

SEVENTH MEETING

Thursday, 26 January 2006, at 09:10

Chairman: Mr M.N. KHAN (Pakistan)

TECHNICAL AND HEALTH MATTERS: Item 4 of the Agenda (continued)

Intellectual property rights, innovation and public health: Item 4.10 of the Agenda (Document EB117/9)

The CHAIRMAN invited the Chairman of the WHO Commission on Intellectual Property Rights, Innovation and Public Health to brief the Board on its work to date.

Ms DREIFUSS (Chairman, Commission on Intellectual Property Rights, Innovation and Public Health), expressing sympathy for the suffering and loss of life among the people of Pakistan as a result of the recent earthquake, said that the long-term suffering of victims of disease had also been the theme of the work of the Commission. That work had been inspired by the hope of bridging the huge gap between the potential of modern science and its application to the needs of the neglected sick in the developing countries. Having worked for almost two years, the Commission had hoped to present its report to the Board at the current session, but regrettably members had had to extend their work. The report would be completed shortly and published in April 2006, in time for the Fifty-ninth World Health Assembly.

The reason for the delay was threefold: first, the Commission's method of work. Its terms of reference had been defined in the note by the Director-General to the Board at its 113th session.¹ The Commission had been asked to add value to existing work, through research and consultations, and to prioritize consulting and listening. The consultation phase, detailed on WHO's web site, had overrun but provided valuable material on the scientific, economic and political complexities underlying biomedical innovation and access to health care.

The Commission's own ambition had been a second delaying factor, because its rigorous analysis had entailed describing the complex system of biomedical innovation and explaining the failure to yield the results sought by developing countries. The impact of intellectual property rights on innovation differed at each stage of the cycle from basic research via research and development to access to medicines. The Commission was therefore offering an analytical matrix adapted to different types of disease that particularly affected the poor and the differing conditions prevailing in different categories of country. It had also attempted to show how the stakeholders had adapted to economic and political pressure, and to focus attention on their potential and responsibilities. In its report it would therefore distinguish between situations in which intellectual property rights could help to promote research and those in which they were likely to be ineffective. It would attempt to highlight the positive and negative effects of intellectual property regimes on biomedical innovation, access to medicines and the productive and innovative capacities of the developing countries, taking account of the influence of national implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the follow-up to the Doha Declaration on the TRIPS Agreement and Public Health, and the scope of bilateral and regional free-trade agreements on the capacity to attain public health objectives.

¹ Document EB113/INF.DOC./1.

Other incentives and funding regimes were required in order to promote biomedical research into diseases that particularly affected poor people and foster developing countries' capacities in that area. The report would welcome the various public-private partnerships engaged in product development. More effort was needed to ensure both their sustainability and that the medicines, vaccines and diagnostic tools developed reached those in need of them. Member States bore a crucial responsibility for funding research, regulating the marketing of new medical products and organizing health-care systems, to name only three areas.

Thirdly, the Commission's 10 members represented a broad spectrum of experience, opinion and scientific disciplines. Finding common denominators had taken time. Members had striven to put aside ideological considerations and special interests so as to reach a consensus, and to prepare recommendations and proposals for action. The report would come at a time of mobilization and commitment, bringing together international awareness, additional (albeit still insufficient) resources, effective science and new types of partnership. The challenge facing the Commission was to show how to make that movement more sustainable and effective.

The CHAIRMAN invited the Board to consider, in particular, how the report of the Commission would best be presented to the governing bodies. He drew attention to the following draft resolution, proposed by the members of Brazil and Kenya:

The Executive Board,

Having considered current developments regarding access to medicines and the need to develop urgently new medicines and other health care technologies;

Noting the useful work being done by the WHO Commission on Intellectual Property Rights, Innovation and Public Health,

RECOMMENDS to the Fifty-ninth World Health Assembly the adoption of the following resolution:

The Fifty-ninth World Health Assembly,

Recalling resolutions WHA52.19, WHA53.14, WHA54.10, WHA56.27, and WHA57.14;

Considering the paucity of safe, adapted and affordable new medicines developed for such communicable diseases as AIDS, malaria and tuberculosis, and the lack of medicines, vaccines and diagnostics for tropical diseases or other illnesses that primarily affect the world's poorest people;

