AstraZeneca not held liable for additional healthcare costs on appeal – healthcare insurance company can't claim damages for patent enforcement, at least not in this case

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On 14 October 2020 the District Court The Hague held AstraZeneca liable for damages incurred by healthcare insurance company Menzis, resulting from an unjustified enrichment of AstraZeneca.[1] This in turn resulted from enforcing a patent that was later invalidated by the Court of Appeal The Hague. I commented on this judgment in an article, published on www.ie-forum.nl on 15 October 2020, in which I called this a landslide decision, because this was the first such claim by an insurance company.[2] The judgment has now been overturned by the Court of Appeal.

The District Court had held that enforcing a preliminary injunction against Sandoz constituted a tort, since the patent was later invalidated with retroactive effect, which meant that retroactively AstraZeneca was not entitled to such enforcement. Sandoz is a generic company that offered the generic product at a lower price than AstraZeneca's product. Menzis has to repay patients for the costs of the product at the higher level. Menzis had actually claimed that there was strict liability for such alleged wrongful enforcement. Although the District Court was not very specific on this, it seemed to assume such liability quite easily.

The Court of Appeal disagrees.[3] It deals extensively with liability for enforcement of a patent that is later invalidated. The most relevant facts are as follows. AstraZeneca had a basic patent for quetiapine (Seroquel®), and a consecutive SPC which expired on 23 March 2012. AstraZeneca also had a later delayed release formulation patent EP 0 907 364, which was the subject of the litigation. The UK part of this patent was held invalid by the High Court in London on 22 March 2012, which was confirmed by the Court of Appeal on 30 April 2013. The District Court The Hague however held the Dutch part of the patent valid in an action on the merits brought by Sandoz in a judgment of 7 March 2012.[4] There was no counterclaim for infringement in this action. AstraZeneca then claimed a preliminary injunction against Sandoz, which was awarded by the District Court The Hague on 15 August 2013.[5] AstraZeneca enforced this judgment by serving it on Sandoz on 20 August 2020. Finally the Dutch part of the patent was

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[1] District Court The Hague 14-10-2020, ECLI:NL:RBDHA:2020:10160, *Menzis v AstraZeneca*, see www.rechtspraak.nl.

[2] Wouter Pors, AstraZeneca held liable for additional healthcare costs, www.ie-forum.nl, IEF19496.

[3] Court of Appeal The Hague 28-12-2021, 200.286.638/01, *AstraZeneca v Menzis*, published by Willem Hoyng at http://eplaw.org/nl-astrazeneca-v-menzis-appeal/, with a translation into English.

[4] District Court The Hague 7-3-2012, 397921 / HA ZA 11-1977, *Sandoz & Hexal v AstraZeneca*, www.ie-forum.nl, IEF 11011.

[5] President of the District Court The Hague 15-8-2013, ECLI:NL:RBDHA:2013:10983, *AstraZeneca v Sandoz*, see www.rechtspraak.nl.

invalidated by the Court of Appeal on 10 June 2014 for lack of inventive step.[6] Generic companies then started marketing quetiapine in July 2014.

Menzis claimed that there is strict liability for enforcing the preliminary injunction, but the Court disagrees. Referring to the Supreme Court judgment in *CFS Bakel v Stork* (of 2006), it reiterates that there is no strict liability in the relationship between the patent owner and the alleged infringer if the patent is later invalidated.[7] A certain level of culpability is always required.

There was an earlier Supreme Court judgment from 1984 which seemed to indicate otherwise (*Ciba Geigy v Voorbraak*),[8] so the Court also had to deal with that. In *Ciba Geigy v Voorbraak* the Supreme Court ruled that a party that enforces a preliminary injunction would in principle be liable if it is later decided in full proceedings on the merits that there was no right to enforce. According to the Court of Appeal in the AstraZeneca case that judgment was limited to the facts at hand. The liability in that case was also related to the fact that forfeited monetary penalties for violation of a preliminary injunction could not be reversed by the judgment on the merits, that could only be done in an appeal against the preliminary injunction. In that specific case Voorbraak had not filed such an appeal. Apparently the damage claimed by Voorbraak included penalties paid to Ciba Geigy.[9] The Court of Appeal concludes that this judgment at least doesn't provide strict liability in relation to a third party who is not directly subject to the enforcement, which is the issue at hand in the AstraZeneca case. The Court also adds that it is questionable whether this older judgment is in conformity with the CJEU case law in *Bayer v Richter*, in which the CJEU required "*that legislation permits the court to take due account of all the objective circumstances of the case, including the conduct of the parties, in order, inter alia, to determine that the applicant has not abused those measures*".[10] In my view *Ciba Geigy v Voorbraak* is not in line with the Enforcement Directive (of 2004)[11] and the CJEU case law, but that doesn't really matter because the later Supreme Court judgment in *CFS Bakel v Stork* (of 2006) is. After all, *Ciba Geigy v Voorbraak* was decades before the Enforcement Directive and in *CFS Bakel v Stork* the Supreme Court specifically states that its requirement of culpability is in line with the case law in other European countries.[12] Although the Supreme Court doesn't refer to the Enforcement Directive, which was not yet in force at the time of the judgments in first instance and on appeal, the ruling in *CFS Bakel v Stork* in my view is in line with the Enforcement Directive and *Bayer v Richter*. The Court of Appeal rules at the end of its judgment in *AstraZeneca v Menzis* that there is no need to refer questions on the consequences of *Bayer v Richter* for Dutch law to the CJEU, since "*the answer to those questions is not relevant for the outcome of this case*".

