WIPO Circular C. 8687 (21 August 2017) – Information for the preparation of the draft reference document on the exception regarding acts for obtaining regulatory approval from authorities.

A. Description of the Exception

Section 11, number 2b of the German Patent Act states:

"The effect of a patent shall not extend to […]

2b. studies, experiments and the practical requirements resulting therefrom which are necessary for obtaining authorization to place medicinal products on the market in the European Union, or which are necessary for obtaining authorization to place medicinal products on the market in the Member States of the European Union or in third countries;"

B. Objectives and Goals

According to the recitals of the implementing legislation (14th Amendment of the German Medicines Act, BGBl. 2005 I 2570) the primary goal for the introduction of the so called "Roche-Bolar Exemption" is to allow "certain acts" by manufacturers of generic pharmaceuticals before expiry of a patent (BT-Drucksache 15/5316, p.31), thereby enabling earlier market entry of generic products after the expiry of a patent (or supplementary protection certificate).

Said "acts" are studies, experiments and the practical requirements therefrom, which are necessary for obtaining an authorization by regulatory authorities in Germany or other member states of the European Union or for an authorization pursuant to Regulation (EC) No 726/2004 to place a medicinal product on the market. Production of pharmaceuticals is also exempt by Section 11, number 2b of the German Patent Act, if they are required for carrying out the studies and experiments (BT-Drucksache 15/5316, p.48).

C. National / Regional Implementation

Section 11, number 2b of the German Patent Act was introduced by the 14th Amendment of the German Medicines Act (BGBl. 2005 I 2570) taking effect on 6 September 2005.

It constitutes implementing legislation as required by Article 10, Section 6 of Directive 2001/83/EC and Article 13, Section 6 of Directive 2001/82/EC, as amended by Directives 2004/27/EC, 2004/28/EC, and 2004/24/EC respectively.

Besides that, pursuant to Article 27 (d) of the "Agreement on a Unified Patent Court" (OJEU, 56: 2013/C175/01), limitations of the effects of a patent falling under the competence of the future Unified Patent Court shall comprise the following:

"The rights conferred by a patent shall not extend to any of the following: […]

(d) the acts allowed pursuant to Article 13(6) of Directive 2001/82/EC or Article 10(6) of Directive 2001/83/EC in respect of any patent covering the product within the meaning of either of those Directives;"

D. Challenges Faced by Member States in its Implementation

It is not quite clear which challenges are meant.

E. Results of its Implementation

On condition that there is a direct relation to an (intended) application for a marketing authorization e.g. the following acts are exempt from patent protection according to German case law:

- Studies, in particular clinical trials of phases 1, 2, 3 conducted by the entity which wants to obtain a marketing authorization or a contractor of this entity.
- Experiments "on" and "with" the patented invention by said entity or a contractor (going beyond section 11, number 2 German Patent Act on "experimental use").
- "Practical requirements" for conducting studies or experiments, i.e. production or import of the patented invention (usually a pharmaceutical substance) by said entity. Suppliers are only generally exempt, if they are themselves involved in the process for obtaining a marketing authorization (e.g. co-sponsors of clinical trials). If this is not the case, the supplier is obliged to take precautions against any infringing use of the supplied products and has to ensure that the protected products are only used within the scope of the exemption (considering in particular the amount of supply and providing for a contractual penalty in the supply agreement).

To the contrary, any acts that are not required for obtaining a marketing authorization constitute an infringement.

With regard to the marketing authorization, it is irrelevant whether the application is intended in Germany, in another EU member state or in any other country. The respective national law is relevant for assessing which acts are required for obtaining a marketing authorization in this country and which acts consequently are allowed by the exemption pursuant to section 11, number 2b of the German Patent Act.