Recognizing the importance of providing support for the development of treatments for diseases that have small client populations;

Concerned about the need for appropriate, effective and safe health tools for patients living in resource-poor settings;

Mindful that more than 70% of new drug approvals are for medicines that do not provide incremental benefits over existing ones;

Considering the urgency of developing new medicines to address emerging health threats such as multidrug-resistant tuberculosis, and other poverty-related and infectious diseases;

Aware that funding for research and development for new vaccines for AIDS and other illnesses is insufficient;

Recognizing the importance of global public undertakings such as the Human Genome Project, and the increasing relevance of open and accessible public research in advancing science and the transfer of technology;

Further aware of the promise of new, open models for the development of medical science, enhanced participation in, and access to, scientific advances, and increased knowledge;

Recognizing the importance of public/private partnerships devoted to the development of new essential drugs and research tools, but concerned about the need for governments to set a needs-based priority agenda for health, and to provide political support and sustainable sources of funding for such initiatives;

Recognizing the importance of public and private investment in the development of new medical technologies;

Considering that a number of developing countries have been strengthening their capacity in new health technologies, and that their role will be increasingly critical;

Recognizing that intellectual property rights are one of several important tools to promote innovation, creativity, and the transfer of technology;

Recognizing at the same time the importance of providing for a proper balance between intellectual property rights and the public domain, and the need to implement intellectual property rules in a manner that is consistent with the basic human right to health and the promotion of follow-on innovation;

Noting that UNDP's Human Development Report 2005 states that "the WTO's Trade Related Intellectual Property Rights (TRIPS) agreement, along with 'TRIPS plus' variants in regional and bilateral agreements, strikes the wrong balance between the interests of technology holders and the wider public interest";

Taking into account Article 7 of the TRIPS agreement that points out that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations";

Stressing that the Universal Declaration of Human Rights recognizes the right to protection of interests resulting from any scientific production balanced by the right to share in scientific advancements and its benefits;

Considering that it is imperative to reconcile the public interest in accessing new knowledge, with the public interest in stimulating invention;

Concerned about the impact of high prices of medicines on access to treatment, and the need to implement intellectual property laws in a manner that reconciles incentives for development of new medicines with the need to promote access to all, consistent with paragraphs 4, 5 and 7 of the Doha Declaration on TRIPS and Public Health;

Aware of the need for a new global framework to provide adequate and sustainable levels of financial support for patient-driven research, including in particular for priority medical research;

Bearing in mind a call from 162 scientists, public health experts, law professors, economists, government officials, members of parliament, nongovernmental organizations and others for an evaluation of proposals for a new global framework on medical research and development;

Considering the global appeal on research and development on neglected diseases launched on 8 June 2005 with the support of 18 Nobel Laureates, over 2500 scientists and health experts, academics, nongovernmental organizations, public research institutes, governments officials and members of parliament, calling for new policy rules to stimulate essential research and development in health, especially for the most neglected patients;

Aware of the need to promote new thinking in the mechanisms that support innovation;

Recognizing the importance of strengthening capacity of local public institutions and businesses in developing countries to contribute to, and participate in, research and development efforts,

1. URGES Member States:

- (1) to make global health and medicines a strategic sector, to take determined action to direct priorities in research and development according to the needs of patients, especially

those in resource-poor settings, and to harness collaborative research and development initiatives involving disease-endemic countries;

(2) to take an active part, within WHO and with other international actors, in the establishment of a framework for defining global health priorities, providing support for essential medical research and development predicated on the principle of equitable sharing of the costs of research and development, and determining incentives to invest in useful research and development in the areas of patients' need and public interest;

(3) to ensure that progress in basic science and biomedicine is translated into improved, safe and affordable health products – drugs, vaccines and diagnostics – to respond to all patients' needs, especially those living in poverty, and that essential medicines are rapidly delivered to people;

2. REQUESTS the Director-General:

(1) to establish a working group of interested Member States to consider proposals to establish a global framework for supporting needs-driven research, consistent with appropriate public interest issues and taking note of the work of the WHO Commission on Intellectual Property Rights, Innovation and Public Health;

(2) to ensure that bilateral, regional and global free-trade agreements and other trade agreements do not jeopardize the flexibilities of the TRIPS agreement and are in accordance with the Doha Declaration on TRIPS and Public Health;

(3) to submit a progress report of the working group of interested Member States to the Sixtieth World Health Assembly (May 2008) and a final report with concrete proposals to the Executive Board at its 121st session (January 2009), and to suggest alternative systems for protection of intellectual property, with a view to enhancing accessibility to new medicines;

(4) to ensure that the report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health is included on the agendas of WHO's regional committees in 2006.

