

# SCIENCE & TECHNOLOGY FOR DEVELOPMENT AND L20 LEADERS INTELLECTUAL PROPERTY

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## Introduction

In the past 20 years, advances in science and technology have opened up enormous opportunities to improve economic growth in the developed and the developing world. Developments in the life sciences, agriculture and information technology offer to improve human health, crop yields and access to information. The protection of some of these developments through the use of intellectual property (IP) rights has expanded very substantially in developed countries. At the same time, the increased pace of globalisation has led to the growing adoption of systems of global governance for IPRs. If developing countries are to harness these new scientific and technological developments to improve the lives of poor people, they must adapt their own IP systems to promote national innovation, and to obtain access to foreign technologies. Equally, industrialised countries, and emerging economies have a responsibility to help assist this process by removing possible obstacles.

Within the developing world, there is great variation in national capacity to innovate in science and technology and to make use of foreign technology. Yet most countries, rich and poor, are subject to TRIPS, the global trade rules which set out a common regulatory framework for IP. We all accept that developing nations were not well prepared to play a full part in the negotiations to agree TRIPS in 1995. Since the WTO Declaration of Doha, their voice has been better heard. But the majority are in a weak position to take advantage of the flexibilities of TRIPS which can be used to improve access to medicines, and to resist pressure from other nations to make bilateral agreements which entail TRIPS+ standards. A more concerted approach, involving a full and frank discussion of the various interests at stake is therefore required.

### **As a first step, we therefore endorse the recommendation of the 2005 Africa Commission of the UK Government:**

Patents are important for innovation because they protect the investment in research and development. But Africa can't afford high medicine prices. The World Trade Organisation's (WTO) TRIPS agreement contains important flexibilities that can be used to access medicines, including through the use of a compulsory licence allowing local producers to make patent-protected medicines. ...We recommend that the G8 and other donors should support developing countries to make effective use of TRIPS and its flexibilities as appropriate, through financial, technical and political support. In addition, developed countries should commit not to lobby bilaterally for measures that go beyond TRIPS.<sup>1</sup>

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<sup>1</sup> "Our Common Interest: Report of the Commission for Africa", London, 2005. p.193  
[http://www.commissionforafrica.org/english/report/thereport/english/11-03-05\\_cr\\_chapter\\_6.pdf](http://www.commissionforafrica.org/english/report/thereport/english/11-03-05_cr_chapter_6.pdf)

At our Summit, we have considered the implications of IP for development in three key sectors - health, traditional knowledge, and copyright. Within each, we have identified and discussed pressing issues which require action through specific policy recommendations. They are:

- Access to medicines: compulsory licensing for medicines; clinical data protection
- 'Biopiracy' of Traditional Knowledge
- Copyright

### **Access to medicines**

A crucial issue for public health in developing countries is access to medicines and other forms of healthcare. In the developing world, the prevalence of malaria and the HIV/AIDS epidemic claim many lives, despite the existence of medicines or interventions to mitigate or eliminate their effects. We recognise that access is determined by several factors such as funding, personnel, infrastructure, and political will as well as intellectual property rights. We have identified two issues which concern provisions within TRIPS: compulsory licensing and data exclusivity where we believe that concerted action from the L20 could be beneficial.

#### *Compulsory licensing*

The introduction of generic medicines at the earliest opportunity offers for many developing nations the best hope for increasing access to medicines for the many poor people who cannot afford brand medicines. The fall in the price of anti-retrovirals to treat patients with HIV/AIDS has occurred in part because of the generic versions of these drugs that Indian pharmaceutical companies were able to produce before India introduced product protection in its Patents Act in 2005 to comply with TRIPS. These low cost ARVs can continue to be produced in the future provided a royalty is paid. Crucially however, production of generic versions of new medicines will not be permitted.

The affirmation of the Doha Declaration on Public Health and TRIPS of the WTO in 2001 that least developed countries can use compulsory licensing to facilitate the production of generic versions of approved branded drugs where there is a public health emergency was an important step for developing nations. The 'August 30' decision whereby it was agreed in 2003 that countries without manufacturing facilities can apply for compulsory licenses under such circumstances was also key.

