AstraZeneca held liable for additional healthcare costs

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In a judgment of 14 October 2020 the District Court The Hague ruled in a landslide decision that AstraZeneca is liable for the extra costs that health insurance companies Menzis and Anderzorg incurred because of the wrongful enforcement of AstraZeneca's patent EP 0 907 364 (EP 364), which covers its medicinal product Seroquel, against generic quetiapine XR.[1] This is not a landslide decision because it means a change in case law, but because it is the first Dutch judgment ever in which such claims by an insurance company have been decided. It is a very thorough judgment, which is of great importance for all life science companies that have patents for medicinal products. Of course, it can and undoubtedly will be appealed.

AstraZeneca's patent on the substance quetiapine, EP 240 228, expired in 2007 and the SPC expired on 24 March 2012, whereupon generic quetiapine was introduced in the market. The price of Seroquel was 40 times higher than the price of the generic products. However, AstraZeneca also obtained a patent (EP 364) for a sustained release formulation of quetiapine, marketed as Seroquel XR. This patent would expire in May 2017. In 2012 many prescriptions for patients were switched from Seroquel to Seroquel XR. Seroquel and Seroquel XR are not substitutes. However, no generic quetiapine XR was introduced in the market and the Court has now held that this was due to AstraZeneca's enforcement of EP 364.

Generic manufacturers challenged the validity of EP 364 in full proceedings on the merits in 2011, but the District Court decided that the patent was valid in a judgment of 7 March 2012.

On 22 March 2012 the High Court in London ruled that the UK part of EP 364 lacked inventive step. In its judgment the High Court also discussed the Dutch judgment. This judgment was confirmed by the Court of Appeal on 30 April 2013.

Sandoz then tried to reach agreement with AstraZeneca on a delayed market introduction, but the offer was refused by AstraZeneca, whereupon Sandoz launched at risk. In a judgment in preliminary injunction proceedings of 15 August 2013 the District Court The Hague issued an injunction for infringement of EP 364 against Sandoz. AstraZeneca had this judgment served on Sandoz on 20 August 2013. This is important, since because of the service of the judgment it was no longer Sandoz' business decision to discontinue generic quetiapine XR, since Sandoz was now obliged to abide by the injunction. Under Dutch law this meant that AstraZeneca would be automatically liable vis-a-vis Sandoz if the injunction would be overturned. The Court discussed this in some detail, as will be explained hereafter.

On appeal in the validity proceedings the Dutch part of EP 364 was held invalid by the Court of Appeal The Hague in a judgment of 10 June 2014. This automatically meant that AstraZeneca had wrongfully enforced EP 364 against Sandoz between 20 August 2013 and 10 June 2014. That in itself is nothing new.

[1] District Court The Hague 14-10-2020, ECLI:NL:RBDHA:2020:10160, *Menzis & Anderzorg v AstraZeneca,* https://tinyurl.com/yydd64r8

But Sandoz is not the claimant in the current proceedings, since the claimant is the insurance company Menzis.

After the patent had been declared invalid, Menzis included generic quetiapine XR as the preferred product in its reimbursement policy on 1 January 2015. Subsequently Menzis claimed that AstraZeneca was liable for damages to the amount of € 4 million, incurred by Menzis because of AstraZeneca's wrongful enforcement of EP 364. This claim has now been awarded by the District Court, although the actual amount still needs to be decided.

The damages claimed by Menzis relate to the period from expiration of the substance SPC, 24 March 2012, until the Court of Appeal judgment, so not only the period that started with enforcement of the preliminary injunction against Sandoz. The reason is that AstraZeneca would have claimed an exclusive market position on the basis of EP 364 as of the expiration of the SPC on quetiapine. The Court however did not follow this reasoning and took the service of the preliminary injunction on 20 August 2013 as the starting point for damages.

Menzis' claim was based both on tort and on unjustified enrichment (which is a ground for liability under article 6:212 Dutch Civil Code). The market share and the price of Seroquel were maintained at an artificial high level, which led to unnecessary high costs of healthcare, for which Menzis had to reimburse its insured patients.

The District Court held that the mere fact that a patent is revoked doesn't mean that the patentee is automatically liable for maintaining the patent. The relevant Supreme Court judgment on which this is based[2] is not limited to a claim by a competitor, but its reasoning also extends to claims by other parties who claim to be harmed by an unjustified exclusivity of the patentee. According to the District Court, this exclusivity determines the behaviour of generic manufacturers, on which the insurance company is dependent. The Court continues that maintaining the Dutch part of EP 364 after the UK part had been held invalid in itself also doesn't create liability. Liability of the patentee requires a further act than purely maintaining the patent, such as actually invoking the patent against a third party at a point in time when the patentee knows or should have realized that there was a non-negligible chance that the patent will be declared invalid. Forcing a competitor to abide by a preliminary injunction is such an act that may create liability.