Dr NYIKAL (Kenya), speaking on behalf of the Member States of the African Region, noted the difficult and complex nature of the Commission's work, and welcomed the statement by its Chairman. Finding a sustainable means of meeting the health needs of poor people was of great significance to the African Region. The asymmetries of the present incentive mechanisms for research and development needed urgent redress. It was therefore disappointing that the Commission had been unable to submit its report to the current session of the Board.

Access to the products of research and innovation, including vaccines, diagnostic tools and treatments, was the key to improving the health of the people of Africa and the developing countries. Health and support for health were crucial to human development. UNDP's *Human development report 2005* highlighted the imbalance between the interests of the holders of technology and the wider public interest.¹ Unless a new framework secured access to the medicinal products of innovation, people in poor countries would continue to die. The report of the United Nations Millennium Project Task Force on HIV/AIDS, Malaria, TB, and Access to Essential Medicines had shown the inadequacy of research and development in the areas of medicines and vaccines for priority health problems in developing countries, such as the neglected diseases trypanosomiasis and leishmaniasis or second-line medicines for the treatment of malaria, tuberculosis and HIV/AIDS. There was no profit incentive for innovation and production in those areas, because the people affected could not pay for the drugs. That report had concluded that WHO had a significant role to play in supporting countries' efforts to achieve the Millennium Development Goals.

¹ UNDP, *Human development report 2005: International cooperation at a crossroads – aid, trade and security in an unequal world*. New York, UNDP, 2005.

He proposed the establishment of a global framework on essential health research and development, based on the principle of equitable sharing of costs. The draft resolution responded to growing concern at the lack of a global system for supporting innovation in new medicines and other health technologies and the increasing numbers of people unable to gain access to essential medicines.

Dr BUSS (Brazil) recalled that Brazil had been among the countries proposing the establishment of the Commission, partly because of the sheer numbers of its poor and those in other regions unable to gain access to medicines, vaccines and diagnostic tools. He echoed the disappointment at the report's delay, and expressed the hope that it would be debated at the forthcoming Health Assembly. He urged the Board to adopt the draft resolution, which had been endorsed by some of the world's most eminent scientists, including Nobel Prize laureates, in a letter that was available to members.

Dr BOTROS SHOKAI (Sudan), speaking on behalf of the Member States of the Eastern Mediterranean Region, praised the draft resolution. All countries attached great importance to the need to make global health and access to medicines a strategic sector wherever intellectual property rights were applicable. However, the reference to defining global health priorities should be replaced by a definition of the scope of public health. A working definition of public health proposed by Member States of her Region read as follows:

“Public health is the science and art of promoting, protecting and/or restoring the physical, mental and social well-being of the people through prophylactic, diagnostic, therapeutic and rehabilitative measures, applied to human beings and their environments.”

Recent developments in science and technology offered potential benefits for all countries, especially developing countries. The draft resolution should therefore propose the establishment of global medicines funds, which could be used by WHO to purchase patents of new medicines for developing countries and use in public health programmes; to contract research and development for medicines in priority areas required by developing countries; and to establish and strengthen research and development centres in those countries.

She welcomed the Commission's emphasis on accessibility of pharmaceutical and biotechnology products to developing countries. However, in seeking to strike a balance between providing incentives for the development of new medicines and the goal of affordable access to existing medicines, the Commission must not sacrifice accessibility and affordability. The existing WTO patent system was not generating any marked increase in research and development activities for diseases prevalent in the developing countries; malaria was a good example. The Commission should therefore explore both “push” mechanisms, involving financial contributions for research and development, and “pull” mechanisms, aimed at ensuring an attractive level of demand if medicines or vaccines were successfully produced. Public/private partnership could be a viable means of achieving that goal.

She expressed concern that the full report would not be discussed at the current session. The Secretariat should circulate the completed draft document to members for their consideration and comment.

