SUPREME COURT OF THE NETHERLANDS

CIVIL CHAMBER

Number 22/01071
Date 3 November 2023

JUDGMENT

In the matter of

1. MENZIS ZORGVERZEKERAAR N.V.,
established in Wageningen,
2. ANDERZORG N.V.,
established in Wageningen,
PLAINTIFFS in cassation,
hereinafter jointly referred to as Menzis,
lawyer: S.M. Kingma,

versus

1. ASTRAZENECA B.V.,
established in Zoetermeer,
2. ASTRAZENECA AB,
established in Södertälje, Sweden,
DEFENDANTS in cassation,
hereinafter jointly: AstraZeneca,
Lawyers: W.A. Hoyng and F.W.E. Eijsvogels.

1. Course of the proceedings

For the course of the proceedings on the facts, the Supreme Court refers to:

a. the judgments in case C/09/541261 / HA ZA 17/1084 of the District Court of The Hague dated 31 January 2018 and 14 October 2020;
b. the judgment in case 200.286.638/01 of the Court of Appeal of The Hague dated 28 December 2021.

Menzis has filed an appeal in cassation against the judgment of the Court of Appeal. AstraZeneca filed a defense motion to dismiss.

The case was presented orally for the parties by their lawyers, and for Menzis also by R. de Graaff.

The conclusion of Advocate General G.R.B. van Peursem seeks dismissal of the appeal in cassation.

The lawyer of Menzis responded to that conclusion in writing.

2. Starting points and facts

2.1. The following can be assumed in cassation.

(i) Menzis is a health insurer as referred to in art. 1, under b, Health Insurance Act. Menzis has no profit motive.

(ii) AstraZeneca AB and AstraZeneca B.V. belong to the AstraZeneca Group, which is engaged in drug development.

(iii) Within the AstraZeneca group, a drug for the treatment of schizophrenia and bipolar disorder, among others, has been developed with quetiapine as the active substance. This drug was marketed in the form of tablets under the brand name Seroquel, initially only in an immediate release (IR) formulation (Seroquel IR).

(iv) Quetiapine was protected as an active substance by European patent EP 240 228 of (a predecessor of) AstraZeneca Inc. until 23 March 2007. On the basis of this patent, a supplementary protection certificate 980022 (hereafter: the SPC) was granted in the Netherlands, which expired on 23 March 2012.

(v) With European patent EP 0 907 364 (hereafter the patent), granted on 14 August 2002 on the basis of an application dated 27 May 1997, AstraZeneca AB obtained protection for the sustained release formulation of quetiapine. The patent has (had) been effective in several European countries, including the Netherlands.

(vi) AstraZeneca B.V. obtained a Dutch marketing authorization for a sustained release formulation of quetiapine in August 2007 and subsequently marketed the drug in the Netherlands under the brand name Seroquel XR.

(vii) As of 2012, patients were prescribed Seroquel XR rather than Seroquel IR in many cases.

(viii) Almost immediately after the ABC expired on 23 March 2012, generic quetiapine tablets in an immediate release formulation entered the Dutch market, such as the generic quetiapine IR from Accord Healthcare (hereafter Accord).

(ix) Menzis included Accord's generic products in its preference policy for all strengths of quetiapine tablets IR as of 1 May 2012.

(x) Accord and other competitors of AstraZeneca engaged in the sale and distribution of generic drugs had obtained marketing authorizations for sustained release formulations of quetiapine, but did not enter the market with those tablets after the ABC expired on 23 March 2012.

(xi) A number of competitors, including Sandoz B.V. ("Sandoz"), brought proceedings against AstraZeneca AB, claiming revocation of the Dutch part of the patent. By judgment of 7 March 2012, the District Court of The Hague dismissed those claims.

(xii) By judgment of 22 March 2012[1], the English High Court held that the English part of the patent was not inventive and therefore invalid. This ruling was upheld on appeal on 30 April 2013.

(xiii) AstraZeneca AB then sought interim injunctive relief to prohibit Sandoz from infringing the patent in the Netherlands. Sandoz countered that the District Court's judgment holding the patent valid contains manifest errors and that AstraZeneca AB brought the claims only to harm Sandoz. By judgment of 15 August 2013[2], the interim measures judge rejected those defenses and granted AstraZeneca AB's claims. AstraZeneca AB served the summary judgment on Sandoz on 20 August 2013.

