Kluwer Patent Blog

First generic launched, held liable for the price reduction of the original product: who wants to be first?

Miquel Montañá (Clifford Chance) · Wednesday, August 2nd, 2023

On 23 June 2023, the Madrid Appeal Court (Section 32) published one of the most interesting judgments coming from Spanish courts during the last few years. The first point of interest is that this is one of the first judgments handed down by the brand new "Section 32" of the Madrid Appeal Court, recently established for the purpose of specializing in intellectual property, competition and advertising matters. This is the latest development in the positive trend towards specialization started by the Barcelona Appeal Court in 1993 with the establishment of "Section 15" which, since then, has attracted all appeals in intellectual property matters (among others) in Barcelona.

The second point of interest is that this is probably the Spanish judgment which, to date, has discussed damages in more detail. To put in context the points discussed in the judgment, it will be useful to provide some background on the case:

Eli Lilly owned a patent that protected the use of raloxifene in the preparation of a medicament useful for the prevention and treatment of osteoporosis. It also owned a supplementary protection certificate ("SPC") which extended the term of the patent rights until 5 August 2013. Daiichi Sankyo Europe GmbH ("Daiichi") was an exclusive licensee. Laboratorios del Dr. Esteve was a comarketer.

In May 2011, that is, more than 2 years before the expiry of the SPC, a generics company ("X") launched the first raloxifene generic on the Spanish market. As a result, in September 2011, pursuant to the regulatory regime then in force, the Spanish government established a so-called "homogeneous group" (group Nº 2634) comprising all the raloxifene drugs authorized in Spain. According to this regime, pharmacists had the obligation to dispense the drug within the "homogeneous group" with the lowest price. Due to the creation of group Nº 2634, Daiichi, in October 2011, had to reduce the price of its original drug (Evista®) by approximately 40% to try to compete with the generic. Some months later, in particular, in January 2012, another generics company launched the second generic on the market. To be clear, this second generic was launched at a time when Daiichi had already reduced the price of its original drug as a result of the launch of the first generic.

Against this background, Eli Lilly and Daiichi filed a damages claim before the courts of Madrid where, among other concepts, they claimed the damages derived not only from the units that they had failed to sell due to the sales made by those two generic companies, but also the damages

stemming from the price reduction of the original product. For the purpose of this entry, we will focus on the latter aspect.

During the proceedings, the company that had launched the first generic denied any liability for the price reduction of the original product. In a nutshell, it alleged that Daiichi had reduced the price of Evista® "voluntarily" and that, in any event, such price reduction was a natural consequence of the regulatory regime. The Madrid Appeal Court (Section 32), in its judgment of 23 June 2023, rejected this line of arguments on the following grounds:

> "*This court considers that the price reduction is a consequence suffered by the plaintiff until the expiration of its exclusive right, so the corresponding compensation must cover the loss incurred by the plaintiff temporarily until the expiration date. Because in a market without competition, the result of its corresponding exclusive position, there would have been no legitimate reason for a third party to cause a fall in prices as a result of its competition. In addition, there is a party clearly responsible for the reduction in the selling price of Evista®. And this was none other than the first laboratory (X) which, despite the fact that the patent was in force, proposed launching a generic medicinal product, a raloxifene tablet, on the market and then maintained it there despite infringing a patent. X's commercial initiative is in direct correlation with the fact that, pursuant to the regulation in force, in September 2011, a "homogeneous group" (Nº 2634) for raloxifene medicines authorized in Spain was created, in accordance with the regulatory framework of the pharmaceutical sector, that is, for both original Evista® and Optruma® products manufactured by Daiichi and Esteve, and for raloxifene manufactured by Teva. As a consequence, the requirement to substitute prescriptions laid down in Article 85 of the Spanish Drug Act, that imposed on pharmacists the requirement to dispense in any case the lowest-priced drug included in the latter ("lower-price system"), applied to all medicinal products included in the "homogeneous group" (including Evista®). With the creation of group Nº 2634 for raloxifene, Daiichi was forced, with effect from 5 October 2011, almost two years before the expiry of SPC 009900002, to reduce the price of Evista® by 40% in order to bring it to the level of the price of the generic raloxifene, otherwise there was a risk of losing, by virtue of the application of the so-called "lower price system", its entire market share.*
>
> *X is therefore liable for the loss of profit in the sales of Evista® at a 40% lower price for the remainder of the SPC's term in the relevant period (i.e. between 5 October 2011 and 5 August 2013) because it caused damages that extended until the expiration of the plaintiff's exclusive right. Successive generic manufacturers subsequently and gradually joined an already created situation. They could be held responsible for their infringing behavior while the exclusive right of others remained in force, but one may not reproach them for causing the downfall effect that is precisely linked to the presence of X as the first generic product introduced on the market. […]*
>
> *It is true that in Spain the State is the one in charge of setting the selling price of medicines included in the public health service (Law 29/2006, of 26 July, on guarantees and rational use of medicines and medical devices – then RDL 1/2015, of 24 July, which adopted the corresponding consolidated text). But the corresponding "homogenous group", which is how this situation is legally called, is created for each format when the first generic enters the market for the first time, which entails that all medicines with the same active ingredient and format must equal the lowest price. So, if a manufacturer has launched the first generic medicinal product on the market when the innovator's patent is still in force, the*

> *manufacturer's actions will end up causing a price drop which damages the patented product. The liability is then attributable to the party which, being aware of this, either unduly launches the generic on the market or, once it becomes aware of the consequences of the regulatory adjustment, persists, however, in maintaining the undue marketing of what was then the only generic medicinal product on the market. It is the presence of this generic on the market that is decisive, in the context described, to explain the reduction in the price of the reference drug, whereby the requirement for liability is therefore justified […].*"

All in all, this very important judgment, if it becomes final, will send a very clear message to seafarers: who wants to be first?

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

This entry was posted on Wednesday, August 2nd, 2023 at 4:00 pm and is filed under Damages,

Patents, Spain

You can follow any responses to this entry through the Comments (RSS) feed. You can leave a response, or trackback from your own site.