R 2 724 817**, depending on the grading accorded to the Council.

In essence the various figures as outlined above indicates the fact that the cost associated with creating and maintaining a National Council, primarily depends on its composition, function and the scale accorded to it in terms of National Treasury guidelines.

7.2.1.2 National Database

The proposed database will be in the office of the Registrars and will include all information regarding traditional-innovations, copyright, terms and expressions, designs and traditional performances.

Costs

Costs associated with the database will be minimal, since software is already in existence at CIPRO and will accommodate the proposed database. The database will only form part of the subset within the existing CIPRO database, which will be transferred to the Commission.

In terms of the proposal by CIPRO officials, the existing database will only need to be slight modified and adjusted to accommodate the registration of TK. For example there are current forms used for registering Trademarks, Designs, Patents and Copyrights, which can be modified and extended to accommodate the registration of TK.

The current forms are TM form, Designs form and CP forms, the P form for TK related to patents is already catered for in the P26 (TK) form, as a result of the enactment of the Biodiversity Act.

Furthermore, in terms of the proposals all the forms will be extended to accommodate TK, e.g. TM1 200/2010/TK – which indicate the number and the year of the form containing the registered TK.

The estimates by CIPRO officials and Sword Information Technology PTY (LTD), a company currently contracted to design and maintain CIPRO's database, range from R500 000 - R800 000 for modification and extension of the existing database to accommodate TK, depending on when the actually action is undertaken⁸.

As already indicated the cost associated with the modification of the database will be minimal as it does not require an overhaul exercise of the existing dataset but only minor modifications in three areas, Trademarks, Designs and Copyright since Patents containing TK are already catered for under the Patents Amendment Act 2005.

7.2.1.3 National Trust Fund

The proposed trust fund will be responsible for:

- Receiving income derived from use of indigenous knowledge by means of royalties or license fees,
- Benefiting the communities from the income generated, and
- Facilitating commercialization of indigenous intellectual property.

Costs

Currently there is no capacity at CIPRO to manage and administer the Trust Fund. There are two options available in terms of managing the Trust Fund, i.e. either by training CIPRO stuff to become competent or by outsourcing the management to a reputable Trust Fund Management company.

As a result two sets of costs needs to be compared:

CIPRO

Costs will only be in the form of capacitating individual members of the council to manage the trust fund. This might also be time demanding, costly and will also affect the scope of the council by increasing it. Since there is no capacity, council members responsible for managing the Trust Fund will have to be trained in their new role.

Costs associated with training staff, which are once off, might range from **R 3 500** per course to about **R 30 000**⁹ for a full time qualification, depending on the chosen institution.

Furthermore, the fund will vest and be administered by the council and all funds generated or acquired will be held in trust by the council and no additional capacity will be required should the responsible body have been capacitated to administer the Trust Fund.

⁸ Sword IT: An IT company responsible for maintaining CIPRO's Database

⁹ http://training.intoweb.co.za/course.php?course=financefornonfinancialmanagers

However there are risks associated with the Trust Fund being managed by a body or individuals with limited capacity in this field and as a result management by a Trust Fund Management Company might be a viable solution, considering the risk.

Trust Fund Management Company

Management of the Trust Fund by a reputable company might cost between R 500 000 to more than a million rand, depending on the size and worth of the Fund¹⁰. For example, if we assume the Bill will be passed and becomes an Act operational by February 2012 the projected cost of managing the Trust Fund by AOASI Group Holding PTY (LTD) will be more than **R1,556591**¹¹.

However, the advantage of the Trust Fund being managed by a reputable firm is that no training costs will be necessary since the appointed company will be expected to possess all the knowledge, experience and expertise in the area of managing trust funds, including a reputable track record.

Risks of the trust might also be limited since the company will have the desired knowledge and skill to safeguard money put in trust.

Should the Trust Fund be outsourced to be managed by a Trust Fund Management Company, the estimated costs would be determined by the value of the Trust Fund.

Administration of Royalties

The administration of royalties is the responsibility of recognised organisations which have been registered for this specific function for example SAMRO. The cost associated with administering and distribution of royalties, i.e. staff remuneration, office space etc are deducted from monies paid in by users. SAMRO for example is entitled to 20% of royalties paid by users e.g. SABC etc, which amount to millions of rand.

7.2.2 Costs of compliance

- Firms will have to enter into benefit sharing agreements with communities and agree on the royalty fee to be paid to the communities they have negotiated with, this can be referred to as necessary costs, e.g. similar to the drafting of contracts which cost approximately a maximum of R700 per hour to draft. The ultimate cost will depend on the number of hours taken to finalise the contract.
- Additional costs might be incurred in attaining legal advice, where firms need clarity in order to abide by the legislation, however these are necessary costs that accompany each new regulatory measure.
- Some firms may be reluctant to utilize indigenous knowledge from South Africa, which may have an adverse effect in areas such as pharmaceuticals, but due to the richness of SA's bio-diversity there is

¹⁰ http://www.coronation.com/

¹¹ http://www.oasis.co.za/default/fundprices.aspx

- confidence that companies and research institutions will adhere to the proposed legislation.
- Communities will have to bear the cost of registration of IP, which to some extent may be a burden, particularly for poor communities.

