



FÉDÉRATION INTERNATIONALE DES CONSEILS
EN PROPRIÉTÉ INTELLECTUELLE

INTERNATIONAL FEDERATION OF
INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION
VON PATENTANWÄLTEN

Resolution of the Executive Committee, Florence, 17 – 21 October 1998

“Extension of Protection”

FICPI, the International Federation of Intellectual Property Attorneys, broadly representative of the free profession throughout the world, assembled at its Executive Committee held in Florence from 17 to 21 October 1998,

RECOGNISING that the laws of certain countries provide for a period of extension of a patented pharmaceutical compound for which the effective period of protection has been reduced by the period required to obtain government authorisation to market, and that other countries may consider enactment of similar laws;

RECOGNISING that certain of the countries which provide for such period of extension also permit testing by manufacturers of generic pharmaceuticals to show essential similarity to obtain marketing authorisation prior to expiration of the ordinary patent term or extended period of protection, and other countries are considering whether to add similar provisions to their laws;

RECOGNISING that pharmaceutical research is vital in the continuing improvement in public health;

RECOGNISING that pharmaceutical research will continue only as long as an appropriate return on investment is obtained;

RECOGNISING that similar considerations apply to other areas of research; and

RECOGNISING that the TRIPS Agreement provides for a minimum patent term of 20 years for patents in all fields of technology;

URGES that the following principles should guide the enactment of laws in the area of pharmaceuticals, as well as in any other area in which the effective period of protection has been reduced due to a need to obtain government authorisation to market:

- No legislation should be adopted which would have the effect of limiting the patentee's rights during the ordinary term of a patent as provided by the TRIPS Agreement.



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- It may be appropriate to extend the period of protection of a patented product where the effective period of protection has been shortened due to delays in obtaining approval to market.
- If the period of protection of a patented product is extended, it may be appropriate to allow testing to obtain marketing authorisation prior to expiration of the extended period of protection. However, no such testing should be allowed during the ordinary term of the patent.
- There should be a balancing between the period of the extension and the right to test, i.e., they should be considered together to achieve an appropriate balance, rather than independently, so that in any extension of the period of protection, a patentee should be guaranteed some period of exclusivity during which testing by a third party to obtain authorisation to market is prohibited.
- Stockpiling should not be allowed either during the ordinary patent term or the extended period of protection.