

4th International Conference and Exhibition on

Biologics & Biosimilars

October 26-28, 2015 Baltimore, USA

Enforcement of biologics in Europe under the UPC

Willem A Hoyng

Hoyng Monegier, The Netherlands

During 2016 the UP and UPC will come into force in Europe. This means that patentees have to make (tough and difficult) choices in how to protect their inventions in Europe by national patents, European patents and/or Unitary Patents. The Unified Patent Court will change not only the landscape of enforcement and litigation but will also influence the material patent law of Europe in for Biologics and Biosimilars important fields such as the scope of protection and more especially the doctrine of equivalence.

hoyngw@hoyngmonegier.com

Biosimilars in Europe: The role of EMA's guidelines

Wolfgang A Rehmann

Taylor Wessing, Germany

In Europe, biosimilars are governed by the statutory provisions applicable for generic medicines. The legal requirements and the procedures for making an application for a marketing authorization are set out in Directive 2016/83/EC and in Regulation (EC) No 726/2004. There are a number of possible approaches to getting approval for a bio-similar product in Europe, in particular to either submit a full dossier of pre-clinical and clinical data as would be required for any new medicinal product or to apply under the abridged procedure. An applicant for approval of a bio-similar product under the abridged procedure is required to demonstrate that its product is similar to a previously authorized product. The EMA is responsible for assessing applications from companies to market biological medicines for use in the European Union, including bio-similar medicines in case the centralized procedure is applicable. The EMA has published guidelines that govern how biosimilars are to be assessed. There are three guidelines that apply to all biosimilars: an overarching guideline which was first adopted in September 2005 and was amended in 2014, coming into effect on 30 April 2015; and two further guidelines which were both adopted by the EMA on 22 February 2006, one relating to non-clinical and clinical issues and one to quality issues. The guideline on quality issues was also amended in 2014. The presentation will give an overview to the audience about how the legal framework in the EU works and will give an update on most recent legal development within the EU in this regard.

W.Rehmann@taylorwessing.com

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