



To the: WORLD HEALTH ORGANIZATION- WHO
Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG)

Dear Sirs:

In the name of ASDIN - Asociación de Derechos Intelectuales, - we would like to thank you for giving us the opportunity to express our concerns on the WHO DRAFT GLOBAL STRATEGY ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY.

We will only refer to ELEMENT 5 of this Draft, as the issues deal by same falls under the main activity of our Association.

It should be stressed that ASDIN has been working in the field of Intellectual Property, for more than twenty years, in collaboration with international, regional and national organizations. Among the many activities of our Association, we sponsor the publication of the legal collection: Derechos Intelectuales, Editorial Astrea.

Our main concern deals with paragraph 5.2 of Element 5, which in our opinion has severe flaws. Paragraph (a) promotes legislation to apply flexibilities in TRIPs. It should be noted that the first obligation should be complying in good faith with TRIPs., if its goals to foster research, development and fair trade practices are to be fulfilled. Under the term "flexibilities", there are many interpretations of TRIPs rights and obligations that create confusion and tend to weaken or ignore the wording, objectives and fair trade practices aims of the Treaty. It is sad that after more than ten years of TRIPs approval, many of the basic obligations set in the same have not been implemented or have been poorly enforced in many countries. In spite of not allowing the system to work properly, due to the lack of adequate enforcement, the focus is not on compliance - as it should be- but on "escaping" the minimum standards established by the Treaty.

Paragraph 5.2. (b) refers to the promotion of bilateral trade agreements that do not incorporate "TRIPs-Plus" protection in ways that might reduce access to medicines in developing countries. Such a proposal ignores Article of 1 of TRIPs, which clearly states that Members of the Treaty may implement more extensive protection than is required by the Agreement. At the same time, in view of the contradictory interpretations given to TRIPs, and the lack of correct implementation of its norms, bilateral agreements include clarifications that are considered as *TRIPs Plus*, by those who only seek to erode the Treaty.

Paragraph 5.2. (c) insists on taking into account the "flexibilities" in the Doha Declaration. This Declaration should be fully taken into account, and not only "flexibilities", since DOHA Declaration does not reject but -on the contrary- support TRIPs fully.

In our opinion, WHO should be worried by insufficient TRIPs enforcement. Regulatory health agencies have, as their main mission, the safeguard of consumers' in the process of registering medicines that will be marketed. In this respect, several health agencies are, in general, in their rush to approve and promote local copies (imitations) of high-tech innovations, not taking into account basic efficacy and safety requirements that should be observed to allow the marketing of new drugs and generics. It is wrong to confuse generics in the industrialized world -which are approved only after a certain period of time and after fulfilling specific safety requirements- with generics, copies or imitations (branded or un-branded) circulating in many developing countries, because the scientific-technical data for these copies is neither requested by nor submitted to the regulatory agencies.

Acts or omissions of health agencies are a decisive factor in protecting the public, but have also influence and effects in promoting or harming the national research and development (R&D) systems. It is neither in the interest of the patients nor of the national industries - that are theoretically promoted-, to omit data and tests that should be performed. This is not the correct road to access to medicines, it is only a door to the promotion of very poor quality which hurt the health of the population.

The incentives offered by the intellectual property regime are essential to make private investments in research and development (R&D) sustainable. A proper balance should be attained. Post TRIPS bilateral agreements must include adequate intellectual property enforcement, not only in order to protect private rights but, even more important, safeguard the public and promote research and development activities.

Many regulatory health agencies seem to believe that observance of I.P. obligations is outside their duties and that I.P. affects access to medicines and hurt national companies. Thus these health regulatory agencies approve imitations, copies, or generics of pioneering drugs with little requirements. This is not in line with the need to protect consumers and affects negatively national research systems.

TRIPs imposes minimum I.P. standards, but also gives the opportunity for health registration agencies to enhance the requirements on drug quality and supervision that WHO should promote.

Rather than fostering health regulatory agencies as vehicles of misappropriating IP rights, WHO Action Plan should use the interface between Health Registration and Intellectual Property, for better fulfilling health agencies' mission to protect consumers and boost innovation. This is where WHO IGWG. ACTION should aim.

Sincerely yours,
ASDIN.
Director.
Tucuman 335, Floor 7, D
1049 Buenos Aires,
Tel/Fax 4312/0137; 4312-0153.