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Finland: Liability from Unnecessary Interim Measures Re-evaluated (Pfizer v. Ranbaxy)

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About a year ago we had an exceptional case in Finland where Ranbaxy Laboratories Limited, Ranbaxy UK Limited and Ranbaxy Pharma AB ("Ranbaxy") were awarded millions in damages in a case against Warner-Lambert Company LLC and Pfizer Oy ("Pfizer"), given in June last year (Helsinki District Court, case L 10/6838).

Regarding the background of this case, Ranbaxy is the biggest pharmaceutical company in India and among the ten biggest producers of generic drugs in the world. One of these drugs is a generic drug competing with a medicine called Lipitor®, which is produced by one of the biggest pharmaceutical companies in the world, Pfizer, and was possibly the world's most profitable medicine prior to the expiry of its patent in 2009. The case itself regarded preliminary injunctions resorted by Pfizer to stop the entry into and the sale of the aforementioned Ranbaxy's product in the Finnish market. As the Lipitor® patent was later declared invalid on the basis of another case between the same parties, it was undisputed in the case that the preliminary injunctions were unnecessarily sought.

On these grounds, Ranbaxy originally claimed damages in the amount of 23,3 million euros, mainly based on its lost profits on grounds that it was not able to release its product to the Finnish market before the expiry of Pfizer's patent, and the Helsinki District Court accepted 16,5 million euros of the claim. It goes without saying that the ruling was a rather unpleasant one for Pfizer that, as expected, appealed the decision. In one of our earlier articles we referred to the case as a warning example of what unnecessary preliminary injunctions can lead to and suggested careful consideration on whether there are valid grounds for resorting interim measures before taking such actions. While we still believe this is the correct attitude and way to proceed, in the light of the recent ruling of the Helsinki Court of Appeal in the case, essentially overruling the decision of the Helsinki District Court, it might be that we may not have as much to worry as we originally anticipated a year ago (at least for now).

Helsinki Court of Appeal, Case S 14/2532

As it was undisputed in the case that the preliminary injunctions had been unnecessary, and, on the other hand, the awarded damages were abnormally high, it seems only natural that the main focus of the decision of the Helsinki Court of Appeal was on the determination and the amount of

damages. The outcome at least in relation to the latter of these must have been a great relief for Pfizer.

While the Court of Appeal sustained that Ranbaxy had suffered damages due to the preliminary injunctions, the amount of the damages was estimated significantly lower than by the District Court, amounting to merely 231,104.76 euros. Furthermore, the Court of Appeal ordered Ranbaxy to pay a significant portion of Pfizer's overall legal expenses (after, however, first substantially cutting them) that, in the view of the Court of Appeal, amounted to altogether 503,000 euros.

To evaluate the amount of damages, it was necessary for the Court of Appeal to first evaluate, in the absence of the preliminary injunctions, 1) when and how Ranbaxy would have entered the Finnish market; 2) what was the size of the relevant market; 3) what would have been the market share acquired by Ranbaxy and thus 4) what was the amount of the lost profit. The Court of Appeal provided a reasonably well-founded ruling, essentially based on the following main issues.

First, it was held that Ranbaxy would have entered the market only about 9 months later than what Ranbaxy originally claimed, and thus it could have operated in the market merely for somewhat over a year between 2007 and 2009, had the patent not have been in force at the time. This was at least partly due to the fact that it remained unclear whether the intended distributor Orion, was actually willing to any launch before the expiry of the patent.

Second, the Court of Appeal, took into consideration the fact that the circumstances and legislation applicable to the relevant market were substantially different to those after the expiry of the patent, which had, however, been used as a reference in the calculations on the loss of profit. Here, the Court of Appeal referred to the fact that the obligatory medicine exchange, i.e. the duty to exchange the prescribed medicine into a less expensive alternative, if available, did not apply to medicines protected by a patent (subject to certain additional requirements) between the years 2006 and 2009 and thus during the hypothetical time of operation of Ranbaxy. Also, it was estimated that the common practice of doctors, especially for so long as the drugs were not subject to the exchange duty, was to prescribe medicines familiar to them, which hindered the market entry of generic products, and the situation remained unaltered until Spring 2009 when Finland transferred into the so called reference price system. Thus, it was estimated that Ranbaxy's market entry would not have been as simple and fast as claimed by Ranbaxy.

Third, the Court of Appeal seemed to pay careful attention to the role of the intended distributor of Ranbaxy's product, namely Finnish well-known and established company Orion. It attempted to assess whether Orion had withdrawn from its deal with Ranbaxy due to that the patent was still in force at the time and/or due to the preliminary injunctions. As much of the calculated lost profit was based on the reputation and market power of Orion that would have been the chosen distributor, this seemed a fair assessment. However, no answer was ever found to this question on a reliable manner as for some reason Ranbaxy chose not to have anyone from Orion testify in the proceedings. Presumably much due to this, the value-adding and cost-reducing role of Orion was more or less not taken into consideration in the ruling (with the assumption that any such testimony would have led to another outcome), which reduced the estimated lost profits for its part.

Due to these considerations, and with reference to the market entry of a comparable product Cozaar, the Court of Appeal held that the probable market share of Ranbaxy would have actually been 10 % (as opposed to the claimed share of 47 %), and the profit would have likewise likely been 10 %, which led to the awarded figures.

Given the nature of the caused damage and that it was based on the evaluation of a hypothetical scenario, the Court of Appeal further held that Ranbaxy was not in a position to be able to show the damage and its amount, and thus the damage was estimated on the basis of Section 6 of Chapter 17 of the Code of Judicial Procedure, stipulating that if no evidence is available as to the amount of damage or it can only be presented with difficulty, the court shall have the power to assess the amount, within reason. Pfizer would have wished to see more accurate calculations in this respect, but in the case the amount was finally based on the grounds referred to above and thus the referred section.

Furthermore, and unlike Pfizer claimed, the Court of Appeal did not require that Ranbaxy show how the damage caused would be divided to each of its affiliates involved, mainly due to the fact that it was deemed obvious that any profit would have anyway been divided between those entities that had been contributing to the market entry. The chosen approach was most probably the easiest way out, as the opposite would have required a lot more profound analysis, work and, consequently, time. However, due to this, the ruling unfortunately failed to provide general guidance on how the caused damage should be generally divided between those having suffered it in similar cases, which would have been much appreciated. That being said, it does seem challenging to finally divide the damage in a case where the damage is estimated by the court.

While we do find that the ruling of the Court of Appeal perhaps makes a slightly less striking headline than its earlier little brother, we find it a reasonable one and such that enables us patent lawyers potentially facing similar situations as Pfizer to sleep more soundly at night.

This entry was posted on Monday, November 2nd, 2015 at 7:32 am and is filed under Finland
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