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## Obtaining marketing authorization and price earlier than approximately 50 days before the expiry date may be an act of unfair competition

Miquel Montaña (Clifford Chance) · Tuesday, August 28th, 2012

On 30 July 2012, Commercial Court number 5 of Barcelona handed down an interesting decision that has brought again to the fore the legality of so-called “preparatory acts” (in particular, obtaining marketing authorisation and price). The facts of the case may be summarised as follows:

Merck Sharpe & Dohme (“MSD”) owns a Supplementary Protection Certificate (“SPC”) that protects Montelukast until 25 February 2013. KRKA Novo (“KRKA’s”) obtained an authorisation to market a generic of this compound on 14 March 2012, that is, approximately one year before the expiry date. After the marketing authorisation was granted, the Ministry of Health set the price of the generic and included it within the list of drugs financed by the National Healthcare System. According to Spain’s pharmaceutical law, once a new drug has been included on this list, pharmacies must provide the product that contains the active principle at hand (in this case, Montelukast) with the lowest price.

Against this background, KRKA Novo undertook, both in the correspondence that preceded the case and during the proceedings, not to launch its generic before the SPC expires on 25 February 2013.

MSD filed an application for a preliminary injunction based on patent infringement and unfair competition. With regard to the second count, MSD alleged that KRKA’s undertaking not to launch was insufficient to protect its market position, since the publication of the generic on the list of drugs that may be prescribed by doctors and dispensed by pharmacies would create a great deal of confusion in the market place. According to MSD, the only way to guarantee peaceful enjoyment of its patent rights was to order KRKA to request the suspension of its marketing authorisation until the SPC expires.

KRKA contended that it was legitimate for them to obtain marketing authorisation and price sufficiently ahead (8 months) of the date when the SPC was due to expire. In particular, the defendant highlighted that obtaining marketing authorisation and price are acts of an administrative nature that do not constitute patent infringement.

In its decision of 30 July 2012, Commercial Court number 5 of Barcelona embraced KRKA’s argument of defence regarding the fact that obtaining marketing authorisation and price do not form part of the acts to which the patentee may object. However, the Court considered that causing

the generic to be included on the list of drugs to be financed by the National Healthcare System too far ahead of the date when a patent or an SPC are due to expire may constitute an unfair competition act unless the defendant has a legitimate cause. According to the Court, although the defendant's desire to have already obtained marketing authorisation and price to be ready to launch as soon as the SPC expires may well be a legitimate cause, based on the facts of the case, the Court considered that there was no need for KRKA to obtain marketing authorisation and price 8 months before the expiry date of the SPC.

All in all, within 48 hours of the decision, the Court ordered KRKA to request the suspension of its marketing authorisation before the Ministry of Health until 31 December of 2012. Thus the provisional lesson from this decision, which may be appealed, is that having obtained marketing authorisation and price earlier than approximately 50 days before the expiry date may be contrary to the Law on Unfair Competition.

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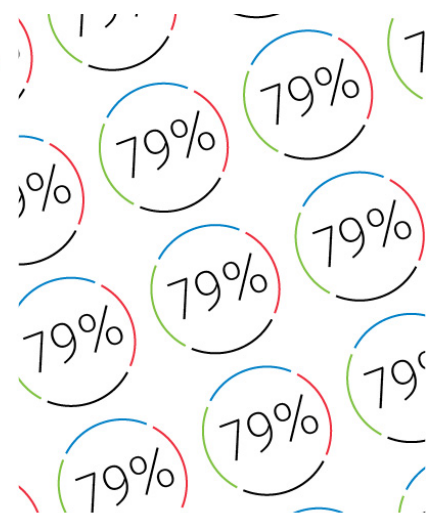
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