However the latter mechanism remains untested and needs urgent clarification. Although a number of manufacturing countries such as India and Canada have amended their legislation to implement the Agreement, no developing nation lacking manufacturing capacity has yet applied to make use of it. However it is axiomatic that the very countries which lack manufacturing capacity, several of which are located in sub-Saharan Africa, do not have the political force or technical capacity to pursue this clarification alone.

**We therefore propose to take action collectively by appointing a special Task Force which will have represented within its membership Ministers of Trade and**

**Ministers of Health from the following member countries: South Africa, Mexico, Korea, Brazil, India, UK, USA, Italy, Canada and Australia). The Task Force will have the following terms of reference:**

- **To assess the viability of the legislation enacted by potential licensor countries to act as recipients of compulsory licenses issued by states without manufacturing facilities for public health emergencies**
- **To ascertain why applications for use of this mechanism have not yet been forthcoming**

**The findings of the Task force will be brought to the forum of the WTO and discussed as an agenda item at the main meeting in 2007.**

*Data exclusivity*

TRIPS under Article 3<sup>2</sup> requires members to protect clinical test data required for marketing approval of a new drug from unfair commercial disclosure. In the USA, the provision means that no other company may seek marketing approval of an equivalent drug using such data for a period of 5 years from the original marketing approval without permission. Some of our members are concerned that this may cause delays to generic companies wishing to introduce an equivalent generic drug without recourse to repeating costly clinical trials. Data protection could also delay or prevent a company from obtaining a compulsory license from obtaining marketing approval for a generic form of an approved drug.

Data exclusivity in TRIPS as interpreted by the USA and the EU gives additional protection by virtue of its confidentiality. Proponents of the protection claim that the data protection requirements are immaterial because in most cases data protection expires before most patents. But a majority of our members agree that extending the protection of drugs in the market by preventing generic companies from having access to clinical data is unlikely to promote the public health of citizens in developing countries. This issue must be addressed if the principles of the Doha Declaration and the August 30<sup>th</sup> Agreement are to be respected, and the benefits realised.

**At the very least, we call for more creative solutions to be developed.** For example, exemptions from data protection could be made in developing country markets so that new generic medicines could be made available at low cost without delay. Concerns about parallel importing of these restricted generic drugs into developed countries could be addressed by existing mechanisms developed for differential pricing. **The L20 will set up a panel of experts to identify workable solutions, to report within 12 months. The findings will put out to public**

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<sup>2</sup> Article 3: Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

## **consultation before being put on the agenda for discussion at the fora of the WTO and WIPO.**

In addition we will provide support to those developing countries contemplating bilateral trade agreements with out countries. Some making bilateral trade agreements with the USA are accepting 5 year terms for clinical data protection for foreign branded drugs. We have already concluded that this extension of exclusivity which delays the entry of cheaper generics is rarely likely to be justifiable in public health terms in resource poor settings. Developing countries themselves must weigh these potential losses against any gains made in these agreements in the context of their own circumstances. But more informed choices will be made through the collective sharing of experience. **The L20 will assign responsibility for coordination of advice and expertise in bilateral trade agreements through new posts in its core staffing to support members engaged in negotiations.**

### **Traditional knowledge**

The generation, refinement and passing on of knowledge has been a feature of human societies for millennia. This ‘traditional knowledge’, which is essential to the food security and health of millions of people in the developing world, has been a feature of the broad debate on IPRs. Several cases of what is often termed ‘biopiracy’ have attracted international attention.<sup>3</sup> They have involved the granting of invalid patents by examiners who were unaware of the prior art in the form of traditional knowledge. The question of benefit-sharing with indigenous peoples has also been raised.

These cases have increased the calls for traditional knowledge in developing countries to be better protected. Some progress has been made through the Convention on Biological Diversity and the issue has been discussed by UNCTAD, WHO, FAO, and UNESCO. **We urge these bodies to share their discussions so that coherent approaches are developed and duplication avoided. However, little substantive progress has been made to date and we consider that bringing the concerted framework of the L20 to bear on the issue would be more fruitful.**

We believe that there are important reasons for protecting traditional knowledge which include concerns of equity, conservation, preservation of culture and avoidance of biopiracy. But the issues around traditional knowledge are not well understood. We hesitate therefore in recommending that international norms for protection be established. Such a step would be premature. We have concluded nevertheless that the misappropriation of traditional knowledge from developing countries continues to be a serious issue. It is unacceptable practice which we wish to repudiate.