Dr BRUNET (alternate to Professor Houssin, France) thanked the Chairman of the Commission for her comprehensive introductory statement. He regretted that the Commission's report was not yet available but could appreciate the difficulties that had had to be overcome in order to ensure a fruitful debate. He requested clarification about the timetable for the report's publication; it must be made available to Member States well in advance of the forthcoming Health Assembly.

Dr TÜRMEŒEN (Representative of the Director-General) said that the report would first be posted on WHO's web site and then circulated to Member States and interested parties, probably in the third

week of April, together with the other documents of the Health Assembly. As the report had been compiled by an independent expert group, Member States were not called upon to provide input.

Dr ANTEZANA ARANÍBAR (Bolivia) pointed out that the Organization had been considering the complex and important issue for more than 10 years. The objective was to provide an alternative for access to both innovation and health inputs for the most deprived countries in order to enhance quality of life. How to achieve that objective had not been resolved. Research and access to knowledge would provide hope for the future. He recognized the need for a resolution on the subject, but the Board could not recommend the adoption of the draft resolution by the Fifty-ninth World Health Assembly because it did not yet know the findings of the Commission's report. A small group consisting of representatives from each region should be established in order to examine the Commission's report immediately after its publication and report to the Board on its findings.

Dr ANDRADE GAIBOR (Ecuador) endorsed the views expressed by the members for Kenya and Brazil. Poor people required access to medicines, and pharmaceutical companies needed to invest heavily in research in order to counter drug resistance. New-generation medicines for HIV/AIDS, malaria and tuberculosis, for example, were accessible only to the lucky few. He called on pharmaceutical companies to donate their medicines and reduce their research costs.

Dr SÁ NOGUEIRA (Guinea-Bissau) said that enhancing human resources and affordable access to medicines was a major challenge. It was paradoxical that, with all the talk about poverty reduction, huge numbers of people still had no access to medicines. He expressed strong support for the draft resolution.

Mr IWABUCHI (alternate to Dr Shinozaki, Japan), acknowledging the work of the Commission, said that its report should be published as soon as possible, including the differences of perspective referred to in paragraph 4 of the Secretariat's report.¹ He asked for a peer review in the interests of objectivity and neutrality.

Protection of intellectual property rights was important for pharmaceutical innovation; the patent system would work effectively as an incentive for the development of new medicines. He emphasized that research and development of pharmaceuticals for diseases prevalent in developing countries had been undertaken through the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases and other programmes.

Mr SHUGART (Canada) said that the issues raised in the draft resolution were of great importance. Canada was committed to accelerating the search for solutions to the twin problems of affordable access to medicines and the development of new medicines of benefit to the whole world and, in particular, the poorest populations with the heaviest disease burdens. It had legislated to facilitate greater access to medicines in the poorest parts of the world and had been supportive of the work of the Commission.

The Commission should aim for consensus, but there should be transparency with respect to any divergence of views, and no undue delay in publication of the report if consensus could not be achieved. The report should point the way forward and propose innovative and viable solutions.

The draft resolution sought to put in place immediately a process to establish a global framework for improving innovation and access to medicines in developing countries. While a procedure would be needed to generate consensus and secure progress on the issue, care should be taken not to duplicate or pre-empt completion of the Commission's work, but rather, to build upon its deliberations on practicable solutions. The proposal by the member for Bolivia to expedite

¹ Document EB117/9.

proceedings was interesting. Once the Commission had completed its report, the Secretariat might wish to establish a group to formulate a draft resolution that could command consensus.

Professor PEREIRA MIGUEL (Portugal), speaking on behalf of the European Community and its Member States, recognized the importance of the highly complex issue set out in the draft resolution. The text, however, needed significant further work. The Member States of the European Union were concerned how best to respond to the important research and development questions identified, and regarded trade and related intellectual property rights as significant issues. Further reflection would be required once the Commission's report was available. A procedure such as the one proposed by the member for Bolivia, to build on the report with a view to achieving consensus, was desirable.

Dr HANSEN-KOENIG (Luxembourg) said that the complex and sensitive subject was of fundamental importance. She regretted that the Commission's report was not yet available, but a delay of a few weeks was understandable given the complexity of the issues. The work of the Commission should result in concrete solutions and a more action-oriented discussion. More sustainable access to medicines and innovation for all, particularly the poor, should be promoted.

