Pathways for enhancing access to health technologies through improved IP management: The MIHR Programme for Health Innovation (MPHI)

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Executive Summary

The effective use of knowledge is critical both for economic development and for the development of health-related products aimed at improving human health and well-being. Whilst developing countries are often able to produce significant scientific knowledge mainly from the public sector, their ability to translate the knowledge into a technology – mainly through the private sector – is less well developed. MIHR has undertaken a needs assessment and environmental analysis in East Africa. The results show that reasons for low success rates of technology development include a lack of effective linkages between the public and private sectors and a lack of innovative capabilities in the private sector. Additional private sector investment in the development of pharmaceuticals coupled with the import and adoption of new technologies from abroad can maintain and improve innovation capabilities. Strong innovation capabilities also require skills in IP management and a supportive IP infrastructure.

Many countries are devoting high level policy attention to science and technology (S&T) and innovation policies. The MIHR study indicates that several East African countries - Kenya, Uganda, Tanzania and Ethiopia - are committed to the enhancement of science and technology capabilities for development and to the strengthening of biomedical innovation capabilities. We found that barriers to effective work in this area include uncertain delineation of institutional responsibilities, lack of appropriately skilled professionals, unclear and underdeveloped judicial systems, and, crucially, lack of awareness among researchers of how to go about technology transfer and development. These factors vary in prominence among countries.

MIHR has launched a programme of training and technical assistance in close collaboration with institutions in Africa to address these barriers and needs.

Introduction

Approximately 14 million people die of infectious diseases each year, with the majority of cases occurring in developing countries (Dentico N. & Ford N., 2005). Whilst there have been improvements in prevention or treatment of some infectious diseases, such as bednets for malaria and therapy regimens for tuberculosis, these technologies can be only part of a long-term sustainable solution for these diseases. Diseases affecting poor people almost exclusively, such as Chagas, leishmaniasis, sleeping sickness, and dengue, still receive a very small share of the total investments in biomedical research and development (MSF, 2005). The combined efforts of the global pharmaceutical industry and public sector institutions are not yet developing needed biomedical technologies for the many millions who most need them – the poorest.

Concern about persistent inequalities in availability of medicines for the poorest populations has led major public, non-profit and private sector actors to establish of a variety of initiatives that aim to accelerate flow of scientific discoveries into the development pipeline. Such initiatives include the Medicines for Malaria Venture (MMV), International AIDS Vaccine Initiative (IAVI) and Global Alliance for Tuberculosis (GATB). In addition, greater attention is being placed on finding ways to help developing country firms (both public and private) to participate in research and development for neglected diseases (Lewis-Lettington & Grace, 2004; Salicrup et al. 2005)[1]. To some extent this attention is based on the thinking of development economists who advocate the enhancement of 'national innovation systems' (NIS) for economic growth (Lundvall, 1992; Nelson, 1993; Kim, 1993; Freeman, 1998; Arnold and Bell, 2001). These economists point out that the "firm" is the primary agent for innovation.

Biomedical innovation - multi-faceted by its nature – requires research capabilities and the ability to translate research findings into usable products. Without this translation, the investments by developing countries may result in academic jobs and publications, but negligible impact on health (Gardner, 2005; Barnett, 2005). To achieve health impact, a NIS must take account of several determinants of innovation (Morel et al., 2004; Mahoney et al. 2005). These include support for R&D, development of domestic and international distribution systems, enhancement of manufacturing capabilities, effective management of IP and operation of capable regulatory systems.

MIHR's Rationale and Mission:

MIHR (the Centre for the Management of Intellectual Property in Health Research and Development) is a non-profit organisation with registered charitable status in the United

[1] This thinking is also enhanced by the fact that research facilities based in these regions 'may be comparatively well placed to achieve quick solutions. This is because 'the practice of health research relies heavily on close contact with other parts of the health sector, on the local epidemiological environment, and on the clinical, behavioural, and social sciences that are tied to both national and global frameworks' (Lewis-Lettington & Grace, 2004).

Kingdom. MIHR was initiated by the Rockefeller Foundation in autumn 2002 and is governed by an independent Board of Trustees with international expertise in intellectual property, technology transfer and health improvement. MIHR was established in recognition of the importance of IP management to help ensure access to needed health technologies by the poor. MIHR recognizes the need for capacity building in science and technology management in the biomedical sector in developing countries.

Mission:

"To contribute to a world in which the ethical stewardship and creative management of intellectual property leads to better health for the poorest."

By helping to increase IP management capacity in developing countries, MIHR aims to help to redress the imbalances in innovation capabilities between developed and developing countries. MIHR helps in (1) capacity building, (2) promoting a "tool kit" for the management of intellectual property, and (3) dissemination of best practices through workshops and MIHR's unique publication, the "*Handbook of Best Practices for Management of Intellectual Property in Health Research and Development*."

