WHO News

Do patents work for public health?

WHO

Carlos Correa

Carlos Correa graduated in economics in 1971 and law in 1972 and later earned his doctorate from the University of Buenos Aires in his native Argentina. Since then, he has pursued an academic career and held posts in the Government of Argentina from 1984 to 1991 as Under-Secretary of State for Informatics and Development, Coordinator of the Inter-Ministerial Group on Intellectual Property and a delegate in international negotiations on intellectual property. He was a commissioner on WHO's Commission on Intellectual Property Rights, Innovation and Public Health, a panel of 10 independent experts, which wound up after publishing its report in April 2006: *Public health, innovation and intellectual property rights*. Correa is Director of the Centre for Interdisciplinary Studies on Industrial Property and Economics Law, at the University of Buenos Aires.

The Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) was set up by WHO Member States at the World Health Assembly (WHA) in 2003 to investigate how to improve access to health products for diseases that mainly affect developing countries, given current international and national rules on patent rights. Last month the commission's report was published, after a year's delay due to differences of opinion among the 10 independent experts appointed as commissioners. In an unusual step, five commissioners published critiques of the final document in the report's annex. In this interview with the *Bulletin*, one of those commissioners, Carlos Correa, discusses the challenges the commission faced, and the task that WHO Member States face, when considering what action to take in response to the report's recommendations (see pp. 351, 414–416). The opinions expressed in this interview are personal and do not necessarily reflect those of the CIPIH or WHO.

Q: Why did the CIPIH fail to deliver its report on time in 2005?

A: The CIPIH had to deal with a very difficult issue: how to promote the development of medicines for diseases prevailing in developing countries. These diseases are neglected in industry's R&D (research and development) budgets because selling medicines to treat them is not profitable enough. The CIPIH chose to cover issues ranging from drug discovery to delivery in the report. This broad coverage — which I personally did not favour — led to the consideration of many issues that were not central to the commission's mandate and for which reliable evidence is limited, such as industry donations of drug compounds. There were also important differences of opinion among the commissioners that led to a lack of depth in the analysis of some critical issues, such as the differential impact of patents in developed and developing countries and in the report's recommendations.

Q: Has the report been discredited by the fact that the comments of a pharmaceutical industry lobbyist were found written directly in a draft of the report, even though these comments were later removed?

A: This incident is now well known. We must wait for the reaction of WHO Member States at the WHA (22–27 May 2006). The influence of the pharmaceutical industry on commissioners' positions further complicated the commission's work. I hope that, notwithstanding all this, the report will spur governments to take action.

Q: Why do we need alternatives to the patent system?

A: One basic problem with the patent system is that it works only where markets are lucrative and profits are high. In a situation where the public health need is great but the market is small, patents do not work at all. This is proven by the lack of investment in diseases that prevail in developing countries, such as malaria, Chagas disease, etc. that could benefit millions of people. New drugs are discovered — in the vast majority of cases — not by private companies but by universities and public research institutions. The monetary reward provided by the patent system does not play a major role in this phase. What the pharmaceutical companies argue is that without patents they would not invest in pre-clinical and clinical tests to prove efficacy and safety. At Duke University they are looking at ways to develop clinical studies for the public good.

Q: Are there other solutions?

A: Governments need to take a different approach. There are already some initiatives at WHO, such as the draft Resolution (EB117.R13) proposed by Brazil and Kenya that will be considered by the WHA this month. New mechanisms should be established to set R&D priorities and coordinate activities with increasing participation from developing countries. For example, WHO could consider a global plan of action to foster drug investment and discovery for diseases in developing countries. The most important initiatives of this kind are so far funded by foundations, but this model is not sustainable; we need stronger, more stable commitment from governments.

Q: The patent system was originally established to encourage researchers to share their findings for the public good. Today, research results can be accessed worldwide using the internet, why do we need the patent system?

A: The justification for the patent system has changed. In the 19th century it was to give inventors an incentive to disclose what they had developed. The idea was that, without the patent, they would keep this information secret. Today, the patent system is regarded more as a way of permitting the recovery of investment based on the argument that, in the absence of exclusive rights, companies will not invest in developing products because once these are available others can imitate them.

Q: Why are there such entrenched positions on intellectual property and health between campaigners and the pharmaceutical industry? Is there no middle-ground?

