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The Swiss Federal Institute of Intellectual Property (IPI) would like to thank the Commission on Intellectual Property Rights, Innovation and Public Health (the Commission) for submitting to the public its Framework Paper of July 2004. It takes note that the following questions are to be answered:

Question 1: What is the most important aspect of the Commission's work?
Question 2: Should more attention be given to some issues than others?
Question 3: Are there important issues omitted?
Question 4: Are there particular pieces of evidence that should be drawn to the Commission's attention?

The Institute would like to make the following remarks:

Ad question 1: What is the most important aspect of the Commission's work?

Generally, the tasks mentioned under point 2. of the Framework Paper are well identified. Of the subjects identified by the Commission, probably the most important aspect on which the Commission should focus is that of **neglected diseases**. The reasons are the following:

1) The patent system has proved to be a system that provides incentives for R&D where there is a market for a given product. For diseases for which there is no sufficient market, in purely economic terms, (i.e. no buyer) in the view of the researcher, developer and producer, there is a need for another stimulation than the one provided by the patent (in particular exclusivity). This is in particular the case for neglected diseases. However, it has to be made clear that the solution to be looked for ought to be a complement to the patent system, and not a replacement. A good solution is one that provides new stimuli for R&D in neglected diseases, without reducing the incentive for R&D in other diseases or fields of technology.

2) In the international discussion about improving access to medicines in developing countries over the last couple of years, the role of patents has been controversial. Irrespective of whether this role has been overstated or not, considerable effort and progress has been undertaken to clarify and confirm existing flexibility in the international intellectual property - and in particular patent - system. The World Trade Organization (WTO) members have acknowledged a great amount of flexibilities in the TRIPS agreement (extended transition periods for least developed countries (LDCs) until 2016, parallel imports, use of compulsory licenses) in the Doha Ministerial Declaration on TRIPS and Public Health of 14 November 2001. Through the Decision on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, dated 30 August 2003, WTO members have extended the use of compulsory licenses, at certain conditions, to the export of patented pharmaceutical products to countries lacking manufacturing capacities in the pharmaceutical sector. It now belongs to the member States who wish to implement these flexibilities to do so. Experiments have to be made before any new assessment of the situation can be made and lead to an adaptation of the system (in whatever direction). Accordingly, it would be very useful if the Commission could direct its efforts on proposing solutions to the more acute and unresolved problems neglected diseases pose.

3) A thorough analysis of the link between intellectual property rights and development, including public health, has been made by the UK Commission on Intellectual Property Rights. Duplication of work should be avoided, and efforts should concentrate on issues for which no solution has yet been found or implemented.

4) At this day, it is generally recognized that there still is insufficient R&D for neglected diseases. Although one explanation may be the lack of commercial interest, reasons for this lack have to be identified in order to find the right solution. This has not, or not sufficiently been done until now. It would be extremely useful if the Commission concentrated on this aspect of public health. In order to do so, an analysis could also be undertaken on the existing R&D that is presently done on such diseases, be it by public institutes (such as the Swiss Tropical Institute, http://www.sti.ch/index.htm), universities or the private sector. Existing stimuli should in a first step be identified; in a second phase, the way to improve those stimuli should be examined; in a third phase, new ways of stimulating R&D for neglected diseases could be put forward.

Hence, a great contribution could be made to the improvement of the public health situation of developing countries by the Commission if new ways of stimulating R&D for neglected diseases could be identified.

Ad question 2: Should more attention be given to some issues than others?

A special attention should also be given to analyzing the reasons of high costs of R&D, and to finding ways to reduce those costs (see points 7- 10 of the Framework Paper). Please also refer to the answer to question 1.

Ad question 3: Are there important issues omitted?

The categorization of countries between "industrialized", "developing" and "least developed" ones is constantly used. One can however question whether, in particular for public health issues, the category of "developing countries" is adequate. Some developing countries lack pharmaceutical manufacturing capacities, whereas others have such a strong capacity in that field, that the issue of production and distribution of pharmaceutical products (both national and international) becomes subject of important commercial considerations. The interests of such emerging countries are quite different than those from countries having a lower level of economic development and that face public health crises without being able to cope with it on their own. A solution to this problem could be found in differentiating between so-called “emerging economy” countries and poor, economically less developed countries. This issue should be addressed by the Commission.

A second important issue that does not appear in the Framework Paper is that of the role of competition authorities in developing countries. Developing countries often lack a competition system. However, such a system could be very useful to prevent anti-competitive behaviors (in particular abuse of a dominant position, possibly cartels), and could have a lowering effect on prices. An analysis of the situation in developing countries should be made (which countries have a competition authority? which do not? if such an authority exists, which are its competences? how should they be enhanced?). A catalogue of competition law instruments that would help avoid abuses of dominant positions and cartels, which may result in preventing the proper distribution of, and access to medicines would prove useful. Competition law is an important issue which has been neglected in this context in the past years.

Finally, the question of public health also covers the question of compliance. It is often said that better compliance could avoid, or slow down, the development of resistance to diseases. As a result, the resources for R&D for new active ingredients could be directed at fighting new diseases or diseases to which so far no remedy exists, rather than at new active ingredients to overcome resistance against drugs already developed.

Ad question 4: Are there particular pieces of evidence that should be drawn to the Commission's attention?

Yes. There are in particular several OECD documents dealing with the issue of intellectual property rights and developing countries, in particular:

- OECD Doc TD/TC/WP(2004)31, Working party of the Trade Committee: "International Licensing and the Strengthening of Intellectual Property Rights in Developing Countries", Paris 21-22 June 2004

- OECD: "Patents and Innovation: Trends an Policy Challenges", Paris 2004

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The Swiss Federal Institute of Intellectual Property looks forward to the further work of the Commission on Intellectual Property Rights, Innovation and Public Health. In particular, it hopes that practical proposals shall be made in the above-mentioned matters. Proposed instruments, while raising the level of R&D for neglected diseases, should not to reduce the incentive for R&D which is currently done.