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[6] Court of Appeal The Hague 10-6-2014, ECLI:NL:GHDHA:20 14:2500, *Sandoz v AstraZeneca*, see www.rechtspraak.nl.

[7] Supreme Court 29-9-2006, ECLI:NL:HR:2006:AU6098, *CFS Bakel v Stork*, paragraph 5.4 – 5.8, see www.rechtspraak.nl.

[8] Supreme Court 16-11-1984, ECLI:NL:PHR:1984:AG4901, BIE 1985/30, *Ciba Geigy v Voorbraak*, paragraph g.3.4 – g.3.7.

[9] The Supreme Court judgment is not very clear on these facts, but does mention that the amount claimed included undue payments.

[10] CJEU 12-9-2019, C-688/17, ECLI:EU:C:2019:722, *Bayer v Richter*.

[11] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights, implemented in Dutch law by the Act of 16-02-2006, Stb 135.

[12] Paragraph 5.7.

Thus, there is no strict liability versus an alleged infringer. According to the Court there is also no ground to assume strict liability versus a third party, such as the "non-competitor" Menzis. Besides, the patent was never enforced directly against Menzis. The public interest in affordable medicines and healthcare doesn't change this. On the other hand, strict liability could be counterproductive, since it would discourage innovation, also when it results in valid patents. Thus the Court clearly rejects strict liability for patent enforcement.

With regard to the culpability of the enforcement, Menzis claims that it was evident that the patent was invalid. The test under the law is whether AstraZeneca knew or should have realized that there was a reasonable chance that its patent was invalid (the criterion confirmed in *CFS Bakel v Stork*) and should therefore have refrained from enforcement. The Court of Appeal rules that this is not the case, since the District Court upheld the patent in full proceedings on the merits. It was only invalidated after the enforcement started. On appeal in the invalidity case AstraZeneca claimed that the man skilled in the art would not have been motivated to develop a delayed release formulation and would not have had a reasonable expectation of success, which are indications for an inventive step. Menzis argued that this would be countered by a single prior art publication on which Menzis relied. The Court states that its finding of lack of inventive step is not based on this publication and certainly not on this publication alone. The English judgments – which were issued prior to the preliminary injunction in the Netherlands – also didn't mean that AstraZeneca should have refrained from enforcement, since for the Dutch part of the patent they are in principle allowed to rely on the Dutch judgment on the merits on validity. The Court adds that at the time of enforcement a majority of the foreign courts had come to the same conclusion as the Dutch Court. This by the way shows that Dutch courts do take foreign judgments into account when forming their own opinion.

Although this outcome is good for AstraZeneca, unfortunately the Court rules that it doesn't need to decide whether a patent owner can be liable versus a healthcare insurance company if in the period of enforcement the patent owner knows or should realize that there is a reasonable chance that its patent is invalid, because that test isn't met in this case for the enforcement against Sandoz. This still leaves open the possibility that a patent owner is not only liable for damages incurred by an alleged infringer in case of enforcement of a clearly invalid patent, but also for damages incurred by a health insurance company.