She welcomed the draft resolution and hoped that a resolution could be approved by the Fifty-ninth World Health Assembly. Luxembourg supported previous speakers in their desire to discuss and take into account the findings of the Commission's report.

Dr VIROJ TANGCHAROENSATHIEN (alternate to Dr Suwit Wibulpolprasert, Thailand) acknowledged the hard work of the Commission. Welcoming the draft resolution, he noted that nine years remained in which to achieve the Millennium Development Goals. Public health interventions were no less important than social mobilization and closing the divide between the developed and the developing countries. The stakes were high; unless urgent action was taken, the Goals might not be achievable by the least developed countries, especially those in Africa and south Asia. Some members' fears that the current text of the draft resolution might not command consensus was understandable, but he urged the Board to recommend a draft resolution, taking account of the findings of the Commission's report, to the Fifty-ninth World Health Assembly for adoption. Failing that, the matter might drag on for several more years. Accordingly, he supported the proposal by the member for Bolivia for a small group to be convened and inform the Board of its findings.

Dr SINGAY (Bhutan) was encouraged that the Commission was focusing on the health needs and diseases of poor people, including access to innovative products. Intellectual property rights and public health had been discussed at the 23rd Meeting of Ministers of Health of Member States of the WHO South-East Asia Region (Colombo, 4-5 September 2005). The need to put patients before patents and to create a health space in trade negotiations had been stressed and agreed. Bhutan welcomed and supported in principle the draft resolution. As concerns and differences of view had been expressed, he supported the proposal to convene a small group to discuss those concerns and formulate a balanced draft resolution for submission to the forthcoming Health Assembly.

Dr TANGI (Tonga) endorsed the comments by the member for Canada on consensus. He looked forward to receiving the Commission's report and supported the proposal by the member for Bolivia. More time was needed for the Board to review and assimilate the report before the Fifty-ninth World Health Assembly. Deeper consideration should be given so that eventually the poor would have access to good quality medicine. That was indeed an exalted dream and difficult to fulfil.

Ms HALTON (Australia) acknowledged the complex and sensitive work of the Commission. Incentives to ensure continued access to new and innovative medicines were important, as was ensuring affordable access to medicines, and a proper balance between those two issues was essential.

It was necessary to progress. Such action, however, must be based on work already done and careful consideration of the report itself. It was particularly important to ensure transparency and that the divergence of views was clearly understood.

For the report to be available for the forthcoming Health Assembly, the timetable would have to be carefully managed. The Board needed the advice of the Secretariat on how its views should be transmitted to the Health Assembly for consideration.

Dr WINT (Jamaica) emphasized the urgency of taking action that would also contribute to progress towards achieving the Millennium Development Goals. The establishment of guidelines for research and development was critical, as was ensuring access to and affordability of products.

He endorsed the proposal by the member for Bolivia on the understanding that the Health Assembly should seek to resolve the issue in May 2006. The terms of reference for the group should include refinement of the draft resolution. As the Director-General would be unable to carry out the requests in the draft resolution without WTO, the Board should, in working out its strategy, find a way of involving that organization, both through national representatives and through the linkage between WHO and WTO.

Dr MIHAI (adviser to Dr Iliescu, Romania) emphasized the need for an accurate, dispassionate and transparent report. The matter must be resolved properly, and more time might therefore be needed.

Dr PHOOKO (Lesotho) recalled appeals for urgent action on several issues at the current session of the Board, including achievement of the Millennium Development Goals by developing countries, particularly in Africa, and reinforcement of their health systems, with a particular focus on human resources. Given the urgency for the developing countries of the issue under discussion, he supported the draft resolution, as it set out a framework for progress towards the availability of medicines in poor communities. He endorsed the proposal to establish a small group to examine the Commission's report and to brief the Board in a timely manner, and supported the proposal for the establishment of an informal group to work on the draft resolution.

Ms 't HOEN (Consumers International), speaking at the invitation of the CHAIRMAN, said that her statement was supported by *Médecins Sans Frontières* – Campaign for Access to Essential Medicines, Health Action International, Medico International, Third World Network and CPTech. Those bodies strongly supported the draft resolution, and particularly the timely and important proposal in paragraph 2(1) regarding the establishment of a global framework for supporting essential health research. Innovation was important for improving health care but had to meet real health needs and would be meaningless unless the results were accessible to all in need. The draft resolution offered a radically new way of looking at innovation by creating a forum for discussions among countries on the setting of priorities for and sharing the cost of research and development.

