



Question Q238

National Group: AIPPI-US Division of AIPLA

Title: **Second medical use or indication claims**

Summary:

Under United States law, patent protection for medical treatments is broadly available, covering both new uses of previously known pharmaceutical compounds and previously known medical devices. The proper format for such claims is a “method of treatment” reciting the active steps of the new use. Claims reciting a product limited only by an intended use or that do not recite an active step are currently impermissible. United States law provides that medical practitioners are exempt from liability for performance of a medical activity that constitutes an infringement. However, under current law, medical practitioners are not exempt for liability for the use of a patented drug or the practice of a patented use of a drug. Method of medical treatment claims can be enforced on the basis of either direct or indirect infringement. In order to prove indirect infringement, it generally must be shown that at least one party is a direct infringer. Thus, proof that a manufacturer of a medical product is indirectly infringing a claim directed to a method of medical treatment will often require proof that a medical practitioner is carrying out the steps of that claim, even if the medical practitioner is exempt from liability.

United States practitioners broadly agree that harmonization is desirable in this area. Many believe that “Method of treatment” claims represent the most desirable format, provided that a broad exemption for liability of medical practitioners is adopted. Some other practitioners believe that such method claims may be perceived as inflammatory even with a broad exemption for medical practitioners.