(xiv) By judgment of 10 June 2014[3], the Court of Appeal of The Hague set aside the 7 March 2012 judgment mentioned above under (xi) and revoked the Dutch part of the patent for lack of inventive step.

(xv) As of July 2014, competitors of AstraZeneca launched their sustained release quetiapine tablets.

(xvi) Menzis included Accord's generic sustained release quetiapine tablets in its preference policy as of 1 January 2015.

(xvii) By letters dated 22 December 2016, Menzis held AstraZeneca liable for damages suffered by Menzis as a result of maintaining the patent, or at least keeping (potential) generic competitors off the market.

2.2. Menzis claimed in these proceedings a declaratory judgment that AstraZeneca had acted unlawfully towards Menzis, or at least had been unjustly enriched at Menzis' expense, and was obliged to compensate Menzis' damages, with a (joint and several)

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[1] Teva UK Ltd v AstraZeneca AB [2012] EWHC 655 (Pat).

[2] District Court of The Hague August 15, 2013, ECLI:NL:RBDHA:2013:10983.

[3] Court of Appeal The Hague 10 June 2014, ECLI:NL:GHDHA:2014:2500.

order for AstraZeneca to compensate Menzis' damages, to be assessed at € 4,168,935.67, or at least at an amount to be determined.

2.3. The district court ruled that AstraZeneca had been unjustly enriched at the expense of Menzis, through its insureds, and was liable to pay the claim for damages transferred from those insureds to Menzis by way of subrogation.[4]

2.4. The court of appeal overturned the district court's judgment and held that there was no unlawful act or unjust enrichment.[5] To this end, the court of appeal considered the following (footnotes in the cited judgment not reproduced):

> "no unlawful act
>
> *no strict liability*
>
> 5.1 The court of appeal rejects the argument of Menzis that AstraZeneca had acted unlawfully vis-à-vis Menzis by relying on the patent in the period from 24 March 2012 (date of the end of ABC protection) to 10 June 2014 (date of the judgment declaring the Dutch part of the patent invalid), even though this patent was retroactively revoked afterwards for lack of inventive step. The argument of Menzis argument that the revocation of the patent is at AstraZeneca's risk finds no support in law. The court will explain this below.
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> 5.2 It is not disputed that in the relationship between a patentee and his competitors, strict liability does not apply to a reliance on a patent that is later revoked. It follows from the CFS Bakel/Stork judgment that Dutch law conforms to the view - also held in our neighboring countries - that some form of culpability on the part of the patentee is required in order to assume liability after the revocation of a patent. That the patentee who has invoked the patent is liable for the damage suffered by his competitors or others as a result of that conduct on the sole ground that a patent is subsequently revoked is not accepted, according to that judgment.
>
> 5.3 Unlike Menzis argues, there is no reason to assume strict liability in the patent holder's relationship with non-competitors such as Menzis. On the contrary, the fact that Menzis does not itself produce or market drugs and AstraZeneca therefore never invoked the patent against Menzis, argues against the application of strict liability in the relationship with Menzis. The fact that Menzis did not have the opportunity to "ignore" the patent also does not substantially distinguish Menzis' position from that of the competitor in the case that led to the CFS Bakel/Stork judgment. In that case, the patent holder CFS Bakel had invoked its patent against (potential) customers of its competitor Stork. The resulting damage to Stork could also not be prevented by Stork simply ignoring CFS Bakel's patent claim.

[4] District Court of The Hague October 14, 2020, ECLI:NL:RBDHA:2020:10160.

[5] Court of Appeal The Hague 28 December 2021, ECLI:NL:GHDHA:2021:2535.

5.4 Nor does the fact that this case involves a patent on a drug compel the application of strict liability. In itself, Menzis rightly points to the general interest of good and affordable care. Strict liability can contribute to this in the sense that the prices of drugs will go down if patent holders no longer invoke their patents or damages are paid if those patent holders do and the patent is subsequently revoked. However, as the Supreme Court considered in the CFS Bakel/Stork judgment, strict liability can also reduce the incentive to develop innovative drugs. The latter is also not in the interest of health care. The fact that in this case the drug claimed by AstraZeneca in the patent was found not to be inventive does not change that. Accepting strict liability would also affect holders of valid patents. Indeed, strict liability implies that a patent holder should never rely on his estimation that the patent will survive invalidity proceedings.

