# Report of the Commission on Intellectual Property Rights, Innovation and Public Health: a call to governments

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The Commission on Intellectual Property, Innovation and Public Health (CIPIH) was given the task of reviewing existing research and development (R&D) efforts, examining the role of intellectual property (IP) in stimulating innovation, and to make concrete proposals for action by national and international stakeholders, both public and private, to encourage R&D for diseases that disproportionately affect developing countries. The Commission focussed exclusively on the application of IP to pharmaceuticals, and did not address the public health implications of copyright law, or genomic patents, which are covered elsewhere in this issue.

The report[1] presents a wealth of evidence and analysis in support of the view that the current system of drug development is fundamentally flawed and leaves huge health needs unmet, because of its reliance on patents and commercial incentives for the priority-setting and financing of medical R&D. The report calls for improved mechanisms that promote research that responds to patients' needs, and that ensure access to innovations for all. However, it fails to provide alternatives and concrete new proposals.

Many of the data presented in the report illustrate the urgent need for change. I will discuss some of the Commission's more salient conclusions, on intellectual property rights, international trade, access to medicines, and global frameworks.

## Intellectual property rights

The report recognizes that IP is a means and not an end. It concludes that IP is irrelevant in stimulating innovation in developing countries where markets have limited purchasing power, confirming the same finding by the UK Commission on Intellectual Property Rights in September 2002.[2] The report says: "There is no evidence that the implementation of the TRIPS Agreement in developing countries will significantly boost R&D in pharmaceuticals on Type II and particularly Type III diseases. Insufficient market incentives are the decisive factor."[1]

The report also points out that even in regions with strong IP protection, innovation results are declining. In the USA for example, medical R&D spending has doubled between 1995 and 2002, while in the same period, the registration of new products has declined, as well as the therapeutic significance of products reaching the market. In other words, although worldwide patent standards have been strengthened since 1995 as a result of the TRIPS Agreement, and global spending on medical R&D has increased, pharmaceutical innovation has declined both in quantity and quality.

Furthermore, the report draws attention to the fact that patents can actually hamper innovation, by blocking follow-on research or access to research tools. The CIPIH identifies patent pools, compulsory licensing, and the application for research exemptions as potential solutions to overcome barriers caused by patenting.

## International trade and competition

The report warns against trade agreements that include so-called "TRIPS-plus" measures. The Commission concludes: "Bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries." (Recommendation 4.21).[1]

"Data exclusivity" is one example of a TRIPS-plus provision often included in bilateral trade agreements with the US. The report offers much awaited clarity on issues related to the protection of data submitted by companies to obtain marketing approval for new medicines. WTO Members are obliged to protect undisclosed test or other data against unfair commercial use. But this does not imply property rights, nor a right to prevent others from using the data, or from relying on the data for the marketing approval of the same product by a third party — except where unfair, dishonest commercial practices are involved.

Developing countries have been pressured during bilateral talks to accept TRIPS-plus provisions including data exclusivity rules that would delay the introduction of generic medicines.

The Commission's analysis here may help, but it is doubtful whether it will be enough. Médecins sans Frontières (MSF) regrets that the Commission fails to support the call for an international moratorium on TRIPS-plus provisions in bilateral and regional trade agreements that may hamper access to medicines. Nor does the report suggest a role for WHO on this issue.

## Access to medicines

The Commission analyses the medical innovation cycle according to three components: discovery, development, and delivery. The report stresses that innovation is only meaningful when people can have access to the results of the innovation. This is obviously not the case when new drugs are priced out of reach of the people who need them.

The report recommends that governments should create competitive environments in their countries, as competition is the key means of driving prices down and improving access to medicines. Yet the TRIPS Agreement — implemented worldwide in 2005 — was designed precisely to impede countries from doing so. Second-line acquired immunodeficiency syndrome (AIDS) medicines illustrate the consequences of such protectionism. These new antiretrovirals are priced far beyond the reach of the people, as they are mostly available from the patent holder only — if at all — in the countries that need them most.

In response to such dilemmas, the report recommends the use of compulsory licensing to increase generic competition and ensure access to more affordable products. It also calls on companies

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to work towards reducing prices. This appeal is not new. MSF has collected the evidence to show that companies are immune to such pleas when there is no generic competition to convince them otherwise.[3] The call for equitable pricing is unlikely to be more than wishful thinking, unless countries develop the ability to make it happen.

