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SUBMISSION BY THE AFRICAN CENTRE FOR BIOSAFETY

TO THE DEPARTMENT OF SCIENCE AND TECHNOLOGY

ON THE DRAFT INTELLECTUAL PROPERTY RIGHTS FROM PUBLICLY FINANCED RESEARCH BILL: GOVERNMENT GAZETTE NO 29950 OF 8 JUNE 2007

18 JULY 2007

INTRODUCTION

The African Centre for Biosafety (ACB) is a non-profit organisation based in Johannesburg, South Africa. Its main focus of research is to provide credible, accurate and current information for the public, with regards to issues of Genetically Modified Organisms and biosafety; and the protection of Indigenous Knowledge, biological Resources and biopiracy.

First, we would like to thank the Department of Science and Technology (DST) for providing the public with an opportunity to comment on the Draft Intellectual Property Rights from Publicly Funded Research Bill ('Draft Bill').

According to the United Nations Environmental Programme, South Africa is home to 10% of the world's plant and 15% of the world's marine species. It is also ranked as Africa's 5th and the world's 24th richest in terms of existing endemic animal life on land.[1] Wealth in biological diversity means there is a demand for research and development, to bring new products to the market to meet the ever- increasing demands of a consumerist globalised world.

Indigenous people play a vital role in the "discovery" of products based on natural biological resources, as detailed knowledge of the use of such resources has accumulated through trial and error over centuries, and has been passed on through the generations. In recent years, indigenous knowledge regarding healing methods has become so essential in research and development of pharmaceutical products that it is near impossible to find useful plants without this knowledge. Studies have therefore shown that by the 1990's, out of 119 of the world's best selling drugs, 74% were based on indigenous knowledge.[2]

In recent years, it has also become evident that there has been no consent by the indigenous people for the use of their knowledge, or sharing of benefits derived from the final product, and this unauthorised appropriation has come to be termed 'biopiracy'. Whilst income derived from products based on natural biological resources is expected to grow from $60 billion in 2004 to $5 trillion by 2020[3]; the United Nations has estimated that developing countries lose out at least $5billion each year, due to biopiracy.

In light of this, South Africa is desirous of promoting and regulating research and development in order to ensure that revenue derived from such research is kept within our country. However, more importantly, as a Party to the Convention on Biological Diversity and current legislation, South Africa has an obligation to protect its biological resources as well as the rights of those who hold such knowledge, and in so doing, prevent biopiracy.

We believe that the new Draft Bill; when read together with the Patent Act 57 of 1978 (Patent Act), National Environmental Management: Biodiversity Act 10 of 2004 (NEMBA), and its Draft Regulation GG no 29711 (Draft Regulation); gives rise to inadequate protection of indigenous people and their rights, and therefore is in need of amendment. We recommend the rationalisation of Intellectual Property laws, so that South Africa is able to provide better protection for its indigenous people.

Section A of this submission sets out a general commentary on the need for rationalisation and harmonisation of Intellectual Property Laws and NEMBA to bring about the effective protection of indigenous people. Section B, consists of specific commentary and suggestions regarding each of the sections of the Draft Bill.

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[1] UNEP *Convention on Biological Diversity* http://www.cbd.int/countries/default.shtml?country=za (9Jul2007)

[2] Laird 'Natural Products and the Commercialisation of Traditional Knowledge' in T Greaves (ed) *Intellectual Property Rights for Indigenous Peoples: A Sourcebook* (1994) 148.

[3] Alikhan and Mashelkar *Intellectual Property and Competitive Strategies in the 21st Century* (2004) 81

A) GENERAL COMMENTARY ON THE NEED FOR HARMONISAION OF IP LAWS

Currently, South African intellectual property legislation is highly fragmented, a situation that gives rise to a number of gaps and anomalies that undermine the rights of indigenous people. 'Indigenous people' is not clearly defined by NEMBA or it Draft Regulations except to refer to such people as residing in a defined geographical area to which indigenous knowledge is found.

In order to register a patent, the Patent Act requires that the innovation be novel, involve an inventive step and be capable of industrial application. The 'novelty' requirement demands that there be no publication of the innovation by others before the patent application date. It takes into account indigenous peoples' rights by including in the definition of publication, the use of the invention as well as oral publication, since these are the methods by which indigenous people pass down their knowledge. However, the Registrar (who is in charge of issuing the patent) will have no way of knowing of the publication of such indigenous knowledge through **use or oral publication**, if the applicants do not disclose it. Thus, patents based on indigenous knowledge can be granted through the Patent Act, yet it but can also be said to amount to 'biopiracy'. Biopiracy is therefore, poorly acknowledged or dealt with by the Patent Act.

The biopiracy problem is only partially dealt with by the provisions of Chapter Six of NEMBA, which was enacted in order to meet South Africa's obligation under various international treaties such as Trade Related Aspect of Intellectual Property Rights (TRIPs) and the CBD (taking also into account the 'Bonn Guidelines'). NEMBA makes it a criminal offence for anyone to bioprospect without a permit. In order to acquire a permit, the applicant is required to provide evidence of a benefit sharing agreement concluded with the indigenous people concerned as well as prior informed consent. However, it is not yet clear whether research by public institutions is covered by the definition of "bioprospect" in terms of NEMBA, as it includes commercial research, but is silent on academic research, or state funded research, which may or may not be for commercial purpose. Furthermore, there are frequent legal disputes as to whether legislation in general applies to government institutions (including all of the public institutions listed in the Draft Bill), as the purpose of most legislation are to regulate the private sector and natural persons.

