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Pregabalin – second medical use claims construction in Denmark

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In one of the ongoing Pregabalin disputes, the Danish specialty court for IPR, the Maritime and Commercial Court in Copenhagen, recently rendered a 50-pages decision in a PI-action filed by Warner-Lambert (“WL”) and Pfizer against Krka and the Danish Association of Pharmacies. The Danish Health Agency intervened in support of the Danish Association of Pharmacies.

WL applied for interlocutory injunctions to be granted against Krka and each of the 220 individually named pharmacies in Denmark.

The principal claim against Krka was a claim for an order according to which Krka would only be allowed to sell Pregabalin in Denmark if it were able to ensure that the pharmaceutical was not distributed or dispensed for treatment of pain, and alternatively that Krka be ordered to submit a comprehensive and specified written instruction to Danish wholesalers and pharmacies to the effect that Pregabalin should not be distributed or dispensed for the treatment of the pain.

As regards the pharmacies, a number of different claims and alternatives were entered by Krka, principally that the pharmacies be prohibited from dispensing Pregabalin for the treatment of pain and alternatively that the pharmacies be ordered not to dispense Pregabalin for the treatment of pain, unless the prescribing doctor had stated expressly on the prescription that Pregabalin Krka must be dispensed for the treatment of pain (and that there should be no substitution).

As regards the facts of the case, Pfizer – inter alia – presented documentation that in 2009, 74 % of all Lyrica prescribed was for the treatment of pain whereas the number in 2013 was 53 %. As for the prescription and dispensing of pharmaceuticals, the court noted that a prescription in Denmark must state for which indication the pharmaceutical is prescribed just as the indication must be marked clearly on a label attached by the pharmacy to the dispensed pharmaceutical packaging. Furthermore, the Danish rules of substitution entail that the pharmacy must dispense the cheapest pharmaceutical of the same group (Lyrica and Pregabalin Krka belonged to the same group). The profit remains the same regardless of whether the pharmacy sold Lyrica or Pregabalin Krka.

On 18 September 2014, Pfizer had contacted the Danish Health Agency asking for a meeting to account for the problems following from the fact that the Danish legislation on substitution failed to take second medical use patents into account, allegedly leading to potential patent infringements.

The Danish Health Agency in turn asked the Danish Patent Office to render an opinion on this and the opinion confirmed that patent infringement could occur if a generic pharmaceutical were prescribed/dispensed for a second medical use indication protected by a third party patent.

Against this background, the Health Agency informed Pfizer that any issues relating to patent infringement should be decided by way of legal proceedings.

On 4 February 2015, the Danish Association of Pharmacies also called upon the Danish Health Agency to point to a solution of the conflict between the rules of substitution and the patent act.

The Danish Health Agency responded – as it had to Pfizer – that patent infringement issues will have to be settled by way of legal proceedings. Ultimately, the Danish Health Agency informed the Association of Pharmacies that the pharmacies must give priority to the rules of substitution.

On 11 March 2015, Krka informed all pharmacies in Denmark that it would constitute patent infringement to dispense Pregabalin Krka for the treatment of pain, and Krka called upon the pharmacies not to do so. Furthermore, Krka sent similar information to Danish MDs.

On 19 March 2015, Krka's legal counsel called upon the Danish Health Agency to resolve the rules' conflict and reiterated that Krka had no interest in – or intention to – infringe the WL second medical use patent. Also, Krka's legal counsel wrote to the Danish wholesalers, giving them the same information, and after Pfizer made Krka aware that several websites stated that Pregabalin Krka can also be used for the treatment of pain, Krka's legal counsel expressly asked each of those websites to change their wording in order that it should no longer be stated that Pregabalin Krka was authorized for the treatment of pain.

During witness examination, it was further established that the sales of Pregabalin Krka had risen steadily since its introduction to a current market share of 50 %. And that from an it-perspective, it should be technically possible to amend it-systems to avoid the existing problems.

In its decision, the Maritime and Commercial Court found in favor of Krka noting that the principle claim of the patentee (ordering Krka to ensure that the pharmaceutical be neither distributed or dispensed for pain treatment) was not sufficiently clear to be enforceable, and consequently could not serve as the basis of interim relief.

Furthermore, the Court stated, Krka already complied with the alternative claim (to instruct pharmacies) and therefore an interlocutory injunction in this regard was unnecessary. Krka was therefore acquitted and awarded legal costs.

As regards the pharmacies in their capacity as defendants, it was held that the pharmacies are private enterprises against which interlocutory injunctions may indeed be granted.

The Court found that there is no legal basis in the regulatory framework relating to pharmaceuticals which provide a legal basis for limiting or restricting the exclusive rights obtained by a patentee, and that this understanding is further substantiated by TRIPS Annex 1C, articles 28 and 30.

On that basis, the Court granted an interlocutory injunction against all 220 pharmacies while noting that any practical difficulties encountered by the pharmacies in connection with respecting such an injunction, would not be disproportionate to the patentee's interest in obtaining interim relief..

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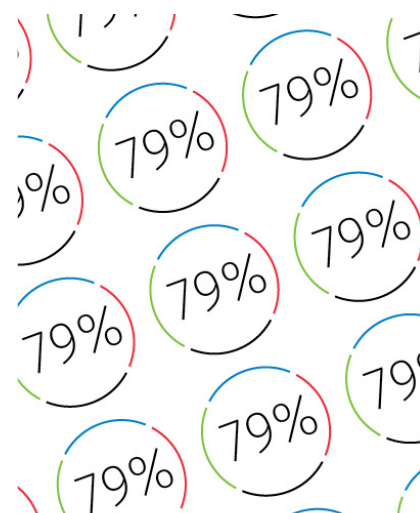
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