

**Strengthening multilateral cooperation on
intellectual property and public health
Address at the World Intellectual Property
Organization Conference on Intellectual Property
and Public Policy Issues
Geneva, Switzerland, 14 July 2009**

Director-General, Mr Francis Gurry, honourable ministers, distinguished heads of agencies, distinguished delegates, ladies and gentlemen,

WHO values its collaboration with the World Intellectual Property Organization. The areas where our mandates intersect touch on some of the most pressing problems in public health.

We are fully aware of the need for a system of intellectual property that rewards innovation in the interest of keeping it sustainable.

I greatly appreciate this opportunity to speak to an audience with expertise in the field of intellectual property, and most especially so given the focus on public policy issues.

Progress in public health depends on innovation. Some of the greatest strides forward for health have followed the development and introduction of new medicines and vaccines.

Innovation is further needed to stay ahead of the development of drug resistance, especially for diseases like malaria and tuberculosis. Innovation is needed to keep pace with the emergence of new diseases, including pandemic influenza caused by the new H1N1 virus.

Innovation contributes to the operational efficiency of control programmes. For many diseases strongly associated with poverty, smart product design helps circumvent weaknesses in delivery systems. Products that can be administered safely by non-medical staff help compensate for the shortage of skilled health workers.

Products made suitable for home-based care help compensate for the failure of health services to reach remote areas. This is especially important for diseases like malaria, which can kill within 24 hours of symptom onset.

Simplified packaging or treatment regimens increase patient compliance, especially when health literacy is low. Better diagnostic tools contribute to the more rational use of drugs, and this helps delay the development of drug resistance.

While no one questions the need for innovation, a related set of questions is now being asked with growing urgency. Why are so many people excluded from the benefits of innovation? Why do so many diseases associated with poverty have imperfect tools?

Can something be done to make the cycle of product discovery, development, and delivery more efficient and more sensitive to health needs in the developing world?

Or to phrase these questions with the voice of civil society: Is it not time to put people and patients, especially those with unmet needs, first?

With progress towards the health-related Millennium Development Goals stalled in some parts of the world, additional questions are being raised. Why do so many millions of people continue to die each year for want of access to existing interventions? What strategies can be used to make existing interventions more affordable and accessible?

Nearly all of these questions can be answered, fully or in part, with reference to a single word: poverty.

Gaps in health outcomes have multiple causes, but poverty is the most pervasive factor. Poverty impedes access to existing interventions. As poverty tends to concentrate in hard-to-reach places, it constrains access to the services that deliver existing interventions.

The costs of care, including the price of medicines, can be an absolute constraint for impoverished households, especially when expenses are covered by out-of-pocket payments. WHO estimates that the costs of care drive around 100 million people below the poverty line each year.

This is a bitter irony at a time when the international community is engaged in the most ambitious drive in history to reduce poverty and reduce the great gaps in health outcomes.

Poverty also impedes the development of new products for diseases of the poor. Given current intellectual property regimes, poverty is a disincentive for innovation. Patent protection operates as a stimulus for research and development for new products, but the quest is for products that generate a profit.

In short, market forces and the incentives, such as patent protection, that propel them cannot by themselves adequately address the health needs of

developing countries. Incentives need to be found to overcome the problems arising from this market failure.

Here is the critical question. If businesses, like the pharmaceutical industry, are driven by the need to make a profit, how can we expect them to invest in R&D for diseases of the poor, who have no purchasing power?

And here is the critical problem. Systems and rules, such as those for intellectual property and patent protection, that make perfect sense in many sectors raise some questions when applied to human health.

The HIV/AIDS epidemic brought unprecedented attention to the issue of fair access to medicines. When effective antiretroviral treatments became available, an ability to pay became equivalent to an ability to survive for many millions of people.

The ethical principle is straightforward: people should not be denied access to life-saving interventions for unfair reasons, including an inability to pay.

These are difficult questions and dilemmas. As the title of this session implies, strong multilateral action is needed. Strong collaborative action is also needed among agencies, such as WIPO, the World Trade Organization, and WHO.

We also need this collaboration to solve some other difficult public health issues, including those surrounding counterfeit medical products and legitimate generic products.

Ladies and gentlemen,

I am pleased to report that much ground-breaking activity is now under way.

This past May, the World Health Assembly adopted a resolution on Public health, innovation and intellectual property. This was one of the most difficult, and divisive, issues ever negotiated by WHO and its Member States. The consensus finally reached, after hours and hours and years and years of tense negotiations, represents a triumph for public health.

The resulting global strategy and plan of action provide agreed lines of action for making health care products more accessible and affordable, especially in the developing world.

With this plan now in place, WHO and a host of partners, from academia and industry to governments and civil society, are harnessing systems of innovation and intellectual property to meet health needs in the developing world.

Why do I call this a triumph? Let me be frank. Time and time again, health is a peripheral issue when the policies that shape world affairs are set. When

health policies clash with prospects for economic gain, economic interests trump health concerns time and time again.