7.3 General Comments on the Costs and Benefits.

As illustrated above, the impact of reviewing the legislation have tremendous long term benefits for the holders/owners of indigenous knowledge, consumers, government and to a certain extent, the economy at large. The cost to the registrant of patents, trademarks and so forth, mainly come from the registration costs and compliance costs due to stricter enforcement of the Act, which are minimal.

The implementation costs to Government will arise mainly from the provision of additional budget to capacitate the Regulator (Commission) to improve its management, administrative and monitoring activities more effectively. This will include the provision of improved IT (i.e. in terms of accommodating the database) and related administrative systems to facilitate and enhance registration of IK rights for licenses, capacity development of staff including management, to take on the new and expanded roles and an enhanced monitoring system to strengthen enforcement.

The above costs are necessary and in line with the implementation of the three newly proposed structures as contained in the Bill, i.e. the National Council, National Database and National Trust Fund. These costs are minimal and necessary in nature to advance the objective of **the dti** in trying to safeguard the rights of IK holders and owners.

The aforementioned costs, compared to the expected benefits that will arise from the legislative review are relatively small.

The key trust of this review exercise is directed at giving increased protection to holders/owners of indigenous knowledge, to amend provisions of the current IP legislation and to adequately resource and empower the Commission to be more effective in enforcing the inserted amendments and to more adequately ensure the efficient implementation of the legislation, in its entirety.

7.4 Other impacts

The RIA methodology that has been approved by Cabinet requires that all new legislation be tested in respect of impacts on the following dimensions:

- Employment effects
- Economic growth and development impact on:
 - economic growth,
 - competition implications,
 - small business implications and
 - broad-based black economic empowerment impacts
- Distribution and equity impacts, including poverty reduction, income distribution and geographical distribution

- Racial equity
- Impacts on vulnerable groups
- Environmental effects
- Health effects

The proposed amendments relate to the protection of indigenous knowledge by communities. Past experience indicates that they have been exploited in a variety of ways over the years. To this end, the passing of this legislation will improve the protection of IK in the possession of these vulnerable groups. The distributional effects have been distorted in the past, in that communities that shared their indigenous knowledge did not share in profits made. With the passing of this law, the distributional effects can be corrected.

There are no direct impacts on employment, competition, economic growth, health and the environment. The proposed amendments are not meant to stop discussions between communities and interested parties such as pharmaceutical firms, but merely to ensure that communities are properly recognised and remunerated for knowledge imparted. Where firms feel aggrieved for incurring additional costs, this is deemed necessary to correct the inappropriate system of compensation that currently exists.

Implications for Vulnerable Groups

The Bill allows indigenous knowledge holders/owners to commercialise their knowledge under a legally protected environment. Indigenous knowledge holders/owners will also access markets with countries that may choose to protect indigenous knowledge in their markets if they incorporate the tenets of the Bill. Persons who were freely exploiting the IK may feel negatively impacted upon. This is so, moreover if they are used to getting and using IK unlawfully and if they do not change their conduct to accommodate benefit sharing arrangements with IK holders/owners.

8. Brief Analysis of the Policy Reform Proposed Solutions.

This section considers the impact of the regulatory proposals on the policy option proposed. Including a brief consideration of other alternative solutions that could address the identified problems where it is deemed necessary.

No	Identified Problem	Regulatory Solution Alterna		tive Solution	Assumptions/ Evidence	
	Problems	Solution	Impact	Solution	Impact	
1.	Limitations of the IP system	To amend the Intellectual Property system, so as to incorporate the protection of indigenous knowledge which was lacking before	 The proposed law review would benefit various sectors such as culture; pharmaceutical and chemical sectors; agriculture and medical or health sectors. The rights of holders/owners of indigenous knowledge will be afforded more protection and they stand to benefit from the insertion requiring disclosure and the signing of benefit sharing agreements. 	Maintain the status quo	The current challenges relating to the limited nature of the current regulatory framework in protecting IK holders would persist. Will require the creation of a special regulatory regime to protect IK, thus deviating or formulating mechanisms outside the existing IP system.	Study on the Economics of Intellectual Property of South Africa (WIPO) Intellectual Property and Indigenous Knowledge, Booklet no2 (WIPO)

