WORLD HEALTH ORGANIZATION

FIFTY-SIXTH WORLD HEALTH ASSEMBLY A56/17
Provisional agenda item 14.9 12 May 2003

Intellectual property rights, innovation and public health

Report by the Secretariat

PUBLIC HEALTH NEEDS AND INNOVATION

1. Innovation in public health involves the introduction of new ideas, policies, methods and programmes to improve the population's health status. Although such innovation is broad in scope, the present report examines one aspect: biotechnology, including genomics, pharmaceuticals, medical devices and other diagnostics.

2. The need is greater than ever for innovation in health-care products, including medicines, pharmaceuticals, diagnostics, and medical devices. Molecular genetics combined with an enhanced understanding of immunology is also resulting in new and improved vaccines. New methods for preventing and controlling many of the causes of chronic ill-health can be expected from a growing understanding of the human genome. New classes of diagnostics, vaccines and therapeutic agents, and new approaches to vector control can derive from the study of human, pathogen and vector genomes. A better understanding of gene functioning in health and disease, and in medicinal chemistry, makes it possible to evaluate candidate compounds more quickly, and to develop products more closely tailored to needs. Genetic modification of plants offers the potential to influence plant growth, fertility and disease resistance – thus impacting on food security and nutritional status.

3. Nonetheless, a significant proportion of the world's population, especially in developing countries, has yet to derive much benefit from innovations that are commonplace elsewhere. The reasons range from weak supply systems to unaffordable prices. The factors that drive innovation are often biased against conditions that disproportionately affect the populations of developing countries. For example, of the 1325 new medicines launched between 1975 and 1977, only 11 were specifically for tropical diseases. Innovation to address conditions primarily affecting poor people is held back by a combination of market failure and underinvestment by the public sector. The process of bringing a new product to the market is both expensive and lengthy. Because of the resource implications and the uncertainties involved, creating an environment conducive to successful innovation is essential.

MECHANISMS FOR STIMULATING INNOVATION

4. An environment conducive to innovation has several components: adequate financial and infrastructure support for basic science; funding and investment for translating basic science into

usable products, including both the means for protecting the investment of innovators and the technical capacity to innovate; mechanisms to establish research priorities that fit public health and health care needs; and a regulatory and licensing system which facilitates innovation while adequately protecting public health.

5. **Investment in basic science.** Advances in basic science take place to a large extent in publicly funded academic institutions. Strategically managed investment in these institutions from governments and development agencies is thus essential, as is ensuring easy access to the scientific information that is produced. Financial needs for basic research on health conditions prevailing in low-income countries are estimated as being in the order of US$ 1500 million a year.[1]

6. **From basic science to new products.** Where there is a limited market, translating academic discoveries into needed health products often requires public sector support, frequently in partnership with the private sector. Long-standing programmes that work in this way include the Special Programme of Research, Development and Research Training in Human Reproduction and the Special Programme for Research and Training in Tropical Diseases.[2] More recently, a number of new ventures have been launched, including ones that focus on drug-specific indications such as malaria, tuberculosis, and selected tropical diseases,[3] on vaccines[4] or on diagnostic development.[5] These initiatives often build upon the work of publicly financed institutes, including several based in developing countries. Private companies have also established new not-for-profit institutes to address neglected diseases and to consider how to encourage research and development in developing countries.

7. One notable effect of international public-private partnerships has been to increase the number of smaller companies from developing countries that are becoming active in these areas of research. At the core of most public-private research and development partnerships is an agreement that provides for preferential pricing of products in developing countries in return for reduced financial risk which comes from patent protection and the "push" of public-sector investment.

8. Other mechanisms are designed to give investors some form of guarantee that their products will find a secure market – so-called "pull" mechanisms. Advance-purchase funds or agreements, for example, guarantee investors a particular price and market for a product once it has been developed. New initiatives such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and the Global Alliance for Vaccines and Immunization send signals to investors about the potential size of the market and real level of demand for specific drugs and vaccines in developing countries. However, the "pull" value will be relatively low at early stages of new product development, when the outcome is uncertain, but the level of investment still required is high.

9. In cases where the private sector provides the bulk of the investment for product innovation, a system of intellectual property protection serves as an important incentive for innovation, by allowing

[1] *Macroeconomics and health: investing in health for economic development. Report of the Commission on Macroeconomics and Health.* Geneva, World Health Organization, 2001.

[2] In its 27 years of existence the latter Programme has been engaged in the development of over 60 disease control interventions. This includes approximately half of all new drugs that have been introduced for tropical disease indications over the past two decades.