## Global plans and global frameworks

The Commission recommends that WHO develop a global plan of action to secure enhanced and sustainable funding for developing affordable and accessible products that address diseases that disproportionately affect developing countries. It urges WHO to continue monitoring from a public health point of view the impact of IP on the development of new products, as well as on access to medicines. It calls for action to ensure that health technologies are adapted to needs of people in developing countries, and draws attention to the fact that innovation and access are key in tackling both communicable and noncommunicable diseases. Recommendation 4.5, for example, reads: "Policies for biomedical innovation must take account of the fact that health systems in many developing countries remain resource-constrained. Policies must emphasize affordable innovations adapted to the realities of health-care delivery in developing countries, and covering appropriate technologies for the diagnosis, prevention and treatment of both communicable and noncommunicable diseases. Mechanisms for promoting such adaptive research in a systematic way must be improved."[1]

MSF agrees with this point, but the billion-dollar question remains: how can this be achieved? What should these "mechanisms" look like?

During the forthcoming World Health Assembly (22–26 May 2006), a resolution proposed by Kenya and Brazil will be debated. It calls for the establishment of a Global Framework on Essential Health R&D. This resolution asks WHO to facilitate talks between interested governments to establish new international mechanisms that ensure needs-driven medical R&D that delivers products that are affordable and accessible.

This offers a unique and timely opportunity to build on the CIPIH's work. In the words of the sponsors of the resolution: "This resolution is a response to a growing concern over the inadequacy of the current global system for supporting innovation in new medicines and other health technologies, as well as concern about the impact of an increasing percentage of people without access to essential medicines and other technologies for health care, both in terms of their financial affordability and availability.

The resolution seeks the establishment of a global framework for supporting essential medical research and development predicated upon the principle of equitable sharing of the costs of research and development, and incentives to invest in useful research and development in the areas of patients' need and public interest. The process to carry this forward include the creation of a working group of interested Member States … . As the lead global agency on health needs, WHO plays a crucial role in priority setting and the development of policy recommendations on how priority research can be carried out."[4]

One way of ensuring that priority research gets done is through a medical R&D treaty. Here, the CIPIH report says: "Recognizing the need for an international mechanism to increase global coordination and funding of medical R&D, the sponsors of the medical R&D treaty proposal should undertake further work to develop these ideas so that governments and policy makers may make an informed decision." WHO is well-placed to take up this recommendation, and the next World Health Assembly offers an opportunity to do so.

## Conclusions

The report contains a thorough analysis on the shortcomings of the current system for R&D. Dramatic change in the way health R&D is approached is long overdue.

However, the Commission's recommendations are somewhat disappointing. Although many are appropriate, they lack teeth, or novelty.[2,5] I am left with the impression that the Commission got stuck tinkering in the margins of a fundamentally flawed system, lacking the courage — or the power — to propose bold changes. This may be a reflection of the constitution of the Commission and the strong pressure exerted upon it by the pharmaceutical industry.[6]

That the TRIPS Agreement is today's predominant international model for encouraging innovation is not questioned anywhere. Instead the Commission appeals to the pharmaceutical industry to avoid filing or enforcing patents in low-income countries, and to grant voluntary licences. This is a somewhat naive recommendation in the light of the fact that the same industry has invested three decades of intense lobbying for the establishment of the TRIPS Agreement. As soon as the CIPIH report was published, the International Federation of Pharmaceutical Manufacturers' Association issued a statement on behalf of the industry rejecting any calls for weakening of IP systems.[7]

Nevertheless, one message comes through loud and clear from the CIPIH, and that is the need for governments to play a more proactive role to ensure health R&D meets real needs, and that products are available and accessible. Countries should not passively assume that recent partnerships devoted to the development of drugs — no matter how promising some of these initiatives look — constitute a sufficient response. Instead, the Commission urges governments to provide stronger commitments and sustained efforts to address the research gaps identified in this report. The report also recommends that governments prioritize health care, and ensure that pricing is consistent with their public health policies. In the words of the Commission "Access to drugs cannot depend on the decisions of private companies but is also a government responsibility".[1]

The health ministers who meet in May at the World Health Assembly to discuss the CIPIH report can do just this. This report deserves a strong debate, and follow-up action. Médecins Sans Frontières urges governments to take up this challenge, and fulfil what the Commission is right in calling a "moral imperative". ■

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