No	Identified Problem	Regulatory Solution Alternative Solution		Assumptions/ Evidence		
	Problems	Solution	Impact	Solution	Impact	
2.	indigenous knowledge using the IP system for a r acknowledge indigenous to also benefi agree terms Amen any re owner	To make it a requirement for a registrant to acknowledge the holders of indigenous knowledge and to also enter into a benefiting sharing agreement with them, in terms of the Patents Amendment Act, before any registration of ownership can be approved.	Holders of traditional or indigenous knowledge will benefit from being acknowledged and would also be entitled to benefit from proceeds made from commercialization of their IK.	Maintain the status quo	No benefits will accrue to communities and their IK will continue to be misappropriated without any benefit to them	
				Sui generis	Special measures or mechanisms will have to be developed so as to curb misappropriation of IK.	Currently, only a few <u>nations</u> offer explicit <u>sui</u> <u>generis</u> .
3.	International resistance To incorporate indigenous knowledge into the existing IP system to protect collective ownership of such knowledge nationally, agains exploitation and to afford legal redress to owners of indigenous knowledge, in the event of an infringement.	s given the same protection as done for IK found in member states (i.e. signatories of	Maintain the status quo	Resistance of protection of IK using existing IP systems by multinationals will persist.	WIPO and WTO Forums	
			Sui generis	Further experience is required from countries having established the mechanisms, before a fair assessment can be made.	Currently, only a few <u>nations</u> offer explicit <u>sui</u> <u>generis</u> .	

9. Enforcement and Sanctions

The Commission established by the Companies Act will be responsible for enforcement and will also have necessary powers to apply sanctions afforded for in the legislation (IP Bill) by referring any matter to the proposed tribunal, i.e. administered by the National Council, which will have the prerogative to revert to the normal courts of law, where no amicable solution can be arrived at.

The new Monitoring and Evaluation Framework (Presidency) which provides an outcomes performance management system, might be employed for purposes of monitoring and evaluating the IP Laws Amendment Bill once it becomes an Act of Parliament.

10. Monitoring and Review

The new Commission established by the Companies Act, will be responsible for developing mechanisms for monitoring and review of the proposed regulatory measure, including the performance of the proposed institutions in relation to the IP Bill.

11. Consultation

11.1 Within government

11.1.1 Departments:

- Science and Technology
- Minerals and Energy
- Health
- Agriculture
- Arts and culture
- Environmental Affairs and Tourism
- Water and Forestry
- National Treasury
- Provincial and Local Government
- Land Affairs
- Agriculture, Forestry & Fisheries
- Cooperative Governance & Traditional Affairs
- Rural Development
- Sports and Recreation

11.1.2 Regulatory Agency:

- Company and Intellectual Property Registration Office (CIPRO)
- Council for Scientific and Industrial Research (CRSIR)
- Medical Research Council (MRC)
- National Research Foundation (NRF)

11.1.3 Provinces

- Gauteng (Health Dept)
- GPSAC

11.2 Private Sector

Law Firms

- Spoor and Fisher
- Adams and Adams
- DM Kisch
- Bouwer Attorneys
- Bowman Gilfillen Attorneys

11.3 Various Community Groups

 Traditional leaders of various communities in the Eastern and Western Cape, North West, Kwa-Zulu Natal and Gauteng provinces.

12. Conclusion and recommendations

It can be safely concluded that there are various means of protecting indigenous knowledge as evident from the literature reviewed in conducting the RIA, including reports from WIPO intergovernmental committee meetings.

This emanates from the views of different countries regarding which approach is best in protecting indigenous knowledge. Some believe that IK can be adequately protected using the existing IP system and that no additional measures or systems of protection are necessary or appropriate. The other view is the need to establish new, specific measures and/or statutory systems to either complement the existing IP rights or to act as a substitute since they are regarded as inadequate and/or inappropriate. The latter are referred to as 'sui generic", by its proponents.

Having said that it is recommended that **the dti**, should continue with the process of amending the existing Intellectual Property Law System, in order to facilitate for the protection of Indigenous Knowledge as already commenced with, e.g. Patents Amendment act.

However it is also recommended that risks and challenges identified in the RIA report be addressed and that the second version of the Bill should reflect all agreements and trade-offs concluded via the NEDLAC process and any other related forum, so as to enhance its quality.

Furthermore, it should also be stressed that the value system aimed at protecting Indigenous Knowledge is crucial for South Africa and cannot be left unattended.

The RIA report has raised a number of likely costs associated with the proposed amendments, even though conclusive monitory values could not be arrived at in some instances. As a way forward, it should be noted that the intention of the Bill far outweighs the cost with which it is associated and of outmost importance is its intention to benefit communities and reduce poverty in line with government strategic objectives.

13. Declaration of the Intellectual Property Laws Amendment Bill, RIA Report.

I have read the Regulatory Impact Assessment Report on the Intellectual Property Laws Amendment Bill and am satisfied that based on the information and analysis available, the benefits are likely greater than the costs.

Signed:
Date:
Name:
Title:

Department of Trade and Industry

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