Except for discussions within the G8 group of countries, no existing agreement on trade, drug-pricing or intellectual property rules covered public-sector support for or market failures in research and development, such as for neglected diseases or the Human Genome Project. A balanced global framework for research and development was needed, with a mechanism that encouraged work in priority areas in order to ensure the development of essential medicines while allowing governments to protect consumers from high prices and access barriers. Recent examples had shown how political will could ensure international cooperation and the marshalling of tremendous resources. Unfortunately, the sense of urgency that had resulted in swift and efficient responses to the outbreak of severe acute respiratory syndrome and the potential avian influenza pandemic was entirely lacking with respect to research and development for diseases that predominantly affected poor people in developing countries.

WHO was well placed to host and encourage discussions on a new global framework that would ensure that essential health tools were developed and made available to all; adopting the draft resolution would be a major, first step in that process.

Sir John SULSTON (OXFAM), speaking at the invitation of the CHAIRMAN, fully supported the comments made by the previous speaker. He read an open letter to the Board, signed by more than 200 well known scientists, expressing their support for the draft resolution. They were concerned at the deficiencies in the translation of biomedical research results into treatments to improve health outcomes, particularly the lack of sustainable support for the research and development of medicines for neglected diseases, and deeply concerned by the inability of existing mechanisms to convert the huge progress in basic research science into a global improvement in public health. Legal restrictions such as intellectual property rights could interfere with data exchange and limit biomedical research progress, and the balance between medical need and resource allocation was not good. The draft resolution dealt with those issues in a balanced way and proposed long-term solutions for sustainable funding, prioritization and access, and deserved the Board's full support.

Dr BALE (International Federation of Pharmaceutical Manufacturers and Associations), speaking at the invitation of the CHAIRMAN, said that everyone shared the goals mentioned by the previous speaker. The question was whether the intellectual property system generated what was needed across the world. He recalled that 28 avian influenza vaccine projects were being given priority by companies on the Influenza Vaccine Supply International Task Force, and the International Federation welcomed the close collaboration with WHO in that regard. Research was also continuing on medicines and vaccines to combat other diseases. For HIV/AIDS, 20 antiretroviral agents had been developed and there had been substantial investment in the development of 80 new medicines, including vaccines. For rotaviral disease, which killed around 500 000 children every year in developing countries, two new vaccines had been launched. Two new vaccines had been developed against human papillomavirus infection which caused cervical cancer (most of the disease burden of which was in the developing world), and vaccines were being developed against malaria, Ebola haemorrhagic fever and other tropical diseases. At least five public-private partnerships existed for the development of innovative antimalarial agents (including the Medicines For Malaria Venture), three for tuberculosis (through the Global Alliance for TB Drug Development) and four targeting African human trypanosomiasis, leishmaniasis and Chagas disease. The industry had developed almost 90% of the medicines on WHO's Essential Medicines List. It had also established major research and development laboratories in India, Singapore and Spain to develop new medicines for dengue fever, malaria, tuberculosis and other tropical diseases. The International Federation had presented its ideas for encouraging such partnerships to the WHO Commission. In addition, member companies were collaborating with WHO and other partners to limit or eradicate a variety of tropical diseases.

A comprehensive survey in 2005 of member companies' programmes in developing countries had shown that the industry had made available some 539 million health interventions since the adoption of the Millennium Development Goals in 2000, and access to antiretroviral agents was continuing to expand, with some 500 000 AIDS patients in developing countries currently receiving treatment.

The key element in all those activities was innovation protected by intellectual property rights. Such rights were essential. Patents and other elements of intellectual property encouraged the pharmaceutical companies, including a fast-growing number in countries such as China, India, Mexico and Singapore, to undertake research and to engage in partnerships with developing countries. Countries seeking to acquire technology also needed intellectual property protection, for example for patent licensing and clinical trials. That protection was just as important in relation to transfers of technology and knowledge from developing to industrialized countries as for the reverse. Intellectual property was the foundation of the global effort to develop new medicines and vaccines to combat viral pandemics, for the expansion of health care and for the spread of technological know-how around the world.

