

# Report of the Commission on Intellectual Property Rights, Innovation and Public Health: an industry perspective

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The report issued by WHO's Commission on Intellectual Property, Innovation, and Public Health<sup>1</sup> (CIPIH) makes a number of positive recommendations for improving health in developing countries. However, the report understates the value of intellectual property rights for promoting public health and overstates the importance of intellectual property in affecting access to health care. Indeed, the report favours compulsory licensing as a method for improving access to medicines, which is not justified by the evidence available. The mixed recommendations of the report reflect the fact that there was no consensus among the Commissioners regarding intellectual property issues.

## Constructive proposals

The report recognizes the important contributions of the research and development (R&D)-based pharmaceutical industry to the health needs of developing countries, including those made by public-private partnerships focusing on tropical diseases.

One constructive recommendation made in the report is the elimination of tariffs and taxes on health-care products (Recommendation 4.12). Several studies, including one commissioned by the CIPIH, show that tariffs and taxes on medicines and other health-care products raise costs for consumers,<sup>2-4</sup> yet the revenues raised are not spent on health care. Thus, countries that are serious about improving affordability of medicines should eliminate tariffs and reduce taxes.

The report also supports advance purchase schemes as a market-based incentive for promoting R&D (Recommendation 3.5). Advance purchase schemes are a way of creating markets for products which would otherwise be too uncertain to attract sufficient investment. This kind of market-based incentive has proven to be effective in the Global Alliance for Vaccines and Immunization and other purchasing

funds. On untested alternatives, such as the proposal for a global medical R&D treaty, the CIPIH report says "... it is unclear to many people how the proposal would work in practice. Many comments emphasized that the proposal was set out in a broad-brush fashion, making it difficult to assess, without further information and analysis, how various legal, financial, technical and institutional issues could be addressed, as well as genuine concerns about political and practical feasibility."

The report usefully highlights the importance of drug quality and the fight against counterfeit drugs (Recommendation 4.4). Effective regulation and enforcement of quality standards play a vital role in protecting public health. The R&D-based pharmaceutical industry is active in this fight and the International Federation of Pharmaceutical Manufacturers & Associations is working with WHO to put the fight against counterfeit drugs higher on governments' policy agendas.<sup>5</sup> However, the report's discussion of broader quality issues would have benefited from a more in-depth discussion of the importance of bioequivalency — how the product works in the human body — with regard to generic copies.

Another useful recommendation made by the CIPIH report is to stop the brain drain of trained health-care workers from developing to developed countries (Recommendations 4.2 and 4.3). Trained health-care workers are vital to ensure that treatments are used effectively and appropriately. Yet many developing countries face shortages of such workers due to emigration.

## Counterproductive messages

Throughout the report there is too much emphasis placed on the use of compulsory licensing, the benefits of which are not justified by evidence. For example, the report states that Mozambique,

Zambia and Zimbabwe have issued compulsory licences for some antiretrovirals, but neglects to give the full picture: the multinational versions of the drugs in question were not covered by active patents in Zambia and Mozambique. Another example of the high profile given to compulsory licensing is where the report states that compulsory licensing could be an incentive for R&D (Recommendation 2.10). It is simply illogical to assume that a mechanism designed to encourage copying, but not research, would promote R&D for diseases which particularly affect developing countries.

The report is also self-contradictory. For example, although it notes important concerns about the feasibility of an R&D treaty, the report nevertheless calls for further elaboration of such proposals (Recommendation 3.6). Experience has shown that state-driven R&D has not successfully developed new drugs in comparison with the market-based R&D model.<sup>6</sup> Doing further work on this proposal, as recommended by the report, involves real costs, however. According to an official estimate by the WHO Secretariat to the Executive Board in January 2006, facilitating a discussion among Member States on international R&D guidelines would cost US\$ 1.2 million over two years, money that could be better spent on vaccinations or treatments for tropical diseases.

The report shows a fundamental misunderstanding of the role patents play with regard to drug prices and access (Recommendations 4.10 and 4.16) by repeating the myth that patents give the power to set prices. Such a misinterpretation ignores the effect of competition between drugs, including between patented drugs. Experience has shown that company access programmes, including partnerships with the public sector and nongovernmental organizations, is a proven and effective way of expanding access to needed drugs. The Accelerating Access to AIDS drugs Initiative (AAI) is

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bringing antiretroviral therapy to more than 582 000 people in developing countries, including 341 000 patients in Africa.<sup>7</sup>

The report overemphasizes the impact of patents on essential medicines when over 95% of essential drugs — as defined by WHO — are not patented anywhere in the world. Patenting of such drugs is also particularly low in low-income countries.<sup>8</sup> Yet access remains poor, with a third of the world's population having insufficient access to essential medicines. Lack of access is thus not due to patents, but rather a lack of financing and misplaced government priorities.

Furthermore, the report emphasizes a mistaken belief that parallel trade is in the interests of developing countries (Recommendation 4.19). The report correctly notes that developed countries should prohibit parallel importation to remove incentives for product diversion. The report then says that countries should continue to benefit from differential pricing while simultaneously pursuing parallel imports. However, par-

allel importation eliminates the basis of differential pricing systems.

The report also repeats criticism of the intellectual property chapters of Free Trade Agreements (Recommendations 4.20 and 4.26). The report should have investigated the experience of developing countries in using enhanced intellectual property incentives, including so-called "TRIPS-plus" measures, to promote the development of their domestic pharmaceutical industries and overall economic development. Sovereign states negotiating free trade agreements with large markets look for an overall package which will meet their economic and social needs including enhanced intellectual property incentives, such as data exclusivity, for a certain number of years.

The report also has a fundamental misunderstanding about the role of data exclusivity and access to medicines. In most cases, data protection expires before the patent does. Without data exclusivity, copiers could rely on the innovator's data to gain market approval at the same time as, or even before, the innovator. However, a limited period of

effective data exclusivity can justify the investment needed to bring products into markets without patents. Where patents do not exist, or where delays in registration greatly reduce effective patent life, data exclusivity can promote domestic innovation and/or importation of innovative medicines.

## Conclusions

The report is an important effort to investigate the relationship between intellectual property rights, innovation and public health. While it makes several useful and important recommendations, it also repeats some myths and misconceptions about the role intellectual property rights play in innovation and access to medicines. Policy-makers should be careful in selecting which recommendations to follow. ■

**Competing interests:** The author is employed by the Federation of Pharmaceutical Manufacturers & Associations, which represents the interests of the R&D-based pharmaceutical industry.

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