The uncertainty of whether NEMBA covers research by public institutions or intellectual property right applications by the State is exacerbated when NEMBA is read together with the ABS Draft Regulations and the current Draft Bill. NEMBA makes it a criminal offence for anyone to bioprospect without a permit, and the Draft ABS Regulations only allow bioprospecting permits to be granted to a natural person who is a citizen or permanent resident of South Africa, or a juristic person who is registered in South Africa. Foreign persons or companies will have to acquire a permit jointly or in collaboration with a South African natural or juristic person. Foreign persons or companies will be reluctant to apply for a permit jointly with private persons or companies due to the risk of losing out on patent application to rival companies, and therefore, it is highly likely that they will approach public research institutions. This means that more and more bioprospecting and related research will be carried out by South African public institutions in partnership with foreign companies. There is therefore an urgent need for the Draft Bill to clarify the research and bioprospecting rights of public institutions and the State, vis-à-vis their obligations in terms of NEMBA in order to bring about legislative certainty and coherency.

Put in a different way, in light of the above, since the Draft Bill deals with regulating publicly funded research by public institutions; and since NEMBA and its Draft Regulation imply (or encourage) that more bioprospecting and research be carried out through and by public institutions; NEMBA and its Draft Regulation need to be reflected in the Draft Bill, as far as is possible. It is necessary to mention in the Draft Bill, the need for State as well as the public institutions in its research process, to comply with NEMBA and its Draft Regulation. This will go a long way towards bringing about certainty with regards to rights of indigenous people as well as those of public institutions and the State, and bring about a more harmonized body of legislation affecting the rights of indigenous people and the protection of their knowledge.

The importance of regulating public institutions cannot be overemphasised, as illustrated by the now famous case involving the Hoodia patent, held by the Council of Scientific and Industrial Research (CSIR). Initially Hoodia, was used by the San as an appetite suppressant to assist on long hunting journeys, and was later patented by CSIR without prior informed consent or any agreement with the San. This was seen as an act of biopiracy by many, and after much publicity, CSIR entered into a benefit sharing agreement with the San.[4] There are currently other instances of biopiracy in South Africa, currently being investigated.

[4] For detailed discussion on the Hoodia issue, see R Wynberg "Rhetoric, Realism and Benefit-Sharing: Use of Traditional Knowledge of Hoodia Species in the Development of an Appetite Suppressant" *Journal of World Intellectual Property* (2004) 852.

Omissions and uncertainty in the law can easily result in biopiracy and infringement of the rights of indigenous people. As such, public institutions as well as the State who may be likely holders of intellectual property rights need to be subject to NEMBA and its Draft Regulations. Thus we recommend that the Draft Bill play a vital role of bridging the gap between other intellectual property laws and NEMBA and its Regulations.

Furthermore, any rights which indigenous people might have (such as those accruing under benefit sharing agreements with public institutions) need to be dealt with in the Draft Bill. Additionally, if the State decides to exercise intellectual property rights for any reason, the consequences or the effects on the existing rights already held by the indigenous people need to be dealt with in the Draft Bill. Other specific recommendations will be dealt with in Section B of this submission.

B) SUBMISSION ON SPECIFIC SECTIONS OF THE DRAFT BILL

1. Preamble

We realise that the main purpose of the Draft Bill is to advance South African development though research, and as such, there is a need for regulating publicly financed research by providing incentives, collecting revenue and using the revenue for further research.

There is also, however, the need for government to emphasise and reiterate the need to protect indigenous knowledge. We are aware that this is attempted through the National Environmental Management of Biodiversity Act (NEMBA) and its Draft Regulations; however, when read together with the current Bill, as discussed earlier, there is still a lacuna in the law. In light of this, we recommend the insertion of an additional purpose, which is to 'regulate the State and Public Institutions in order to ensure compliance with the objectives of NEMBA and provide further protection of the rights of indigenous people and their knowledge.'

2. Section 2 – Application of the Act

We recommend that the Draft Bill be placed within the overall context of the applicable provisions of the Patents Act, NEMBA, and its Draft Regulation, and also to provide for appropriate mechanisms to deal with conflicts arising between these pieces of legislation.

Various pieces of legislation affect indigenous people and their rights with regards to their knowledge and use of biological resources, but these are fragmented and thus may be ineffective, conflicting or vague. Therefore, legislation that may impact on the rights of indigenous people, should, as far as possible, refer to all other applicable legislations, and clarify the relationship between them, thereby ensuring cohesion, harmony and most of all, the protection of the rights of indigenous people.