5.5 The fact that AstraZeneca had 25 years of protection for the active ingredient quetiapine also does not compel the strict liability advocated by Menzis. Unlike Menzis argues, AstraZeneca's reliance on the patent did not extend that market exclusivity. Indeed, the patent in question does not cover that active ingredient as such, but the sustained release formulation of quetiapine. During the period covered by Menzis' claim, competitors were free to offer generic versions of Seroquel IR, and it is not in dispute that competitors actually did so.

5.6 Nor does strict liability follow from the Health Insurance Act and the Supreme Court's interpretation of it in the VGZ/Nutricia and CZ/Momentum judgments. Health insurers such as Menzis have a duty under the Act to ensure good and efficient care and to control care costs where possible. The Supreme Court clarified in the aforementioned judgments that violation of that statutory duty of health insurers can also be unlawful with respect to healthcare providers. It does not follow that the holder of a patent that has been invalidated must bear the risk of the incorrectness of his assumption that the patent was valid.

5.7 Menzis' reference to the Ciba Geigy/Voorbraak judgment cannot lead to a different opinion either. In that judgment, the Supreme Court ruled that, in principle, it should be assumed that the person who, by threatening enforcement, forced his opposing party to behave in accordance with an injunction issued in summary proceedings, has acted unlawfully if, as the judgment on the merits of the case shows with hindsight, he was not entitled to require the opposing party to refrain from the acts in question. Irrespective of whether that judgment is consistent with the rules of the European Enforcement Directive as interpreted in the Court of Justice's judgment in Bayer/Richter (AstraZeneca disputes that), it does not follow from the Ciba Geigy/Voorbraak judgment that the patentee has strict liability to others other than the party who has been forced to comply with an interlocutory injunction by threat of enforcement. The rationale for this judgment focuses exclusively on the special position of that opposing party and is based in part on the consideration that penalties forfeited for failure to comply with the interlocutory injunction will continue to be forfeited following a contrary judgment on the merits. The latter strikes a certain balance between the clashing interests. That balance is lacking when extending strict liability to parties such as Menzis, which are not liable to forfeit penalties for non-compliance with the injunction.

5.8 Incidentally, Menzis also does not take the position that AstraZeneca is liable because AstraZeneca served an interlocutory judgment. Menzis believes that the strict liability assumed in Ciba Geigy/Voorbraak should apply by analogy, because patent grant, like an interlocutory judgment, is an interim measure. This reasoning already cannot succeed because, as the court of appeal has considered above, the judgment in Ciga Geigy/Voorbraak is not exclusively based on the provisional nature of a decision in summary proceedings, but also on (the precisely definitive nature of) the indebtedness of forfeited penalties. Moreover, a decision of the European Patent Office granting a patent cannot be equated with a judgment in summary proceedings. The fact that that decision of the EPO can be revoked and annulled does not make that decision a provisional measure by its nature like a summary judgment. Moreover, the validity of (the Dutch part of) the patent in this case was not only tested by the EPO but also by the Dutch court on the merits.

5.9 Nor does the fact that the patent was invalidated on the ground that the claimed invention was obvious to the average skilled person imply that AstraZeneca knew that the invention was non-inventive. That it is now established that the claimed invention was obvious is somewhat different from establishing that the non-inventiveness was obvious. As the court of appeal will explain below in the context of assessing culpability, the latter is not the case.

no culpability

5.10 It can be left open whether AstraZeneca's reliance on the patent in the period between the expiry of the SPC and the judgment of this Court of Appeal in the nullity cases was unlawful vis-à-vis Menzis if AstraZeneca knew, or should have realized, in that period that a serious, non-negligible chance existed that the patent would not stand up in opposition or nullity proceedings. In the view of the Court of Appeal, it cannot be concluded that AstraZeneca knew or should have known that at the time.

5.11 In this regard, Menzis first argues that in the relevant period there could not reasonably be any discussion about the invalidity of the patent and that this invalidity was even evident. This cannot be sustained in light of the judgment of the District Court of The Hague dated 7 March 2012, in which the District Court precisely concluded that the patent was valid. In support of its argument about the obviousness of invalidity of the patent, the court refers Menzis mainly to the judgment given by this Court of Appeal in the 10 June 2014 judgment. However, that judgment was not yet available at the relevant time. The fact that the court of appeal came to a different judgment on inventive step than the district court does not imply that AstraZeneca already knew or should have realized, prior to that judgment, that a serious, non-negligible chance existed that the patent would still be invalidated on appeal.

