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Authority	Rotterdam District Court
Date of decision	13-02-2025
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Case number	ROT 23/5311
Areas of law	Criminal Law
Special features	First instance - plural
Content indication	The ACM imposed a fine on a drug manufacturer for abusing its dominant economic position by charging and collecting an excessive price for its own CDCA drug in the Netherlands. The court held that the ACM had properly found that the drug manufacturer had abused its economic dominance. The ACM carefully and objectively assessed the excessiveness and fairness of the price of the CDCA drug. With the ACM, the court finds that registration of the CDCA drug as a drug for the treatment of CTX does offer benefits that may justify some increase in price, but a price that , at intervals, from 46.00 to 13,090.00 per package, in the absence of a sound rationale, is beyond all reason. The active ingredient in the CDCA drug had been successfully used for decades to treat CTX, and all the drug manufacturer did was take advantage of the opportunity to register the drug administratively for that decades-old method of treatment in order to acquire an exclusive right. The exorbitant price increase subsequently applied is a textbook example of abuse of an economic dominant position. This abuse is even more insistent because it took place on the backs of vulnerable patients who cannot without this drug. The drug manufacturer exploited this for its own financial gain. The ACM was right to impose a fine, but the amount of the fine should be reduced because of the excessive length of the entire procedure. Otherwise, the appeal is unfounded.
Findings	Rechtspraak.nl

Excerpt

ROTTERDAM COURT

Administrative Law

Case number: ROT 23/5311

judgment of the plural chamber dated February 13, 2025 in the case between

[manufacturer 1] , from [location 1] , [manufacturer 2] , from [location 2] , [manufacturer 3] , from [location 3] ,

(hereinafter collectively [name of manufacturer])
(Agents: Mr. M.O. Meulenbelt, Mr. K. van Lessen Kloeke and Mr. K.M. Mulder),

and

The Consumer & Market Authority (the ACM),

(Agents: Mr. H.B.M. Römkens, Mr. M.O.G. Temme and Mr. P. Amador Sanchez).

Summary

In this ruling, the court reviews [name of manufacturer]'s appeal against the fine imposed on it by the ACM, against the rejection of its application to declare a commitment binding and against the decisions by which the ACM proceeded to publish its decisions imposing fines.

[name of manufacturer] is a pharmaceutical company active in the field of drugs for rare diseases (orphan drugs). Since 2008 on the Dutch market, (the legal predecessor of) [name of manufacturer] has supplied a chenodeoxycholic acid (CDCA)-based drug, Chenofalk, which it from a manufacturer. Chenofalk cost 46 per 100 capsules. In late 2009, (the legal predecessor of) [name of manufacturer] changed the name of this drug to Xenbilox. [name of manufacturer] subsequently applied for and obtained orphan drug status and marketing authorization to treat cerebrotendinous xanthomatosis (CTX) patients with a CDCA-based drug. CDCA-based drugs, such as Chenofalk, had been successfully used for off-label treatment of CTX for decades. In 2017, [name of manufacturer] withdrew Xenbilox from the and launched [CDCA brand name]. At that time, [name of manufacturer] set the price for [CDCA brand name] at 13,090 per pack of 100 capsules.

The ACM imposed - after objection - a fine of 17,044,000 on [name of manufacturer] for [name of manufacturer] abusing its economic dominance1 charging and collecting an excessive price for [CDCA brand name] in the Netherlands. [name of manufacturer] raised numerous grounds of appeal against this.

In this ruling, the court comes to the conclusion that the ACM properly found that [manufacturer name] abused its economic dominance position. The ACM has carefully and objectively assessed the excessive and fairness of the price of [CDCA brand name]. With the ACM, the court considers that registration of [CDCA brand name] as a drug for the treatment of CTX does offer advantages that justify a certain price increase, but a price that , with intermediate steps, from 46.00 to 13,090.00 per package goes all limits in the absence of sound substantiation. The active ingredient in [CDCA brand name] had been successfully used for decades for the treatment of CTX, and all [name manufacturer] has done is take the opportunity to administratively register the drug for that decades-old method of treatment in order to acquire an exclusive right. The exorbitant price increase subsequently applied is a textbook example of abuse of an economic dominant position. This abuse is even more insistent because it took place on the backs vulnerable patients who cannot do without this medicine. [name of manufacturer] took advantage this for its own financial gain.