The MIHR Programme for Health Innovation (MPHI)

In collaboration with the South African Medical Research Council, and working closely with government departments and biomedical research institutions as well as other regional capacity building initiatives in this area, the MIHR Programme for Health Innovation (MPHI) is a training and technical assistance programme working to deepen capacity in biomedical innovation and enhancing access to medicines by the poor.

The MPHI works with scientists, administrators and policy makers in developing countries to conduct thorough needs assessments and environmental analyses, deliver training and technical assistance relating to technology transfer, biomedical innovation and socially responsible licensing to ensure access by the poor.

MIHR has worked with partners to build capacity in South Africa, India and Latin America and is developing programmes in East Africa and South East Asia. For example, in India, MIHR, in partnership with The Wellcome Trust and in collaboration with The National Centre for Biological Sciences (India), organised an in-depth workshop on intellectual property management. The workshop addressed the fundamentals of IP management with specific reference to issues and practices that impact on R&D institutions. It enhanced knowledge and skills in applying appropriate IP management solutions during the translation of research. In South Africa, MIHR has provided assistance to the Medical Research Council (MRC) to develop its IP policy and together, the MRC and MIHR have delivered introductory, advanced and 'Train the Trainer' workshops to develop institutional IP management capacity for health innovation.

Case Study - APHI

The component of MPHI being undertaken in East Africa is the Africa Programme for Health Innovation (APHI), and focuses on Kenya, Tanzania, Uganda, and Ethiopia.

As much of the biomedical research in Africa is conducted in public research institutions, the APHI's focus is on enhancing public sector research institutions' capacity for engaging in the health innovation process. This is not a short-term goal, and requires a step-wise process to achieve it, building on resources (such as IP/technology management policies and offices/processes to implement them) where they exist, and catalysing the development of them where they are absent or only nascent.

Needs Assessment

Between January and May 2005, the APHI completed a comprehensive needs assessment and environmental analysis pertaining to capacity in IP management and technology transfer in the biomedical arena in the four East African countries - Kenya, Tanzania, Uganda and Ethiopia. MIHR led an international team in the completion of this work and, through consultation with R&D leaders, this exercise identified problem areas experienced by East African institutions in the translation of discoveries in health research into health products.

Methodology and Approaches

The needs assessment involved

- desk-based research on IP systems, leading institutions, governmental and NGO activity in the area;
- circulation of a survey questionnaire to senior representatives from research institutions, government and quasi-governmental departments;
- conducting focus group meetings and one-on-one semi-structured interviews with governmental, quasi-governmental and non-governmental institutions, IP officers and senior administrators and senior scientists at public sector research institutions and universities as well as private sector representatives.

In addition, the APHI was invited to attend the African Joint Scientific Conference (AJSC), Arusha, Tanzania, and to present at the Inter-Universities Council of East Africa Annual General Meeting, Mombassa, Kenya[2]. MIHR has also been requested to give a presentation on IP management 26th to 29th October 2005 at a conference co-organised by Makerere University, entitled 'The Contribution of Research in Advancing Health Care in Uganda'.

Findings

[2] The IUCEA is a body comprising Vice-Chancellors of major universities in East Africa as well as Directors of national science and technology councils and committees.

Our work revealed that there is a low level of experience in managing the process of technology transfer and that some fundamental issues such as the basics of IP are often ill-understood and some believe that IP is contrary to the social functions of publicly funded science. Even Kenya, which is the most advanced in terms of IP infrastructure in the region, does not possess many experts in this area. In countries where the needs assessment was conducted, the professional network is limited which, in turn, constrains potential regional scale effects. We found that other barriers to effective work include uncertain delineation of institutional responsibilities; absence of appropriately skilled staff; unclear and underdeveloped judicial systems; and, crucially, lack of awareness among researchers hampered by inefficient communication systems. The assessment revealed that the greatest related needs in some of the most important institutions in East Africa, including Makerere University (Uganda), Kenya Medical Research Institute (KEMRI, Kenya), Muhimbili University College of Health Sciences (MUCHS, Tanzania) and National Institute of Medical Research (NIMR, Tanzania), relate to the development of institutional IP policies, and the development of technology transfer/management practices that apply those policies.

Whilst senior scientists and administrators at many of the public sector research institutions that we visited in East Africa have a notion of the importance of IP and technology management for research translation, they want more education regarding its implementation. In some cases, IP and/or technology transfer offices exist, but the infrastructure and skills are relatively weak, and the research scientists lack awareness of relevant policies and processes and their implications. IP professionals and senior administrators have stated that they would benefit from training in practices related to technology transfer.

