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Questions submitted on scope of Bolar provision

In its judgment of December 5 2013, the Higher District Court of Düsseldorf referred to the Court of Justice of the EU the question of whether Article 10(6) of Directive 2001/83/EC on the Community code relating to medicinal products for human use should be interpreted as meaning that the exemption from patent protection also extends to the supplies by a third party of a patent-protected active agent for purely commercial reasons to a generics producer who intends to conduct studies or trials for a marketing authorisation.

Pursuant to Article 10(6) of Directive 2001/83/EC "studies and trials and the subsequent practical requirements necessary to obtain permission to market [a drug] in the Member States or in third countries according to the effective pharmaceutical regulations" shall not constitute patent infringement.

Article 10(6) was implemented by Section 11 (2b) of the German Patent Act. It provides that patent protection does not apply to those studies and the resulting practical requirements which are necessary to obtain market authorisation for pharmaceuticals in the European Union or for the authorisation of a drug as a pharmaceutical product in the member states of the European Union or third states. This exemption applies to both generic medicinal products and to non-generics, but only those that are similar to the reference product and which do not fulfil the generic definition for specified reasons.

The exemption allows generic manufacturers to obtain a marketing authorisation for their generic drug or to have that drug authorised as a pharmaceutical product by using a patent-protected active ingredient even before the expiry of the patent, enabling them to offer their generic products on the market as soon as the patent has expired.

The District Court of Düsseldorf had decided that this privilege as set out in Section 11 (2b) of the German Patent Act does not apply to provisions of the active ingredient by third parties to a generic manufacturer conducting the trials. It held that the privilege could only apply to the party directly conducting the trials itself. Only by way of exemption, a third party supplier may qualify for the exemption, if it can be considered to be a (direct) "co-organiser" of the trials and has some specific interest in its results beyond commercial reasons.

The Higher District Court of Düsseldorf, however, took the view that supply activities by third parties for purely commercial reasons may also be covered, at least if the third party may assume that the active ingredient would actually be used for privileged purposes. The Court underlined that the third party must however make arrangements to ensure that the active ingredient is not used for non-privileged purposes.

The argument of the Higher District Court is convincing as it is not only in accordance with the purpose of the privilege, but also leads to economically appropriate results. As in particular smaller generic manufacturers are often not capable of producing all the necessary ingredients, the privilege would in effect arbitrarily favour larger generic manufacturers that are able to manufacture the active ingredient themselves over smaller generic manufacturers dependent on third party suppliers. Such a restrictive interpretation of the exemption would also be contradictory to the general aim of the European pharmaceutical regulatory directive, which is that of facilitating the movement of generic products within the European market.