In the present case both parties have assumed that service of the preliminary injunction is the first act by which AstraZeneca went further than purely maintaining EP 364 and actually enforced the patent by legal means. Therefore, the Court didn't need to decide whether this is correct, but in my opinion that would certainly have been the decision if AstraZeneca had disputed this. Thus AstraZeneca actively prevented the market introduction of generic quetiapine XR. Therefore by enforcing the preliminary injunction while EP 364 was later held invalid AstraZeneca committed a tort vis-a-vis Sandoz.

The Court rules that is doesn't need to decide whether service of the preliminary injunction on Sandoz also constitutes a tort of AstraZeneca vis-à-vis the insurance company Menzis, since it decides to award Menzis' claims on the basis of unjustified enrichment, and therefore doesn't need to address the issue of tort..

[2] Supreme Court 29-9-2006, ECLI:NL:HR:2006:AU6098, *CFS Bakel v Stork*, https://tinyurl.com/y5kw28ne

According to the Court the unlawful enforcement of EP 364 had direct consequences for the whole market for quetiapine XR products, taking into account that AstraZeneca did not dispute that as a consequence no generic company introduced quetiapine XR until EP 364 was invalidated by the Court of Appeal, although they were ready to do so and had already prepared for a market introduction. As a consequence Menzis could not apply a preferred product policy. If competitor products had been on the market, Menzis would have indicated a preferred product and the costs of reimbursement of quetiapine XR to insured patients would consequently have been much lower (since under health insurance law Menzis would not have been obliged to reimburse more than the price of the preferred product). AstraZeneca thus benefited from its market exclusivity by means of its large market share and the relatively high price it could charge for Seroquel XR, which Menzis was thus forced to reimburse. As a consequence AstraZeneca enjoyed an unjustified enrichment to the detriment of Menzis, or at least to the detriment of the patients who had a Menzis insurance.

AstraZeneca had also raised as a defence that Menzis had not incurred any damages, since it could raise the insurance premium that it would charge to its clients to recover the additional costs. Menzis pointed out that health insurance under Dutch insurance law is technically an insurance against damages, as a consequence of which claims for damages that the insured may have are automatically transferred under article 7:962 Dutch Civil Code to the insurance company that reimburses its insured. Menzis therefore has a claim to the amount of the price difference between the price of Seroquel XR and the price it would have had to reimburse for generic quetiapine XR, for each reimbursed patient.

The amount of the insurance premium that Menzis charges is irrelevant in the view of the Court, since Menzis can invoke the transferred claims for damages, which is independent of Menzis' own behaviour. Besides, the premium is decided by many factors and it is not directly determined by the price of a specific medicinal product. Further, if that price would influence the premium, the reimbursement of damages by AstraZeneca would also influence the premium, by which the Court seems to indicate that Menzis will not benefit from the damages claim. The Court also mentions that Menzis is a non-profit company, which may have played a role here.

AstraZeneca had also argued that awarding this claim would erode the patent system. The Court held that the public interest is served by a system that stimulates inventions, but on the other hand there is also a public interest in affordable healthcare by way of a free market. The promotion of free competition can be a ground to hold a patentee who enforces a patent accountable in certain circumstances, if his pretended claims are incorrect, as in the present case. In addition there is a public interest that a patentee is not rewarded by improper profits if he wrongfully enforces a patent. The Court adds that the fact that there can be a liability of patentees towards an insurance company is not an undesirable extension of the liability of patentees. According to the Court the reproach made against AstraZeneca is completely in line with the prevailing legal views, whereas AstraZeneca's behaviour has direct consequences for insurance companies and their insured, who have no options, since they are dependent on the market for medicinal products.

In the end Court could not yet actually award damages in this judgment, since it needed some further information on the amount of damages. Therefore it ruled that AstraZeneca is liable for damages towards Menzis, but asked Menzis to submit some additional information.

The Court added that the fact that it already issues a decision that AstraZeneca is liable also means that this interlocutory judgment can be appealed.

In my view the Court's reasoning is completely logical and well-founded. The outcome therefore is not really a surprise from a legal perspective, the surprise rather is the fact that an insurance company did bring such a claim or actually that this hasn't happened before. I think that it is quite likely that this ruling will be upheld on appeal. Certainly, life science companies do need to take this into account when deciding their patent enforcement policy. On the other hand, liability in this case was the result of enforcing an injunction that was not yet final, it was not the result of obtaining that injunction. Thus, the evaluation that needs to be made when deciding to actually enforce such an injunction is whether there is sufficient confidence that the patent in the end will be held valid and infringed. That's an important business decision that carries a clear risk, but not such an unusual situation in developing a patent strategy.