Time and time again, health bears the brunt of short-sighted, narrowly focused policies made in other sectors, such as financial markets, energy use, and food production and trade.

But not in this case. For once, the health sector can take a pro-active role in addressing a fundamental cause of much ill health. The agreement on a global strategy and plan of action demonstrates that the forces that govern the development and pricing of medical products can indeed be steered in directions that favour more equitable access to medicines.

R&D can indeed be needs-driven as well as profit-driven. International agreements that govern the global trading system can indeed be shaped in ways that favour health needs of the poor.

During the negotiations, some in civil society had a radical proposal: abolish the current system of intellectual property and patent protection, and replace it with something inherently more responsive to health needs and concerns.

As you know, this was not the solution eventually agreed upon. Instead, many imaginative strategies have been devised to circumvent the consequences of market failure for neglected populations and neglected diseases.

These strategies are part of an innovative and invigorating quest for new products, better product design, and lower prices. In addressing such needs, new initiatives, and new incentive schemes are also finding pioneering solutions to a range of related problems.

Let me give just three examples among many.

First, public-private partnerships have recently emerged as a promising way to develop new products for diseases that disproportionately affect the poor. In the past, the quest for new products for neglected diseases has usually been opportunistic. Existing products, often developed for veterinary purposes, were screened for their potential efficacy in treating human diseases.

More recently, this quest has become strategic. An unmet need is identified, an ideal product is defined, and a public-private partnership is formed to develop the product.

These partnerships, which are developing new tools for AIDS, TB, malaria, and the neglected tropical diseases, usually bring together expertise from academic research, industry, and public health, with funding from philanthropic sources.

The Meningitis Vaccine Project illustrates the many value-added benefits that can accrue when a product is designed with the needs of very poor countries in mind. The project, launched in 2001, responds to the need for a better vaccine for epidemic meningitis, a devastating disease that occurs exclusively in a belt of countries in sub-Saharan Africa.

The objective was strategic: to develop a new vaccine that could move control programmes away from the present reactive response to emergencies, and towards an opportunity to eliminate the very threat of epidemics in the first place.

An affordable price was considered central to the project's success. African health ministers were consulted about what they could afford to pay, and the price was fixed accordingly. The project required collaboration with several commercial companies, and broke new ground in the management of intellectual property rights.

As a second example, international mechanisms, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and the GAVI Alliance for childhood immunization, have demonstrated their capacity to ensure a steadily growing market demand for medicines and vaccines.

During 2006, these mechanisms were joined by a major innovation: UNITAID. This drug purchasing facility uses funds from a levy on airline tickets to purchase quality-assured drugs for the developing world.

UNITAID has provided an incentive for product improvement, such as the development of paediatric formulations of TB drugs. Large procurement volumes have secured substantial price reductions. They have also motivated manufacturers to increase their production capacity, thus ensuring uninterrupted supplies of life-saving medicines as health initiatives continue to expand their reach.

UNITAID has also launched a patent pool initiative as another strategy for boosting innovation.

As a final example, WHO operates a pre-qualification programme for pharmaceutical products, which includes on-site inspections of manufacturing facilities. By giving products of assured quality a seal of approval, the system brings uniform quality standards to the market, introduces order, and increases the base of suppliers.

Equally important, it is helping manufacturing companies in the developing world become internationally competitive at no sacrifice of quality, and no compromise of consumer safety.

Competition from a broader base of suppliers is changing the dynamics of the market for public health vaccines. Supplies are more abundant and reliable,

and healthy, broad-based competition is bringing prices down, sometimes substantially. As yet another advantage, improving the competencies of regulatory authorities and of manufacturers is an explicit component of the programme.

Ladies and gentlemen,

Last month, WHO announced the start of the 2009 influenza pandemic.

Although we estimated that the pandemic will be of moderate severity, at least in its early days, the announcement triggered a surge of interest in pandemic vaccines and a scramble to place orders.

This situation brings back, in a highly visible and universally relevant way, some of the problems I mentioned at the start.

Manufacturing capacity for influenza vaccines is finite and woefully inadequate for a world of 6.8 billion people, nearly all of whom are susceptible to infection by this entirely new and highly contagious virus.

The lion's share of these limited supplies will go to wealthy countries. Again we see the advantage of affluence. Again we see access denied by an inability to pay.

But we also see the need for innovation. This shortfall in vaccine supplies, in the face of universal need, is the result of limited global manufacturing capacity. It is not, in essence, a result of intellectual property issues.

As the experts have long advised, the ideal vaccine would be one that protects against seasonal influenza viruses as well as a range of candidate pandemic viruses. This would be the best and most rational insurance policy for increasing supplies and encouraging more equitable access.

Good will, much determination, and some spirited negotiations have found ways to circumvent some problems of access and price associated with intellectual property, and these efforts are most welcome.

However, ability to pay, whether at the individual or the national level, remains a distinct advantage. In the field of health, public policy will remain imperfect as long as access to life-saving interventions is biased in favour of affluence.

In the field of health, fairness matters in life-and-death ways. This is the heart of the public policy issues we face.

Thank you.