[3] Medicines for Malaria Venture; Global Alliance for TB Drug Development; Drugs for Neglected Diseases.

[4] International AIDS Vaccine Initiative; Malaria Vaccine Initiative.

[5] Sexually Transmitted Diseases Diagnostics Initiative; Tuberculosis Diagnostics Initiative.

the innovator to recoup the cost of research or product development and to make a profit.[1] Patent protection, originally varied widely in different parts of the world, WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) seeks progressively to introduce global minimum standards, whereby WTO's 144 Member States provide patent protection for all products and processes for at least 20 years. Nonetheless, it recognizes that Members may adopt measures necessary to protect public health and nutrition. Further, by singling out pharmaceutical products for special treatment in the Doha Declaration on the TRIPS Agreement and Public Health (2001), WTO Members have also recognized that health products need to be treated differently in certain circumstances. For example, the deadline for least developed countries to implement TRIPS in regard to pharmaceuticals has been extended to 2016.

10. Success in innovation requires high-quality human resources in science, information and management. Currently, much of the expertise, capacity and financial resources for health-related innovation and manufacturing is located in high-income countries, notable exceptions notwithstanding. In most developing countries, there are shortages of skilled personnel in many technical areas. Innovation is more likely if the educational system trains people with the requisite entrepreneurial and creative skills. Hence the significance of technology transfer, capacity development, and greater international cooperation.

11. The TRIPS agreement also provides that intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology. Technical capacity can be developed through joint research and development projects, as noted above, and also through voluntary licensing agreements, by which a patent-holder agrees to license another company to produce a patented product and, critically, to provide the technical wherewithal to do so. Such capacity enables scientists to further pursue and develop knowledge indigenous to their countries.

12. Sharing of information is essential to ensure transfer and development of technology. In 2000 the United Nations Secretary-General and WHO launched an initiative to ensure that health personnel have equitable access to health information. Known as the Health Internetwork Access to Research Initiative, it involves six major science publishers which are making over 1000 scientific journals accessible to users. Although not directly linked to innovation, this initiative contributes to expanding the knowledge of researchers in developing countries.

13. **Setting research priorities.** Successful innovation must respond to genuine public health concerns, taking into account the needs of specific groups such as women and older people. Hence, an enabling environment needs to ensure that the research priorities reflect the point of view of all components of society, especially the poorer segments.

14. **A conducive regulatory environment.** An efficient, effective regulatory system tuned to the realities of research and development facilitates innovation. A considerable part of the long period and hence the cost of innovation is related to the requirements of product approval and licensing. Regulatory and licensing systems need to be geared to the nature of the product concerned, with greatest stringency being applied to those with a direct or indirect impact on human health. Recent developments in which regulatory bodies have become more closely involved with product developers at an early stage in the design process have resulted in shortening the period for market entry.

[1] The term "intellectual property" encompasses patents, trademarks, copyright, and technical knowledge and know-how (as in the case of vaccines).

15. All the components need to operate in a wider enabling environment. A sound legal and judicial system gives innovators confidence that action will be taken when their rights are infringed, and reassures consumers that any abuse will be acted upon.

INTELLECTUAL PROPERTY AND HEALTH

16. The role of intellectual property rights in stimulating innovation has been the subject of study by a number of high-level bodies at national and international levels, in particular in relation to the pharmaceutical sector.[1] WHO's Advisory Committee on Health Research examined the effect of international property rights in its report on genomics and world health (see below).[2] A review of this growing body of work suggests a number of common themes, described below, which merit further monitoring and research.

17. **Intellectual property rights and pricing**. The exclusive right to market a product during the life of a patent allows the holder to recoup some or all of their initial investment, by charging more for the product. However, the cost to society, particularly in developing countries, would be high if intellectual property rights were used beyond the original intent of stimulating innovation, as a commercial tool that overly restricts competition. Although price is only one of the factors that determine access, it is a highly significant one. Three recent studies, each using different methodologies, predict price increases of twofold or more with full implementation of TRIPS requirements in developing countries.[3] As views vary on the potential magnitude of the price effect, continued monitoring, using consistent and transparent methodologies, appears to be warranted.

18. Reconciling the needs of patients and patent-holders is a challenge to improving access to essential health care. Given the potential impact of intellectual property rights on price, there has been a growing interest in mechanisms designed to bring about the most favourable pricing for developing countries. Relaxed patent requirements, tiered pricing, voluntary licensing, compulsory licensing, bulk purchasing, and corporate donations have each been evaluated as potentially effective mechanisms to achieve the most favourable pricing of patented medicines in developing countries.[4] The analysis suggests that those approaches which facilitate competition have the greatest impact on reducing price. These approaches need to be evaluated both individually and in combination in order to ensure that the balance between exclusive patent rights – and the investment stimulus they provide – is balanced against the objective of reducing prices, and the impact of these approaches needs to be monitored in different national contexts.