Dr NYIKAL (Kenya) pointed out that the Commission's report and the draft resolution were not mutually exclusive. Both should be submitted to the Fifty-ninth World Health Assembly. The two should proceed at the same time synergistically. The Board should be able to reach a decision on the draft resolution at the current session. There was still room for further input at the Health Assembly and into the Commission's report. Currently, no conclusions could be drawn about the content of that report and it might therefore not be appropriate to set up a sequential process. It was surely preferable to move forward in both areas with a working group on the report and a drafting group on the resolution and to bring the two together in due course, or the sense of urgency might be lost. The draft resolution called for the establishment of a global framework on essential health research and development by interested Member States. Nobody was excluded. Similarly the information from the Commission's report was not excluded. The significant work in preparing the draft resolution and by the Commission must not be lost.

Mr AITKEN (Director, Office of the Director-General) said that, after informal consultations, it had been suggested that, given the support expressed, efforts should be made to make progress on the draft resolution at the current session. To that end, further informal consultations should be held following the present meeting, to be chaired by the Vice-Chairman, Dr Shangula. It had also been suggested that the working group proposed by the member for Bolivia should essentially consist of 12 Board members, two from each WHO region, but be open to all interested Member States, and should be convened in Geneva following publication of the Commission's report. With the help of the Chairman of the Commission, the Secretariat would prepare a draft resolution on the report, which might also be considered by the working group, whose comments would then be forwarded to the Health Assembly. It would be difficult to make any further decisions regarding the draft resolution currently before the Board until after the proposed informal consultations. Should outstanding work on the resolution remain following the conclusion of the current session, the working group might possibly also be requested to take that forward.

Dr NYIKAL (Kenya) asked for further information on the possible interval between the meeting of the proposed working group and the Health Assembly. It might not be appropriate to anticipate the content of the Commission's report by suggesting that a separate resolution on the report should be prepared, while also suggesting that the current draft resolution would be reviewed in the light of the report.

Mr AITKEN (Director, Office of the Director-General) confirmed that the Commission's report was expected to be available by mid-April 2006. The Health Assembly would start on 22 May 2006. The working group would therefore need to meet towards the end of April 2006.

Mr ALCÁZAR (alternate to Dr Buss, Brazil), endorsing the remarks made by the member for Kenya, said that during the earlier discussions no objection to the draft resolution had been raised. Indeed, the member for Thailand had appealed for urgent action. The procedural problems would not have arisen had the Commission's report been available at the current session. There was no time for further delays and the Board should take a decision on the draft resolution before it.

Dr VIROJ TANGCHAROENSATHIEN (alternate to Dr Suwit Wibulpolprasert, Thailand) welcomed the proposal to consider the draft resolution further at informal consultations. However, careful consideration should be given to the proposal to establish a working group to consider the Commission's report and a draft resolution to be prepared by the Secretariat. If the draft resolution before the Board was adopted at the present session, then the second resolution would need to take that into account. Would a second resolution really be necessary? The Board should send a clear signal of its views to the Health Assembly with no possibility of contradiction, which two separate resolutions might introduce.

Mr SILBERSCHMIDT (Switzerland)¹ affirmed the consensus that the Fifty-ninth World Health Assembly ought to adopt a broad and strong resolution; the question was how to attain that goal. The draft resolution currently before the Board undoubtedly covered some of the same ground as the Commission's report would but it could not anticipate that report, in the light of which its text would need to be reviewed. He therefore endorsed the proposal to submit two draft resolutions to the Health Assembly.

Ms DREIFUSS (Chairman, Commission on Intellectual Property Rights, Innovation and Public Health) apologized for the delay in the publication of the Commission's report, and the ensuing procedural difficulties. She assured the Board that its sense of urgency was shared by the members of the Commission. The main difficulty was how to achieve a balance between the requirements of innovation, no longer only but still mostly in the industrialized countries, and the needs, in particular those relating to public health, of underprivileged populations in the developing countries. Several speakers had emphasized the need for a range of measures, not just relating to intellectual property rights. Organization of health systems to ensure delivery was as important as promotion of research and development. The report would therefore try to show the range of activities needed to promote innovation that was strategically directed towards the control of previously neglected diseases or to patients in populations that did not have access to the medicines, vaccines and diagnostic agents that were currently available. A second aim was to provide guidance to Member States, the Secretariat, and other international organizations, such as WIPO and WTO, in respect of the decisions they must take. Decisions might of course differ, depending on the governments and conditions concerned. The Commission could not dictate what those decisions should be but it could set out the elements that must be taken into account in order to take sound decisions and bring closer together those with responsibilities for trade and health. That was very much in line with the resolution on international trade and health adopted by the Board at its sixth meeting.²