Menzis also argued that AstraZeneca had abused a dominant position in the relevant market, which would have been in violation of competition law. However, Menzis' definition of the relevant market was incorrect, since it didn't include all the relevant substitutes for quetiapine. More importantly, the Court rules that, since it finds that AstraZeneca can't be blamed for maintaining and enforcing the patent under the above-mentioned test, there can be no abuse under article 102 TFEU. This very short paragraph basically refers to the balance between patent protection and freedom of competition; enforcing a valid patent in general can't result in abuse of a position, not even if that position is dominant. This reflects the ruling of the CJEU in paragraph 46 of its judgment in *Huawei v ZTE*.[13]

Finally the Court of Appeal has to deal with the claim for unjustified enrichment, which was granted by the District Court. This is the easy part; since the Court rules that there was no unlawful conduct versus

[13] CJEU 16-7-2015, C-170/13, ECLI:EU:C:2015:477, *Huawei v ZTE*.

third parties, this conducted also could not have led to an unjustified enrichment of AstraZeneca at the expense of Menzis.

The retroactive effect of the invalidation of the patent doesn't change that. According to the Court it also follows from the criteria of *CFS Bakel v Stork* that the enrichment doesn't have an unjustified character. Besides, it is a result of the sales agreements concluded by AstraZeneca (which in the end leads to the reimbursement of patients by their insurance company). Article 75 section 6 of the Dutch Patent Act specifically provides that the retroactive invalidation of a patent doesn't affect agreements concluded prior to the invalidation, with regard to performance under those agreements prior to the invalidation.[14] There can be an obligation to repay amounts paid based on equity, but according to the Court of Appeal this was not intended for situations like these. Besides, the fact that AstraZeneca can't be made a reproach for its enforcement also means that there is no reason to deviate from the principle that performance under agreements prior to invalidation .is not affected.

What conclusions can be drawn from this judgment?

The test for wrongful enforcement of a later invalidated patent provided in *CFS Bakel v Stork* poses a relatively high threshold for liability. It indeed is a safer approach not to start with preliminary injunction proceedings, but first to obtain a judgment on the merits in first instance on validity. In almost all cases started by the patent owner there will be a counterclaim for invalidity, which achieves this. If a generic company first starts an invalidity action, the patent owner can of course counterclaim for an injunction on infringement. The current case is somewhat rare, since there was no such counterclaim, instead AstraZeneca claimed a preliminary injunction after the patent was found valid.

Enforcing a patent for which the patent owner has good reasons that it is valid, doesn't constitute a tort. That can be different if the patent owner knows or should realize that there is a reasonable chance that its patent is invalid, but that is not easily assumed. Nevertheless, patent owners should carefully evaluate the strength of their patent, as always. Anyway, except for exceptional cases, litigating a patent doesn't create liability, the risk normally is in the enforcement of an injunction.

Whether an insurance company can claim damages from a patent owner who wrongfully enforced an injunction against a generic company is still not completely clear. However, the fact that the damages result from agreements concluded by the patent owner prior to invalidation of the patent makes that very difficult.

Maybe this is not the last on this issue. The deadline for filing a Supreme Court appeal only expires on 28 March.

[14] There are two typos in this paragraph of the judgment, where the Court refers to article 70 instead of 75.

Links to the sources:

District Court The Hague 14-10-2020, ECLI:NL:RBDHA:2020:10160, *Menzis v AstraZeneca*: ECLI:NL:RBDHA:2020:10160, Rechtbank Den Haag, C/09/541261 / HA ZA 17-1084 (rechtspraak.nl)

Wouter Pors, AstraZeneca held liable for additional healthcare costs: https://www.ie-forum.nl/artikelen/wouter-pors-astrazeneca-held-liable-for-additional-healthcare-costs

Court of Appeal The Hague 28-12-2021, 200.286.638/01, *AstraZeneca v Menzis,*

Dutch: http://eplaw.org/document/nl-az-v-menzis-appeal/

English: http://eplaw.org/document/nl-az-v-menzis-appeal-en/

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President of the District Court The Hague 15-8-2013, ECLI:NL:RBDHA:2013:10983, *AstraZeneca v Sandoz*: ECLI:NL:RBDHA:2013:10983, Rechtbank Den Haag, C-09-439326 - KG ZA 13-295 (rechtspraak.nl)

Court of Appeal The Hague 10-6-2014, ECLI:NL:GHDHA:20 14:2500, *Sandoz v AstraZeneca*: ECLI:NL:GHDHA:2014:2500, Gerechtshof Den Haag, 200.108.409-01 (rechtspraak.nl)

Supreme Court 29-9-2006, ECLI:NL:HR:2006:AU6098, *CFS Bakel v Stork*: ECLI:NL:HR:2006:AU6098, voorheen LJN AU6098, Hoge Raad, C04/334HR (rechtspraak.nl)

CJEU 12-9-2019, ECLI:EU:C:20 19:722, *Bayer v Richter*: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62017CJ0688&from=NL