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# DAMAGES FOR PHARMACEUTICAL PATENTS INFRINGEMENT: THE CASE OF RALOXIFENE.

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Raloxifene, a drug used to treat osteoporosis, has been at the center of a legal dispute in Spain between the pharmaceutical company ELI LILLY, the patent holder, and the generic industry. This dispute recently reached an important milestone with a ruling by the Provincial Court of Madrid in June this year. Although not yet final, this decision could mark a turning point in the launch and commercialization of generic medicines.

There are many nuances and details to this case, including the litigation in various Spanish courts and the liason to the patent revocation proceedings relating to the ELI LILLY drug before the European Patent Office (EPO). However, we will focus on the broader perspective of why this decision is of paramount importance to the generics industry in its business practice and strategy.

In the pharmaceutical industry, it is common to see a significant reduction in the price of reference medicines when a generic enters the market. This reduction can be as much as 40% or more compared to the price of the reference product. However, this benefit for consumers poses significant challenges for generic companies.

When a generic company launches a product, the owners of the reference product experience a significant loss of revenue. On the one hand, they lose significant market share. On the other hand, as mentioned above, the price drops significantly. A reduction in sales of around 75% is possible. If an infringement is later found after the generic has been launched, compensation must be paid for the economic damage caused to the patent holder. According to this decision of the Provincial Court of Madrid, the first generic company or companies to enter the market, and therefore responsible for the reduction in the reference price, would face the greatest financial impact, as they would have to compensate for the price reduction in addition to the loss of sales.

As mentioned above, this decision is based on very specific circumstances, so it is uncertain whether the same criteria would be applied in other situations or whether the Supreme Court will overturn the Provincial Court's decision.

In summary, generic companies will need to evaluate whether it is advantageous to enter the market as early as possible under this new framework, with the additional financial risk that this may entail, or to wait for other companies to launch the generic and the price reduction to occur before launching their own generic. In any event, it is advisable to closely monitor future decisions on this issue, which should provide clearer guidance on the direction the Spanish courts will take in such cases.

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