5.12 More substantively, Menzis argued that AstraZeneca defended the patent's inventive step by arguing that the average skilled person would not have been motivated to develop an XR formulation of quetiapine and would not have had a reasonable expectation of success. According to Menzis, that contention was obviously untenable because a

publication by Gefvert et al. identified by the court of appeal as the closest prior art concluded, ‘a more convenient dosage regimen would be beneficial’. From that conclusion by Gefvert et al. however, it does not follow without question that the average skilled person would have been motivated to develop an XR formulation of quetiapine and would have had a reasonable expectation of success in doing so, also in light of what AstraZeneca has argued about that motivation and expectation of success. In its 10 June 2014 judgment, this court of appeal also did not - let alone exclusively - base the lack of inventive step on that conclusion of Gefvert et al. That AstraZeneca's aforementioned contention was evidently untenable for other substantive reasons, Menzis did not and certainly did not sufficiently substantiate.

5.13 Second, Menzis argues that the English court, in a judgment dated 22 March 2012, found the claimed invention not inventive, and that other foreign courts have also reached that conclusion. That circumstance, too, does not entail in this case that AstraZeneca knew, or should have known, that a serious, non-negligible chance existed that the patent would not stand up in opposition or invalidity proceedings. This case involves reliance on the Dutch part of the European patent. In that context, the patentee may, in principle, rely on the validity judgment of the Dutch court on the merits given by the 7 March 2012 judgment. Moreover, the foreign courts that had ruled on the validity of the patent in the relevant period had in the majority reached the same decision as the Dutch court.

(...)

no unjust enrichment

5.16 Menzis' reliance on unjust enrichment within the meaning of Article 6:212 of the Dutch Civil Code cannot succeed either. The aforementioned opinion that AstraZeneca did not act unlawfully by invoking its patent rights vis-à-vis third parties in the relevant period implies that and why the enrichment alleged by Menzis is not of an unjustified nature. The circumstance that the revocation of the patent is retroactive does not change this.

5.17 The foregoing judgment on the unjustified nature of the alleged enrichment follows from the CFS Bakel/Stork judgment. The judgment also fits within the scheme of the law. Menzis argues that AstraZeneca was enriched by the profits AstraZeneca made from the sale of Seroquel® XR. However, that enrichment is in principle justified by the agreements under which AstraZeneca sold those products. The retroactive effect of the annulment of the patent does not change that. Article 75(6) Dutch Patent Act provides that such retroactive effect does not affect agreements entered into before the revocation to the extent that they were executed prior to the revocation. That rule applies in this case and serves legal certainty.

5.18 Article 75, sixth paragraph, Dutch Patent Act provides that, for reasons of equity, reimbursement of amounts paid under the agreements may be claimed to the extent justified by the circumstances. The legislative history shows that the legislator had in mind, among other things, the situation where a licensee has paid a license fee in advance for a long period of time and the patent is revoked shortly thereafter. A similar situation does

not arise here. There are no other equity considerations that could justify a deviation from the starting point chosen by the legislator. On the contrary, the fact that, as the court of appeal held above, AstraZeneca cannot be blamed for invoking the patent in the relevant period argues against departing from that premise."

3. Assessment of the plea

3.1. Subsection 1.1 of the plea complains that the Court of Appeal wrongly found, in findings 5.16-5.17, that the finding that AstraZeneca did not act unlawfully by invoking its patent rights against third parties in the relevant period implies that and why the enrichment alleged by Menzis is not unjustified. The mere fact that Menzis did not act unlawfully does not automatically mean that the enrichment is justified, the section argues. Subsection 1.2 complains that the Court of Appeal has in any case failed to recognize that in this case the enrichment of AstraZeneca is unjustified, or at least that the Court of Appeal has insufficiently substantiated why this enrichment vis-à-vis Menzis is nevertheless justified in this case.

3.2. Subsection 1.1 correctly assumes that the circumstance that AstraZeneca did not act unlawfully does not automatically imply that the enrichment alleged by Menzis is justified. However, it cannot lead to cassation for lack of factual basis. The Court of Appeal did not dismiss the reliance on unjust enrichment solely on the ground that AstraZeneca had not acted unlawfully. The circumstances on the basis of which the Court of Appeal ruled that AstraZeneca had not acted unlawfully (see the Advocate General's Opinion at 3.21) also support its judgment that AstraZeneca had not been unjustly enriched.[6] That finding does not show an error of law and did not require any further reasoning. This is also where the complaints of section 1.2 end.