Much traditional knowledge is not documented and is therefore inaccessible to patent examiners based overseas. Pursuing challenges to the USPTO is very costly in terms of human and financial resources for developing nations.<sup>4</sup> **We therefore propose to act on the finding of the Task Force of WIPO that digital libraries of traditional knowledge, which establish prior art in codified form, can be integrated into the existing search tools used by patent offices. We will work with**

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<sup>3</sup> For example, tumeric, neem, Ayahuasca and Hoodia

<sup>4</sup> See the successful Indian challenges to the basmati rice, and tumeric patents granted by the USPTO.

**WIPO to establish regional centres by 2008 in Latin America, Africa, and East Asia. They will be charged with setting up digital libraries to cover the most important medically and agriculturally-related traditional knowledge from member countries.**

**We recognise however, that much traditional knowledge will remain undocumented. We support almost unanimously the concept of absolute novelty whereby any disclosure including through use, anywhere in the world is sufficient to destroy the novelty of invention. Without this safeguard, patents claiming rights to traditional knowledge could continue to be granted. We urge those countries that only include domestic use in their definition of prior art should give equal treatment to users of knowledge in other countries. The United States has agreed to consider paving the way by amending its own patent regulations.**

### **Copyright protection**

Copyright has emerged as one of the most important means of regulating the international flow of ideas and knowledge-based products. Progress in science and technology in developing countries will ultimately depend on people having ready access to knowledge. Copyright will be a central instrument for the knowledge industries of the coming decades and those who control it will have a significant advantage in the new knowledge-based global economy. The fact that copyright ownership is concentrated in the industrialised countries and multimedia corporations places developing countries at a significant disadvantage. Furthermore, the costs of access and the terms of 'fair use' have been made more critical by the extension of copyright to software and digital material.

The crucial issue for developing countries is getting the right balance between protecting copyright and ensuring adequate access to knowledge and knowledge-based products. There are great opportunities such as the development of digital libraries and archives, internet-based distance learning programmes, and access to online technical databases in real time. But there are new and serious threats such as the potential of the internet not being realised as rights owners use technology to restrict access.

Equally, unauthorized copying through weak levels of copyright enforcement prevent industries from being able to recoup their costs to generate revenues for future R&D. While such practices are generally not defensible, we are concerned that stronger protection and enforcement of copyright as agreed in TRIPS will be to reduce access to knowledge-related products in developing countries with damaging consequences.

Companies, whose primary responsibility is to shareholders, look to governments from wealthy countries and development agencies to subsidise access to affordable works for educations and knowledge transfer.

We have considered these opposing arguments carefully. We believe that the application of differential pricing to copyrighted works in developing countries could serve the interests of the rights-holders and the consumer. The existence of no or low costs schemes for on line publications shows that there is more scope for revenue-

neutral or revenue enhancing approaches, with appropriate safeguards. **We recommend that publishers of hard copy and on line books and journals in science and technology review their pricing policies to help reduce unauthorised copying and to facilitate access to their products in developing countries. As a first step in this direction, Ministers of Overseas Development from industrialised countries in the L20 will be establishing new five year initiatives in their departments to encourage publishers in the development of differential pricing, and other mechanisms. The extension of free-online initiatives for developing countries to cover all academic journals will also be a priority**

### **Capacity building**

The issues highlighted during our Summit point to the need for a critical mass of IP expertise in developing countries. Many other bodies, including the DFID Commission for Intellectual Property Rights in Development (2002) have made similar observations. The need for such expertise amongst developing country delegations to the WTO to negotiate the TRIPS agreement in 1995 was readily apparent. Although training initiatives have since been put in place, and the NGO community has assisted in this regard, no one country with the possible exception of Brazil and India can address these complex issues in isolation. **We therefore consider it imperative that industrialised countries play a much more proactive role in helping to strengthen the range and scope of expertise in IP in developing countries *while at the same time improving their own understanding of IP issues in development.* The industrialised members of the L20 have therefore agreed to establish and fund a new institute expressly for this purpose. It will be located in Uganda and will be governed by an independent board. Its remit will be to assist in the building of a critical mass of expertise and to encourage the development of open debate and dialogue to improve the outcomes of science and technology applications for poor people.**