



ALIFAR

Asociación Latinoamericana de Industrias Farmacéuticas

Av. del Libertador 602 P. 6 | C1001ABT | Argentina | Telefax: 5411 + 4812 4532 | email: info@alifar.org.ar

Latin American Association of Pharmaceutical Industries

[ENGLISH TRANSLATION BY WIPO]

Comments on document SCP/12/3 Rev.

Prior art – Novelty – Inventive step – Grace period para. 210 ff.

The criteria for evaluating novelty (prior art) and inventive step are among the main flexibilities of the patent system in the TRIPS Agreement. The definition which each national law provides for these patentability requirements and criteria applied by industrial property offices demonstrates the inappropriateness of establishing uniform standards which limit the margins for maneuver of countries in evaluating and granting patents.

Low standard patents do not promote innovation or development but, on the other hand, avoid others using and manufacturing inventions which are simple obvious modifications of available technologies.

The same is true of the grace period linked to the requirement of novelty and prior art.

Quality. Para. 241ff.

The patent system was devised to reward inventive capacity, stimulate progress and promote innovation. The inventor's contribution to society and the need to recover the investment in the generation of his invention serve as the underlying justification for the system.

However, the achievement of the main objectives has been distorted owing to problems with the management and design of the system. This is translated in the form of a reduction in the standards of non-obviousness or inventive step applied in the examination of the grant of patents, with the result that patents of low quality and broad scope are being granted.

Thousands of patents are granted for commonplace developments and it should be asked whether this exponential growth in the number of patent applications filed

each year is evidence of the increasing importance of knowledge assets in the modern economy or are the result of the slackness of a system which has relaxed its requirements.

The implications of the system include:

(a) industrial property offices have a wealth of cases to resolve, which largely surpasses its capacities and resources. This situation may lead to the flawed examination of applications or to the same steps taken by a number of offices in developed countries being followed, in the belief that the examination which they are conducting is a guarantee of solidity.

(b) commonplace patents may play an important role in hampering competition, extending the life of patents close to expiry or affecting the commercialization of products in the public domain.

(c) commonplace patents are in many cases the cause of “the tangle of patents“ which may constitute an obstacle to the progress of research.

The problem arises when the lax criteria and flawed examination apply in certain areas of particular social and economic impact, as is the case in the pharmaceutical industry. Even where the patent may be weak or questionable, the economic capacity of certain firms will allow them to use patents aggressively in order to exclude from the market especially small and medium-sized producers who lack the resources to meet expenses and prolonged disputes.

The application of the ISO standard may wrongly be assumed to be a presumption of the validity of the patents granted, where the standard applies only to the procedure and has no relation to the quality of the examination.

Support structures for the patent system
Para. 254ff.

The training of human resources should be directly related to the degree of development of the countries which receive training. The information provided should be broad and sufficiently diverse so that each country possesses the necessary knowledge and tools to interpret the international rules and agreements as well as deciding their own criteria for evaluating and granting patents. These guidelines should be followed both in the training of examiners and in training programs for judges and other actors involved (universities, society). The uniformity of rules may be contrary to the needs and degrees of development of many countries.

Incentives for innovation and general public policy objectives.
Para. 286 ff.

The debate on the impact of intellectual property protection on access to healthcare being conducted at the World Health Organization (WHO), the TRIPS Council Declaration of August 30, 2003 and the WIPO Development Agenda promoted by a group of countries demonstrate the difficulties generated by intellectual property in certain sensitive sectors of technology. Healthcare appears to be the area where the use of the available flexibilities appears to be most necessary, instead of harmonizing rules which involve new and more rigorous standards of benefit to rights holders and which may affect access to healthcare in certain countries.