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Ex parte preliminary injunctions in the pharmaceutical sector

Miquel Montaña (Clifford Chance) · Thursday, December 1st, 2011

The requisite of “imminence” introduced by Directive 2004/48/EC, coupled with the measures approved by the Ministry of Health to speed-up the administrative steps necessary to launch generics, has placed owners of patents that protect chemical and/or pharmaceutical products at a crossroads: if they file an application for a preliminary injunction before the generic medicament has been given a price by the health authorities, there is a risk that a Court may deny the preliminary injunction on the grounds that there is no “imminent” threat; on the other hand, if they file the application after the price has been fixed, there is a risk that the Court may not be able to hand down a decision before the generics are launched onto the market.

From the perspective of the patent owner, this gloomy outlook is further darkened by the fact that the launch of the first generic prompts the product of reference to be included in the recently created so-called “homogeneous groups,” which are formed by all medicaments with the same active ingredient. Since doctors now have the legal obligation to prescribe by active ingredient (instead of by brands), and pharmacies have the obligation to dispense the active ingredient with the lowest price, once a “homogeneous group” is created, the product of reference will disappear from the market unless the patent owner reduces its price to the lowest level price.

Against this background, the saying “justice delayed, justice denied” defines very accurately the situation in which owners of invaluable pharmaceutical patents would be left, if an application for a preliminary injunction was not resolved before the first generic is launched. An example of the increasing sensitiveness of the Spanish Courts towards protection of innovation before it is too late can be found in the recent judgment of 14 November 2011 from the Commercial Court of Granada, which ordered an “ex parte” preliminary injunction against a generics company that had just launched the first generic of a pharmaceutical product that will be protected by a patent in force until September of 2012. Among other aspects, this judgment has ordered the notification of the provisional measures to the Ministry of Health, so that the latter is aware that the product launched by the defendant may not be taken into account for the purpose of creating a “homogeneous group.”

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