3.3. Section 2 is based on the premise that the standard for assessing whether AstraZeneca acted unlawfully vis-à-vis Menzis is that AstraZeneca knew, or should have realized, that a serious, non-negligible chance existed that its patent would not stand up in opposition or invalidity proceedings. Sections 2.4 and 2.5 complain, inter alia, that with its judgment in finding 5.13, the court of appeal raised too high a threshold for assuming culpability by assuming that the holder of a European patent, which has (had) effect in various European countries, including the Netherlands, may in principle rely on a validity judgment of the Dutch court on the Dutch part of the patent. In assessing whether AstraZeneca knew or should have known at any time during the period from 24 March 2012 (the expiration of the SPC) to 10 June 2014 (the revocation of the Dutch part of the patent) that there was a serious, non-negligible chance of invalidity, the judgment of the Dutch court on the merits does not carry more weight than the judgments of other European courts, nor is the majority opinion decisive, the sections say. Moreover, the sections complain that the court of appeal

[6] See also Supreme Court 29 September 2006, ECLI:NL:HR:2006:AU6098 (CFS Bakel/Stork), finding 5.10.

did not give sufficiently comprehensible reasons for its finding because, without further explanation, it is impossible to see that in the period from 24 March 2012 to 10 June 2014, it is impossible to point to any moment at which AstraZeneca knew or had to realize that there was a serious, non-negligible chance of invalidity of the patent.

3.4. The court of appeal found in finding 5.10 that in the period from 24 March 2012 to 10 June 2014, AstraZeneca did not know or should not have known that a serious, non-negligible chance existed that the patent would not stand up in opposition or invalidity proceedings. The court based that finding on the following.
(1) In light of the judgment of the district court of The Hague of 7 March 2012, in which the patent was deemed valid, Menzis' contention that in the relevant period there could not reasonably have been any discussion about the invalidity of the patent and that the invalidity was even obvious cannot be sustained.
(2) It does not automatically follow from Gefvert et al.'s conclusion that the average skilled person would have been motivated to develop an XR formulation of quetiapine and would have had a reasonable expectation of success in doing so, also in light of what AstraZeneca has argued about that motivation and expectation of success. Therefore, the argument of Menzis that AstraZeneca's contention was obviously untenable in light of Gefvert et al.'s conclusion does not stand up.
(3) Also the fact that the English court (see above in 2.1 under (xii)) did not find the claimed invention inventive and that also other foreign courts have come to this opinion, does not imply that AstraZeneca knew, or should have realized, that a serious, non-negligible chance existed that the patent would not be upheld in opposition or revocation proceedings. The patent holder may, in principle, rely on the validity judgment given by the Dutch court on the merits. Moreover, the foreign courts that had ruled on the validity of the patent in the relevant period had in the majority reached the same judgment as the Dutch court.

3.5. The court of appeal has taken the circumstances mentioned above in 3.4 into consideration in connection with each other and has not based its judgment on only one of those circumstances. In so far as sections 2.4 and 2.5 ignore this, they lack factual basis. Also otherwise, the Court of Appeal did not raise too high a threshold for assuming culpability. It could rule that AstraZeneca could in principle rely on a validity judgment of the Dutch court on the merits, also in light of the fact that several courts abroad had reached a similar judgment at the time. The opinion of the court of appeal therefore does not demonstrate an incorrect view of the law. Nor is it incomprehensible. The complaints mentioned above in 3.3 therefore fail.

3.6. The other complaints of the plea cannot lead to cassation either. The Supreme Court need not give reasons why it arrived at this judgment. This is because, in considering

these complaints, it is not necessary to answer questions of importance to the unity or development of the law (see Article 81(1) of the Judiciary (Organisation) Act).

4. Decision

The Supreme Court:

- dismisses the appeal;
- orders Menzis to pay the costs of the proceedings in cassation, up to the present judgment estimated on the part of AstraZeneca at € 14,229 for disbursements and € 2,200 for salary, increased with statutory interest on these costs if Menzis has not paid them within fourteen days from today.

This judgment was rendered by Vice President M.J. Kroeze as president and judges C.E. du Perron, F.J.P. Lock, F.R. Salomons and G.C. Makkink, and pronounced in public by judge F.J.P. Lock on 3 November 2023.