---

[1] See, for example:

National Institute for Health Care Management. Prescription drugs and intellectual property protection: finding the right balance between access and innovation. Washington, DC, 2000.

Commission on Intellectual Property Rights. Integrating intellectual property rights and development policy. London, Department for International Development, 2002.

European Commission, High Level Group on Innovation and Provision of Medicines, European Union (G10 Medicines report). Brussels, 2002.

[2] *Genomics and world health. Report of the Advisory Committee on Health Research.* Geneva, World Health Organization, 2002.

[3] Cited in Scherer, FM and Watal, J. Post-TRIPS options for access to patented medicines in developing countries. Commission on Macroeconomics and Health Working Paper Series, Paper No. WG 4: 1, June 2001.

[4] Equitable pricing of newer essential medicines for developing countries: evidence on the potential of different mechanisms. Geneva, World Health Organization, 2003. In preparation.

19. **Scope of intellectual property rights.** Depending on the country, protection of research data from use by potential generic competitors, and certain national provisions related to marketing authorization for medicines, might have the effect of limiting competition. It is unclear therefore whether, and to what extent, such national measures help to stimulate desired behaviour (such as the conduct of clinical trials to generate such data) or to hamper access to innovative products. Further, bilateral and regional trade agreements that go beyond the minimum standards defined in the TRIPS agreement (often referred to as "TRIPS-plus") may fail to reflect the need for special treatment for health-related products. It is also unclear whether extending the scope of patents to include mechanisms of action, uses, and other features of a pharmaceutical product promotes or hinders innovation in the long run.

20. **Adverse effects on future innovation.** In some circumstances, intellectual property rights might have a perverse effect on innovation. Much depends on the stage of product development at which protection is applied, and what, in different jurisdictions, is admissible under patent law as an invention. The recent report of WHO's Advisory Committee on Health Research notes that: "The current situation has gone too far in promulgating a culture of ownership, and if it is allowed to continue it will inevitably lead to further inequalities in health care". It further suggests that unless the "complex and chaotic situation" which currently prevails is addressed, protection of intellectual property could stifle the very innovation it is designed to stimulate. As a result "both the biomedical research community and industry will be severely disadvantaged in their efforts to translate the potential of genomics into improvements of global health." A prudent approach is needed to ensure that legitimate concerns do not give rise to "solutions" that have undesirable effects. For example, the exclusion from patentability of genes would act as a strong disincentive to the biotechnology industry, just at a time when significant numbers of new biotechnology-based pharmaceuticals are coming onto the market. The way in which current law on intellectual property rights and regulatory systems operate therefore need to be carefully examined before changes are sought.

21. **Capacity to manage protection of intellectual property rights.** At national level, the establishment and administration of a patent system is complex and expensive. The resource implications for a developing country of putting in place the structures needed to implement TRIPS are likely to be significant. National systems also need access to a wide range of rapidly changing information in order to function effectively. Broad variations exist among developed countries as to the definition of patentability, provisions for market exclusivity, and other operational factors. Tracking this information and assessing the validity of patent and other intellectual property claims is a costly process and one that requires specialized expertise. Further, patent applicants have the option of seeking or not patent protection at national level. Procurement agencies and authorities in developing countries are therefore faced with the task of determining the patent status of individual products – a task more difficult in countries where accurate record-keeping of patents granted does not exist or is not readily accessible.

22. Researchers in developing countries also face difficulties managing intellectual property. Efforts are being made to provide health researchers and their organizations in countries with expert training and legal counsel to enable them to tackle more effectively complex intellectual property laws.[1] Nonetheless, the question remains of the best way for countries with limited resources to manage intellectual property in the future.

* * *

[1] For example, by the Centre for the Management of IP in Health R&D.

23. In conclusion, there is clearly no universal solution to promoting innovation in public health while protecting intellectual property rights. However, introduction of new technology or establishment of a new or expanded system for the protection of intellectual property in a given country does not necessarily require a radical new approach. Rigorous analysis of the scientific, legal, economic, ethical, and human rights aspects of intellectual property as it relates to public health, and careful monitoring of this relationship in different national contexts, could prove invaluable for national and international policies and practices that ensure both innovation to respond to unmet needs and access to existing technologies for health.

ACTION BY THE HEALTH ASSEMBLY

24. The Health Assembly is invited to note the above report.

= = =