Kluwer Patent Blog

The “warning” by the Italian Antitrust Authority on the authorisation of generic drugs and patent litigation

Daniela Ampollini (Trevisan & Cuonzo) · Saturday, December 18th, 2010

I have already written about the investigation launched last October by the Italian antitrust authority (AGCM) on an alleged abuse of a dominant position by Pfizer in relation to the manner in which Pfizer enforced or attempted to enforce its patent rights. Well, this is actually the first case of this type in Italy, but AGCM had already sent a “warning” to the public, although nobody imagined that a real case would follow so soon. I refer to an opinion that AGCM sent to the Italian drugs agency (AIFA) in March this year, whereby AGCM stated as follows:
“The Authority wishes to highlight (…) the issues related to competition deriving from the procedures followed by AIFA in the framework of the registration of generics. Preliminarily, AIFA is reminded that the Authority has on more than one occasion expressed the hope of a higher consideration of the needs of the promotion of competition in the various phases of the pharmaceutical chain by means of a regulation which, on the one hand, may create the conditions for a better dynamic competition by providing incentives to undertakings to adequately carry out their activity of research and development and, on the other hand, promoting price competition between drugs which are not protected by patents, favouring the entry into the market of generic drugs. In this perspective, the Authority wishes to recall the attention on the possibility that the existence of disputes concerning the beach or not by the generic company of industrial and commercial property law may overly delay the procedure for the registration of the generic drug, posing obstacles to the progress of competition in the pharmaceutical sector. The Authority did not of course omit to consider the right of the originator companies to enforce their patent rights, which represent a fundamental mean to favour the competition based on the innovation of the product. However, it cannon be ignored that strategic litigation may be used by the companies holding patents which have expired to delay or prevent the entry of competitors in the market. In this respect, the Authority noticed that, on the occasion of an application for the marketing authorisation of generics of a polyunsaturated Omega-3 fatty acid EPA/DHA based drug, the processing of said application by AIFA lasted for a very long period due to a stay justified, according to AIFA, by the existence of a patent case before the ordinary courts. Without prejudice to the possibility of undertakings to enforce their rights in the appropriate places and according to the available tools, the Authority believes that subjecting the grant of the MAs of generic drugs to the resolution of disputes concerning alleged violations of industrial or commercial property rights, in the absence of an obligation in this sense by the entity which should grant the authorisation, constitutes a delay to the entry of generic drugs which harms the competition. In any event, the Council of State has already clarified that the indication contained in Art. 10 of Directive 2001/83/EC (reproduced in Art. 10 of Legislative Decree no. 219 del 2006) – which in regulating

simplified marketing authorisation applications of generic drugs states that these be “without prejudice to the protection of industrial and commercial property” – must be interpreted in the sense that the entities granting the marketing authorisations are exempted from any burden of inquiry in the existence of any patent or commercial protection. Therefore, in order not compromise effective competition in the pharmaceutical sector, the Authority hopes that the assessment of the application for marketing authorisation of generic drugs can be carried out respecting the requirements of safety, efficacy and quality of the products so as to fully guarantee the protection of public health, however with modalities which consent the entry of generics in a timeframe which allows effective competition”.
The original text can be found here.

To make sure you do not miss out on regular updates from the Kluwer Patent Blog, please subscribe here.

This entry was posted on Saturday, December 18th, 2010 at 12:20 am and is filed under Italy

You can follow any responses to this entry through the Comments (RSS) feed. Both comments and pings are currently closed.