Referring to the comments made by the members for Canada and Japan, she endorsed the view that it was pointless to waste time trying to achieve consensus when that outcome was unlikely. It was better to set out the disagreements clearly, and to that end the Commission had made great efforts to indicate the points in favour of or against the various positions, crystallizing the points of divergence. That did not mean that the members of the Commission would step back to their original divergent positions; the progress made in achieving convergence would not be lost, but the points where consensus had not been reached would be expressed transparently. The 10 members of the Commission had worked with good will for two years in trying to reach a common view. The areas in which that had not been possible would stand out clearly in the report.

In respect of timing, she suggested that, as soon as it had been finalized, the English version of the report should be made available on the Commission's web site. The other language versions would become available subsequently during April 2006.

The CHAIRMAN suggested that further consideration of the item should be deferred pending the outcome of informal consultations.

It was so agreed.

(For continuation of the discussion, see summary record of the eighth meeting, section 3.)

¹ Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

² Resolution EB117.R5.

WHO's role and responsibilities in health research: Item 4.12 of the Agenda (Documents EB117/14 and EB117/14 Add.1)

Dr NYIKAL (Kenya), speaking on behalf of the African group of countries, underlined the vital importance of health research in promoting health, preventing disease and clinical care. As Member States were in various stages of development, recommendations needed to be broad enough to cover the needs of all. Global research had underpinned the health revolution of the twentieth century, but developing countries had not benefited from those advances to the extent possible. Only 10% of financing for global health research was allocated to health problems that affected 90% of the world's population. In Africa, research into health systems had received least attention. Even in areas where much research had been done, there remained a gap between the knowledge generated and its application. It was crucial that WHO addressed those two issues.

He supported the draft resolution in document EB117/14 but proposed a new subparagraph 3(7), to read: "to assist Member States to develop capacity for health systems research".

Dr OROOJ (alternate to Mr Khan, Pakistan), speaking on behalf of the Member States of the Eastern Mediterranean Region, urged WHO to earmark sustainable resources to enable developing countries to undertake essential health research and to ensure the appropriate use and dissemination of research findings. He also stressed the need for WHO to foster health research networks and interaction between developed and developing countries, and to engage with public sectors other than health and education to promote national health research agendas. Since many interventions failed in developing countries, WHO's research agenda should also evaluate the major disease-control and prevention programmes and initiatives in order to gain a better understanding of the implementation problems in developing countries. The research agenda should aim to contribute to attaining the Millennium Development Goals and should strengthen the capacity of health systems, as recommended by the Ministerial Summit on Health Research (Mexico City, 16-20 November 2004).

Dr VIROJ TANGCHAROENSATHIEN (alternate to Dr Suwit Wibulpolprasert, Thailand) supported the draft resolution. As health research should also pursue the issues of poverty and inequality in health in order to amend policies, he proposed the insertion of a new preambular paragraph after the third that would read: "Recognizing that research into poverty and inequity in health is limited, and its important role in guiding policy to minimize the gap". He also suggested that, as some countries had already begun to allocate part of their health budgets to research, in paragraph 1(1) the words "to implement" should be replaced by "to accelerate the implementation of". In paragraph 2, he proposed the insertion after "medical research" of a comma and the words "especially research into poverty and inequity in health".

Mr GUNNARSSON (Iceland) welcomed the request in the draft resolution that the Director-General should review how and to what extent it based its major policy decisions and recommendations on research evidence. Since time constraints had not allowed WHO's partners to become properly involved in the drafting of the position paper referred to in the Secretariat's report, he asked for a review of that paper, in conjunction with WHO's country and regional offices and partners such as governments, bilateral donor agencies, foundations and nongovernmental organizations. The revised paper should be issued well in advance of the Fifty-ninth World Health Assembly in order to enable informed discussions to take place. Conducting the consultations electronically would save time and money.

The meeting rose at 12:30.