equality for all

aidslaw project

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Dear Mr Sibanda

SUBMISSIONS ON THE INTELLECTUAL PROPERTY RIGHTS FROM PUBLICLY FINANCED RESEARCH FRAMEWORK

The AIDS Law Project ("the ALP") takes this opportunity to thank you and the Innovation Fund's Intellectual Property Management Office for facilitating and hosting the provincial consultation workshop held in Cape Town on 30 March 2006. My colleague Fatima Hassan and I found the event to be extremely useful in understanding the context within which the *Intellectual Property Rights (IPR) from Publicly Financed Research Framework* ("the policy framework") is situated. In addition, it provided us with an opportunity to float, consider and refine our formal submissions on the policy framework.

In principle, the ALP supports the need for – as well as the substance of – the policy framework. We welcome this crucial intervention of the Department of Science and Technology (DST) and view it as an integral part of the state's bona fide attempts to discharge its ethical and constitutional obligations. However, while we may disagree on the relevance and importance of rights in intellectual property (IP) in a developing country context, we nevertheless recognise the public interest in securing rights in IP in respect of innovations that result from publicly funded research. In addition, we support the need to ensure access to innovative products developed in this manner.

This brief submission considers only two of the four identified themes: industry sponsored research; and licensing and commercialisation of IP. In respect of the former, we only deal with what we submit should be deemed to be "publicly funded" research. In respect of the latter, we only consider the issue of how best to ensure that agreements entered into by inventors, institutions and industry ("benefit-sharing agreements") are indeed in the public interest. Our submission is limited to those issues in respect of which we are best placed to comment. Our failure to deal with other matters should not necessarily be considered as a blanket endorsement of the policy framework's approach to such issues.

In our view, the policy framework should not be limited to research that uses public financial resources. Instead, research that makes any use of public resources – including infrastructure, equipment and human resources – should be deemed to constitute publicly funded research. This should apply even in situations where the specific costs of a particular research project are covered by the private sector according to a full cost recovery model. If this were not to be the case, public institutions may potentially use public resources purely to service the private sector. In our view, time spent doing private sector work takes away from any public sector mandate.

While we continue to advocate for the development of an intellectual property framework in South Africa that generally facilitates access to essential products,[1] our primary concern is that the legislation and regulations ("the regulatory framework") that will result from this process make particular provision for ensuring access to the products of research that were developed using public resources. Not only is this desirable from a developmental perspective, but in our view is also required by the Constitution, as read in the light of Article 15 of the International Covenant on Economic, Social and Cultural Rights, which guarantees everyone "the right to enjoy the benefits of scientific progress and its applications".[2] In respect of research conducted – either in part or in whole – using public resources, the obligation on the state to ensure that the benefits are generally accessible is further strengthened.

In short, our concern can be summed up as follows: recognizing that the public interest cannot necessarily be ensured by relying on the goodwill of inventors, institutions and industry, how does the regulatory framework ensure that benefit-sharing agreements entered into by these three partners are – in fact – in the public interest? While the broader questions of appropriate resourcing of public institutions and the current over-reliance on the private sector fall outside the scope of this submission, our concern must be understood with reference to a context within which academic and other public institutions are under increasing pressure to seek commercial deals that have the potential to mitigate the impact of significant cuts in state funding.

Before this submission makes certain recommendations on how best to regulate benefit-sharing agreements, it is important to canvas what we mean by an agreement that is in the "public interest". Understanding that the public interest is best served by agreements that guarantee access to the "benefits of scientific progress", we are nevertheless mindful of the fact that access to such benefits is contingent on their existence. In other words, we acknowledge that a balance needs to be struck between the need to create

[1] In our view, such a framework does not yet exist. In this regard, see Edwin Cameron and Jonathan Berger, "Patents and Public Health: Principle, Politics and Paradox", (2005) 131 *Proceedings of the British Academy* 331. See also AIDS Law Project and Treatment Action Campaign, "Joint submission: Patents Amendment Bill [B 17—2005]", 25 July 2005, available online at http://www.alp.org.za/modules.php?op=modload&name=News&file=article&sid=252.
[2] For an official interpretation of Article 15, see Committee on Economic, Social and Cultural Rights, "General Comment No. 17 (2005)", available online at http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/E.C.12.GC.17.En?OpenDocument.

incentives for innovation and ensuring access to innovative products – the very essence of the rationale underpinning the patent system.

