FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE

INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION VON PATENTANWÄLTEN

Resolution of the Executive Committee, Kyoto, Japan 6-10 April 2014

"Industrial applicability requirement in pharmaceutical patents"

FICPI, the International Federation of Intellectual Property Attorneys, broadly representative of the free profession throughout the world, assembled at its Executive Committee held in Kyoto, Japan, 6-10 April 2014, passed the following Resolution:

Emphasizing that according to Art. 27 of the TRIPS agreement, *patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application;*

Observing that in certain jurisdictions, pharmaceutical patent applications are rejected and/or pharmaceutical patents are found invalid for alleged lack of industrial applicability or utility, because the specification as filed is considered not to contain sufficient experimental data to enable a sound prediction that the compound or class of compounds recited in the claims would provide in humans the effect disclosed in the originally filed application;

Recognizing that data from scientifically acceptable *in vitro* models or animal models, as well as computer-assisted simulations, are frequently predictive that a given effect would be plausibly achieved in humans and are thus normally relied upon as a basis for drafting a patent application as soon as possible;

Further recognizing that, for safety and/or regulatory reasons, it is rare to have *in vivo* data on humans available when initially filing a pharmaceutical patent application, particularly if it relates to a new chemical entity;

Noting that having to wait for the availability of *in vivo* data on humans might seriously prejudice the patentability of the invention for lack of novelty and/or inventive step in particular because of the need or risk of publicly disclosing the invention or of possible intervening publications disclosing the same or similar effect;

Firmly believing that the lack of *in vivo* data on humans in a patent application does not prevent a pharmaceutical invention from being capable of industrial application;

Urges relevant authorities at a regional and/or national level to refrain from requiring the presence of *in vivo* data on humans in the application when evaluating the patentability of an invention in the pharmaceutical field;

And further urges relevant authorities at a regional and/or national level to accept post-filing experimental data to support, if necessary, the fact that the compound or class of compounds recited in the claims provides in humans the effect disclosed in the application.