Comments on the CIPIH Report

Prepared by the Commission on Intellectual Property

Submission to the World Health Organisation's Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)

In April 2006, the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) published its report, as originally mandated by a resolution passed at the May 2003 World Health Assembly. During the preparation of the report, ICC contributed papers and comments to the CIPIH to assist in its thinking on the extent to which patenting so-called "incremental innovation" assists development, and in particular access to medicines in the developing world – (see document no.450/2001 dated 27 May 2005).

Though the CIPIH report contains a great number of valid recommendations, ICC is disappointed by the way in which incremental innovation has ultimately been addressed in the CIPIH's report. The purpose of this paper is to highlight ICC views on this important topic.

ICC's submission

Early on, ICC concluded that the best way to assist CIPIH in its work would be to focus on one key issue, rather than seeking to address all of the issues falling within CIPIH's remit. It considered the issue of "incremental innovation" to be critical, and therefore focussed on this topic. As explained below in its May 2005 submission, ICC considers this issue to go to the very heart of the way in which the patent system operates.

> *"ICC firmly believes that maintaining intellectual property protection for innovation, including so-called "incremental innovation", assists development, and in particular access to medicines in the developing world".*

At a meeting with the CIPIH in March 2005 in Brussels, ICC urged members of the Commission to support its view that proper patent protection should continue to be available for all forms of innovation which satisfy internationally-agreed patentability standards, including those referred to (wrongly in its view) as "incremental".

In addition to discussing this issue as a matter of principle, ICC also gave a number of examples of ways in which patents for what may appear to be relatively minor developments had in fact benefited poor sick people. ICC knows that members of CIPIH were and are aware of many other examples.

International Chamber of Commerce
38, Cours Albert 1er, 75008 Paris, France
Telephone +33 1 49 53 28 28 Fax +33 1 49 53 28 59
Web site www.iccwbo.org E-mail icc@iccwbo.org

CIPIH Report

As Commission Member Professor Hiroko Yamane indicates in her full dissenting opinion, the CIPIH Report recognizes that intellectual property rights provide some potential benefits to both developed and developing countries . However, the CIPIH Report takes a generally negative tone on the strong protection of intellectual property rights in developing countries, while basing its argumentation on US-centric debates that bear little relevance to the situation that can be found in developing countries. For example, rather than providing some of the examples of incremental innovation and how developing country innovators would actually benefit from a better protection of their intellectual property, the CIPIH focuses the discussion on the so-called "ever-greening" issue, which is a US-specific issue that was amply discussed and dealt with in the US.

As regards the specific issue of incremental innovation, ICC fundamentally disagrees with much of the commentary on pages 148-152 of the Report. In particular, ICC disagrees with the recommendation on this point, which reads as follows (from page 152):

> *"4.27 Governments should take action to avoid barriers to legitimate competition by considering developing guidelines for patent examiners on how properly to implement patentability criteria, and if appropriate, consider changes to national patent legislation".*

This recommendation, read in the light of the preceding commentary, implies that countries should impose a particularly high level of inventiveness for "incremental innovations" in the pharmaceutical sector. Neither the inventive step requirement, not the other basic criteria, make any distinction between the different types of innovation – for example between "incremental" and "discrete", or between "me too" and "breakthrough" innovations. As with any innovation, in whatever sector, all of these have to be judged against the same basic rules, and that, in ICC's view, is entirely appropriate.

Patent legislation does not need to be changed in this regard as present systems fully permit patentability criteria to be assessed. The universal criteria of patentability are novelty, non-obviousness and industrial utility. It is inappropriate to try to distinguish inventions which should have higher or different standards of patentability.

Current legal systems already subject patent applications to a rigorous review system and enables third parties to challenge the validity of patents after they have been granted. If inventions fail to meet the fundamental criteria set out above, patents should not be granted for them; and where patents have been wrongly granted in any field (and this issue is certainly not limited to pharmaceuticals), courts should (and have) corrected these errors. That is the reason for having systems which enable third parties to challenge the validity of patents after they have been granted. The fact that the complexity of the subject matter of patent rights creates some level of uncertainty does not justify wholesale changes to the patent system, as suggested by the CIPIH.

ICC would also like to point out that the argument that patents on "incremental" innovation" prohibits access to a product is often not valid because, in many cases in the pharmaceutical area, the "original innovation" is already off-patent and in the public domain. Access to many important therapeutic treatments is therefore not barred by patents on "incremental innovations" building on these as the original invention will be in the public domain.

ICC has specific concerns about the description in the CIPIH Report of the way in which the 2005 Patent Act in India sought to comply with India's TRIPS agreement obligations (see reference on pages 151-152). It accurately quotes the qualification included in the relevant section of that Act, and the "Explanation" given of its intended meaning. The Report fails however to point out that this was a highly controversial issue, and that it is still an open question as to whether the wording chosen for this provision of the Indian Patent Act in fact conforms with the relevant provisions of TRIPS. It would, in ICC's view, have been far more appropriate for the CIPIH Report to quote from the laws of a country which has unequivocally complied with the TRIPS obligations - such as the US or the signatory states to the European Patent Convention.

Context

In its introduction, the Report indicates that the Commission, early on its deliberations, decided to look into issues of a much broader nature than those in its original mandate. However, as a result of this broader ambit, the fundamental IP-related issues were given less attention than they deserve. For example, the issue of so-called incremental innovation, which, as said earlier, goes to the heart of the patent system, only received scant attention, being addressed in only a few of the Report's 228 pages (and ultimately was portrayed in a negative light). The fact that it is also one of the key issues addressed in the dissenting opinions of individual Commission members suggest that a number of the Commission members share ICC's concerns on this issue.

ICC hopes that these comments will be taken into account and considered helpful in the future handling of the CIPIH Report and its recommendations, as well as in the context of discussions in the WHO and elsewhere on the impact of patents on public health policy.

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