A further factor to consider is the need for benefit-sharing agreements to support industrial policies that are aimed at facilitating the development of strategic local industries. This should not be understood as protectionism for South African companies, but rather ensuring that domestic capacity in certain key sectors is stimulated and developed so as to benefit the social welfare of South Africa and her inhabitants. For example, this may include support for a strong local generic pharmaceutical industry as an essential (albeit insufficient) step towards the development of a domestic research-based industry that focuses on diseases of poverty.

We therefore submit that the public interest is best served by an approach to benefit-sharing agreements that balances the need for innovation and the stimulation of key industrial sectors on the one hand with the need for access to innovative products on the other. In our view, this balance cannot be achieved in the abstract.[3] Instead, it must be realized on a case-by-case basis, in accordance with certain guiding principles. In general, we support an approach that recognises the institutions' rights to contract with industry in a manner deemed appropriate by the parties to the contract, subject to certain conditions that are further contingent on a range of factors, such as the nature of the industry partner, the subject matter of the IP concerned and the extent of public funding.

Simply put, we believe that – in general – the public interest is best served by letting the parties to any benefit-sharing agreement decide for themselves what works best, and then for the regulatory framework to attach consequences to whatever choices have been made in the form of specific public interest contractual provisions. Flexibility in contracting would allow for institutions to enter into commercially viable agreements. Attaching specific conditions to the exercise of certain potentially problematic choices, such as the private assignment of intellectual property to offshore multinational corporations, would ensure that access to the benefits of such arrangements could nevertheless still be secured.

Such an approach, however, may not necessarily be feasible for those institutions with limited experience in – or knowledge of – the field of IP management (including assignment and licensing). In such cases, the ability to contract in the public interest may be dependent on significant technical and policy support. With this in mind, it would be appropriate for the regulatory framework expressly to empower public bodies such as the Innovation Fund to play a supportive role. In so doing, the law should ensure that sufficient resources are allocated for this purpose.

[3] We further submit that the current patent framework does not sufficiently address the principle of balance. See above note 1 and the text below accompanying footnotes 7 and 8.

In order to ensure that benefit-sharing agreements are indeed in the public interest, the regulatory framework would – at minimum – have to encompass the following four aspects:

- Statutory provisions would be needed in the proposed legislation to provide the legal basis for the relevant Minister to publish regulations dealing with the specific conditions that – in the absence of any compelling reason – would attach to the choices exercised by contracting parties to any benefit-sharing agreement.

- The proposed legislation would have to provide guidance to the Minister for the exercise of such a power, as well as guidance for the contracting parties on the essential elements that any benefit-sharing agreement would be expected to contain.

- Regulations issued in terms of the Minister's power would provide much of the detail regarding public interest contractual provisions.[4]

- The regulatory framework would have to provide a mechanism (or mechanisms) for ensuring that agreements comply with the law.

In respect of this last aspect, the lightest regulatory approach – which may well be the least effective and, in the long term, the most disruptive – would be to empower interested parties to challenge benefit-sharing agreements in the High Court on the basis of non-compliance with the regulatory requirements. Such an approach would only be possible if the regulatory framework mandated certain disclosure requirements. Whilst not all contractual provisions need to be made public (such as those dealing with certain forms of confidential business information), the public interest provisions – including but not limited to royalty rates, sublicensing and future research – must be accessible to those with an interest in ensuring regulatory compliance.