Workshop, Dar es Salaam, May 2005

To begin to address these needs, the APHI convened a regional workshop at the National Institute of Medical Research (NIMR) in Dar es Salaam, Tanzania on 18-20th May 2005.
The objectives of the course were fourfold: -
1) Provide participants with the basics of issues relating to the transfer of knowledge from research institutions to application for economic and social development.
2) Expose the curriculum to potential future APHI Faculty who would receive further training and pass on knowledge within their institution.
3) Provide training to assist IP officers in conducting technology transfer and prime them for future training and technical assistance.
4) Deepen the APHI's understanding of specific training and technical assistance needs for further curriculum and strategy development.

The workshop had 51 participants from four professional groupings: public sector research scientists; public sector IP officers; government officials and policy-makers at Ministries of Health and Education, at national industrial/intellectual property offices and National Councils of Science and Technology; and representatives from relevant East African and International NGOs. The course was designed and created by the faculty and staff of East African research institutions (Universities and Research Councils) [i]. An important output of

the workshop in Dar es Salaam is a proposal for the formation of an IP Information Centre in Uganda.

Local Partners & Support

The identification of national and regional partners and the specification of a training programme to further develop capacity have followed MIHR's approach to gap assessment which has been used in countries such as South Africa, Egypt and India. The APHI benefits from its rapidly emerging associations with East and South African collaborating partners, some of which are listed in the table below.

Table 1: Supporting Institutions

INSTITUTIONS SUPPORTING THE APHI
SOUTH AFRICA
• Medical Research Council
• Council for Scientific and Industrial Research (CSIR)
KENYA
• International Centre of Insect Physiology and Ecology (ICIPE), Kenya
• Kenya Medical Research Institute (KEMRI), Kenya
• Kenya Industrial Property Institute (KIPI), Kenya
• International Livestock Research Institute (ILRI), Kenya
• National Council for Science and Technology, Kenya
• Moi University
• Uganda National Council for Science and Technology, Uganda
• Uganda National Academies of Science, Uganda
• Ugandan Ministry of Justice
• Makerere University
• University of Addis Ababa, Faculty of Medicine, Ethiopia
• Ethiopian Intellectual Property Office (EIPO), Ethiopia
• Ethiopian Science and Technology Commission (ESTC)
• Armauer Hansen Research Institute (AHRI)
TANZANIA
• National Institute for Medical Research (NIMR), Tanzania
• Muhimbili University College of Health Sciences (MUCHS)
• Suonomi University of Agriculture (SUA)
• University of Dar es Salaam
• Business Registration and Licensing Authority (BRELA)
• Tropical Pesticides Research Institute (TPRI)
• Tanzania Commission for Science and Technology (COSTECH), Tanzania
REGIONAL INITIATIVES
• ASARECA
• BIOEARN
• ABSPII
• Network On Traditional Medicines (University of Nairobi)
• Inter-University Council of East Africa (IUCEA)
• East African Community (EAC)
PRIVATE SECTOR
• Med Biotech, Bridgeworks

APHI – Proposed Next Steps

To achieve sufficient penetration of the public R&D sector and make a significant impact following the initial workshop, MIHR plans an ongoing programme of further workshops. The programme would work with relevant leaders to deliver training to senior scientists and administrators in the leading universities and research institutions. Follow-up workshops are anticipated to address more in-depth training and institutional development needs.

Additional work could focus on:

- Training of IP officers and patent examiners to develop skills in technology transfer
- Training of administrative and science staff
- Technical assistance for the development of institutional IP Policies
- Institutional and national technology transfer capacity development

MPHI – South East Asia

MIHR has also undertaken to contribute technical assistance in South East Asia and has,conducted a needs assessment in Cambodia, Laos, Thailand and Vietnam. Whilst the four countries have widely different IP regimes and competencies as regards biomedical innovation and technology transfer, they have concerns relating to the impact of the TRIPs rules on access to medicines. MIHR is undertaking a comparative study to assess these concenrs and is convening a meeting in Hanoi in 2005 of policy makers from the four countries.

MIHR will also convene a meeting in December in New Delhi to assess the impact of TRIPS on the operation of both national and international product development public private partnerships.

Conclusions and Policy Implications

A major finding has been the need to link Ministries of Education, Science and Technology and Justice with Ministries of Public Health to ensure that biomedical science is applied in the most useful way to address significant public health needs. There is wide-spread recognition of the need for refined skills in IP management and technology transfer. Further, there is a need to exploit possibilities for engagement in the global innovation process through collaboration with global PDPs. There are needs to develop IP management policies at the institutional and national level particularly with regard to health technologies.

In summary, through the promotion of creative and socially-conscious management of intellectual property in the biomedical domain, the APHI is assisting in the development of an enabling environment for product development. While IP is not the most important issue to address, professional attention to its management is an essential component of innovation of needed health technologies.

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