3. Section 3(1)

We recommend an insertion to the effect that the ownership of Intellectual Property may vest in Institutions, only once the provisions of NEMBA have been complied with. Obligations will have to be created to ensure that NEMBA has been complied with, for example, requiring the IPR applicant to provide written proof of this to Intellectual Property Management Office (IPMO) and National Intellectual Property Management Office (NIPMO), created for under Chapter Three of this Draft Bill.

Such a provision will go a long way towards reminding public institutions that they are required to observe the same degree of compliance with laws that have been promulgated to protect indigenous knowledge.

4. Section 3(3) and Section 8

In terms of this section, NIPMO has the option of applying for intellectual property rights, which the public institutions elect not to exercise. We recommend the insertion of a provision to the effect that should NIPMO elect to exercise such intellectual property rights, then it will be required to comply with NEMBA and its regulations. A similar requirement needs to be reflected in section 8 as well, so as to bring about consistency to the Draft Bill.

5. Section 4(1)

Again, we recommend the insertion of the following phrase "after observing all relevant obligations under NEMBA."

6. Section 4(2) and Section 8(3) and (5)

We recommend that "national interest" be clearly defined or refer to other sections in which it does, in order to avoid confusion and unnecessary litigation due to vagueness.

7. Section 4(4)

We recommend a limitation of this section, to enable litigation based on revocation of patent due to lack of title by indigenous people. The Draft Bill allows for State to apply for patents if the public institutions do not wish to, or fail to exercise the IPR. However, there may be situations where the Institution lacked the title to apply for the IPR in the first place, but the title had nontheless passed to the State, whilst not knowing that the Institution itself did not have the title in the first place. In this instance, the option to litigate on the grounds of lack of title by the State should still be available to third parties, who may have had prior right of ownership. This is of particular importance to indigenous people who may have had the original right or title to apply for intellectual property rights, and not the public institution concerned. We recommend a further insertion for the sake of clarity to the following effect 'this section does not preclude action for revocation for any other grounds.

8. Section 6(2)
We are aware that it will be difficult to effectively monitor compliance with the provisions of NEMBA. We recommend that an additional function of NIPMO be inserted, which is to ensure that the Institutions have complied with NEMBA in the research process as well as in the exploitation of intellectual property based on indigenous knowledge. This can be further reflected in section 6(2)(g) where IPMO can be given certain obligations with regard to the process involving the negotiation of benefit sharing agreements with indigenous peoples, as contemplated by NEMBA.

9. Section 8
Under the functions of NIPMO, we recommend the insertion of corresponding obligations, namely compliance with NEMBA by NIPMO, once NIPMO decides to apply for the intellectual property protection, whether due to national interest, or due to IPMO deciding not to seek out the protection. The reason for this is that NEMBA and its proposed draft regulation, read together with the Patent Act, make it a requirement for South African individuals and juristic persons to seek out a permit when bioprospecting, researching etc; and it is a criminal offence not to do so. It is, however, unclear whether the State should do so as well, and, as such, clear provisions to this effect should be created for the sake of clarity and harmonisation of Intellectual Property Laws.

Further, it should be added that any benefit sharing agreement that is entered into by the Institutions shall be honoured by the State, after NIPMO takes over the Intellectual Property Rights on behalf of the State.

In instances where, for reasons of national interest, the State takes over the Intellectual Property Rights already held by the Institution, there should be an additional disclosure requirement. Under section 8(4), we recommend the insertion that the State is required also to inform the parties who entered into benefit sharing agreements with the Institutions under NEMBA.

10. Section 8(5)
There is a gap in this section with regards to any rights, which the indigenous people may hold in terms of any agreement entered into with the Institution under NEMBA. We recommend that any rights that the indigenous people acquired be kept by the indigenous people, and not to be ceded to the State, or deemed to have lapsed.

11. Section 8(6)
Since monitoring and compliance of NEMBA may be challenging, we recommend that an additional function of IPMO be created to ensure that the benefit sharing agreements and prior informed consent requirements of NEMBA are carried out by IPMO and its Institutions.

12. Section 9(1)
We recommend the addition that any proposed access and benefit sharing agreements concluded with indigenous people in terms of NEMBA be disclosed to IPMO, in order to assist IPMO to ensure that these are fair and equitable. This extra layer of protection is necessary, in order to instil in the IRP legislative paradigm, a sense of respect for the protection of the rights of indigenous people.

13. Section 11(2)
We recommend the insertion of an additional item of expenditure, namely any benefit sharing agreement with indigenous peoples under NEMBA.

14. Section15
We recommend the insertion that commercial exploitation, disposal or moving of intellectual property rights must not prejudice the rights held by indigenous communities.

REFERENCES:

I. S Alikhan and R Mashelkar *Intellectual Property and Competitive Strategies in the 21st Century* (2004), Klewer Law International: Hague.
II. T Greaves (ed) *Intellectual Property Rights for Indigenous Peoples: A Sourcebook* (1994), Society for Applied Anthropology: Oklahoma City.
III. UNEP *Convention on Biological Diversity* http://www.cbd.int/countries/default.shtml?country=za (9Jul2007)
IV. R Wynberg "Rhetoric, Realism and Benefit-Sharing: Use of Traditional Knowledge of Hoodia Species in the Development of an Appetite Suppressant" Journal of World Intellectual Property (2004) 852.