Instead of requiring a High Court approach, the regulatory framework could empower interested parties to file complaints with a public body (such as the Innovation Fund), adopting a process similar to that used by the Competition Commission in its investigations of complaints dealing with prohibited practices such as abuse of market dominance.[5] In this way, interested parties would be able to raise legitimate public interest concerns without necessarily having to expend limited resources on litigation expenses. By empowering an adequately resourced public body to act in the public interest, the regulatory framework could provide sufficient "incentive" to contracting parties to ensure that their benefit-sharing agreements comply with the law.

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[4] The regulations could require, for example, that if pub funded IP is assigned offshore, the relevant benefit-sharing agreement would have to include provisions dealing with licences of right for suitably qualified South African firms and/or automatic government-use licences in certain circumstances. In addition, they could specify that any exclusive licensing agreement would have to include provisions dealing with guarantees of supply and/or licences of right in respect of products that are necessary for dealing with any public health threat, circumstance of extreme urgency or emergency.

[5] Chapter 2 of the Competition Act, 89 of 1998

In our view, however, one of at least two further forms of regulation should be preferred:

- The most interventionist approach – which may well be the most effective and, in the long term, the least disruptive – would be something akin to merger control, with certain categories of agreements being subject to prior authorisation by an appropriate authority. Such an approach may be resource-intensive, but it would ensure proper scrutiny of agreements and provide certainty by dispensing with challenges to the agreement post approval.

- An approach that lies somewhere between the "light touch" and "interventionist" models is one that dispenses with the need for automatic prior approval, instead allowing interested parties a right of pre-approval opposition. Institutions could be mandated to publish notice of draft agreements, and in the absence of successful (or any) opposition, the agreement would be deemed to be approved and then subject to ordinary review, whether in the High Court or in Competition Commission-like proceedings.[6]

Finally, in respect of so-called "walk-in" rights, we believe that there would be no need for these to be included in the regulatory framework provided that the following conditions are met:

- The regulatory framework deals adequately with the content of benefit-sharing agreements, as already described above; and

- Relevant provisions of the Patents Act, 57 of 1978 and the Competition Act, 89 of 1998 – including but not limited to sections 4 (government use), 56 (compulsory licensing), 61 (patent revocation) and 78 (state acquisition) of the former and section 58 (appropriate relief) of the latter – are amended. Together, the two statutes should fully incorporate the public health safeguards and other flexibilities permitted by the World Trade Organisation (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs), as clarified in the *Declaration on the TRIPS Agreement and Public Health*[7] and complemented by the WTO decision on *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*.[8]

If the latter were not to occur, the regulatory framework should indeed address the issue of walk-in rights. Their use, however, should not be limited:

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[6] A comparable system of pre-grant opposition to patent protection is found in the Indian Patents Act, 1970 (as amended).

[7] *Declaration on the TRIPS Agreement and Public Health*, WTO Res. WT/MIN(01)/DEC/2, 4th Sess., Ministerial Conference, 20 November 2001. The *Doha Declaration* was adopted at the WTO Ministerial Conference in Doha, Qatar in November 2001.

[8] WT/L/540, 1 September 2003, available online at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

- To emergencies or other circumstances of extreme urgency,[9] as it is conceivable that the public interest may demand intervention in circumstances falling short – or suggesting the possibility – of such dire conditions;[10] and

- Government intervention, as circumstances may dictate that governments are either unwilling or (politically) unable to intervene.

In conclusion, we once again thank you for the opportunity to contribute to this consultative process and express our principled support for the policy framework. Should you need to contact me for any further information or clarity, please do so on 083 419-5779 or bergerj@law.wits.ac.za.

Yours sincerely

Jonathan Berger

cc: Ms Estelle Fidler: Innovation Fund (per email: estelle@nrf.ac.za)

[9] If any mention is made of emergencies, the regulatory framework should define an emergency to include, but not be limited to, government declarations of health and/or other emergencies (excluding states of emergency). In addition, the term should be defined to allow for an emergency to be deemed to exist if certain objective criteria are satisfied.
[10] The threat of avian flu is one case in point.