A: There are reasons for the controversy. Patents may promote some kinds of R&D but, at the same time, limit access to the medicines they help to generate. The key point is that people in developing countries should not be deprived of medicines just because these are patented. This is unethical and against human rights.

Q: Provisions in international trade rules address this lack of access to medicines.

A: Yes, there are mechanisms under patent laws, such as compulsory licensing, use of parallel imports, and exceptions to exclusive patent rights. These are elements built into the system that countries can use. However, the pharmaceutical industry opposes the use of these and, unfortunately, some governments do too. Recent free trade agreements (FTAs) the United States has signed with developing countries, such as Chile, Jordan, Morocco and Peru, have eroded some of these flexibilities.

Q: Generic drug manufacturers in India have become important suppliers of cheap copies of brand-name medicines for certain diseases such as HIV/AIDS. Is this situation changing as India has been bound by international trade rules since January 2005 not to copy brand-name drugs?

A: India's pharmaceutical industry has developed explosively over the last 10 years in the absence of pharmaceutical product patents. Indian companies have been able to produce low-price drugs, and the competition they introduced is the main reason why antiretroviral drugs became more affordable in Africa and elsewhere. This supply of low-price drugs will depend, in the short- and medium-term, on how the Indian patent office deals with more than 8000 patent applications awaiting a decision.

Q: Is this development in India good news for developing countries?

A: No, it's good news for the multinational pharmaceutical industry, which will be able to control sales of their products all over the world. It's bad news for patients, since there will be less generic competition and prices will be higher. One example is Roche's Tamiflu. There is a great demand for this drug because of the threat of a human flu pandemic, but companies must refrain from copying and producing this product in countries where it is patented. Roche is subcontracting production to some foreign companies because it cannot satisfy the demand by itself. The problem is: what will happen if there is a human flu pandemic? The rational response would be to produce and provide the drug — if proven effective — independently of the patent situation. And this would be an acceptable solution under the Doha Declaration that public health interests should prevail, when there is a conflict with patent protection.

Q: The United States allows patenting of discoveries as well as inventions, is this right? What is the public health impact?

A: From a public health perspective this is not the right policy, nor is it right under the fundamental principles of patent law. Genes, for instance, are not invented, but discovered. Some genes that are important for testing diseases have been patented; for example, a gene for a diagnostic test to detect breast cancer. Since the gene is patented, the only company that can produce and market a diagnostic test based thereon is the patent owner. This means that the cost of tests is extremely high.

Q: Pharmaceutical companies say it is expensive to produce a new drug, and costs on average US$ 800 million.

A: There is no sound basis for this figure; it's an average estimated by experts relying on industry's data, which are not available for independent review. The costs of developing drugs by public institutions or public–private partnerships are much lower. The cost of doing trials — an expensive component of drug development — can be lowered, for example when done in developing countries. The problem with the current patent system is that it allows companies to charge the price that the market will bear and not a price related to actual R&D and production costs.

Q: There is a lot of pressure on scientists to patent every genetic sequence. Are universities benefiting from the patent system?

A: The pressure on universities to patent distorts the role of universities as the source of science for the public good. The problem is that what universities patent is often closed to science, so patenting can hinder research. A recent study by Padmashree Gehl Sampath shows that some Indian institutions have abandoned research projects because of this in India.

Q: Will universities start getting less government funding for research, if they get increasing funds from selling patents to industry?

A: This is possible. Many universities have increased patenting activities to compensate for a decrease in government funding for public research.

Q: But if we look at the other side of the coin, patents are also bringing benefits.

A: They may encourage the development of technologies that could otherwise remain unexploited. But in the case of the United States, for instance, the revenues that patents generate just cover the universities' cost of transfer of technology offices, and acquiring patents etc., so it doesn't seem to generate a very significant net benefit.

Q: Are there alternatives ways, such as open access publication, to motivate and reward pharmaceutical development?

A: An open source approach can be used to undertake some phases of the R&D process. Prizes, ex-ante subsidies and advance purchase contracts are other possible ways of motivating and funding drug development. For drugs for which the need is great but markets are not profitable, these may be the only approaches that work.

Q: There have been a few examples of patent donation, can this be a model for others?

A: This is very unlikely, even in cases where titleholders have no immediate commercial expectations. ■