The court finds that the ACM was right to fine [name manufacturer], but that the amount of the fine should be reduced due to excessive length of the entire procedure. The court therefore reduces the fine to 17,029,000. Otherwise, the appeal is unfounded.

Process

1.1. By a decision dated July 1, 2021 (penalty decision), the ACM fined [name of manufacturer] a fine of 19,569,500 imposed With a decision dated July 2, 2021, the ACM decided to publish a summary of the fine decision and a news release (publication decision).

1.2. On July 2, 2021, [fabricator 1] . and [fabricator 2] an enforcement request to the ACM. By a decision dated March 29, 2022, the ACM rejected that request based on its prioritization policy. By a decision on the objection dated June 22, 2022, the ACM joined that rejection

remained. The appeal by [fabricator 1] . and [fabricator 2] against that decision was registered case number ROT 23/5310. The court ruled in that case on February 13, 2025. In that ruling, it upheld the appeal and ordered the ACM to issue a new decision on the appeal in compliance with the .

1.3. With the contested decision of June 22, 2023 (Contested Decision I), the ACM decided on [name of manufacturer]'s objection to the fine decision. In doing so, the ACM reduced the fine imposed to 17,044,000. Otherwise, the ACM stood by the fine decision. The ACM also considered that it saw no reason to revoke the publication decision.

1.4. With the contested decision of June 26, 2023 (Contested Decision II), the ACM decided to publish Contested Decision I.

1.5. [name of manufacturer] filed an appeal against Contested Decision I and Contested Decision II on August 3, 2023.

1.6. The ACM sent the documents related to the case the court. For some of those documents (confidential documents), the ACM informed the court that only it would be allowed to take cognizance of them. It has asked the court to rule that the limited access is justified.2

1.7. The court - after [fabricator's name] had granted permission as referred to in Article 8:29, paragraph 5, of the General Administrative Law Act (Awb) - deemed the restriction on the inspection of the confidential documents justified by the April 26, 2024 decision.

1.8. A request by the Foundation for Pharma to Account (FTV) to be admitted to the proceedings as a third party was denied by the court.

1.9. The ACM responded to the appeal with a statement of defense.

1.10. [name of manufacturer] further submissions on June 1, 2024.

1.11. The court heard the appeal at a hearing on June 28, 2024. The following : for [name of manufacturer] its agents Mr. Meulenbelt and Mr. Van Lessen Kloeke, [name] , CEO, assisted by two interpreters. For the ACM its agents and J. Svitak appeared.

Rationale and genesis of contested decision I

2. Contested Decision I deals with conduct by the company [name of manufacturer] . [fabricator 2] and [fabricator 1] . are the entities within [fabricator name] that were directly involved in the impugned conduct.

2.1. Since 2008, (the legal predecessor of) [name manufacturer] has been supplying on the Dutch market a CDCA-based drug, Chenofalk, which it purchased from a manufacturer in 2008.3 At the end of 2009, (the legal predecessor of) [name manufacturer] changed the name of this drug to Xenbilox and increased the price , which until then had been 46 per package of 100 capsules in the Netherlands, to 885 (including distribution fee).

2.2. [name of manufacturer] subsequently applied for orphan drug status and marketing authorization to treat (CTX) patients with a CDCA-based drug. CTX is a rare, inherited metabolic disease and CDCA is for CTX patients. CDCA was originally used as a drug for gallstones, but has been in use for several decades to halt the progression of CTX. For example, Chenofalk and later Xenbilox were used off-label4 for the treatment of CTX until [name of manufacturer] replaced it with [CDCA brand name] in 2017.

2.3. In July 2014, [name of manufacturer] raised the selling price (including distribution fee) for Xenbilox in the Netherlands to 3,102.90 per package of 100 capsules.

2.4. In late 2014, [name of manufacturer] obtained orphan drug status for [CDCA brand name] and marketing authorization for [CDCA brand name] in April 2017.5 With obtaining marketing authorization, [CDCA brand name] is the first CDCA-based and CTX-indicated drug on the European market.

2.5. In June 2017, [name of manufacturer] marketed [CDCA brand name] and withdrew Xenbilox from the market. At that time, [name of manufacturer] set the price for [CDCA brand name] at 13,090 per package of 100 capsules.

2.6. In late August 2018 and early September 2018, various media reported the significant price increase of [CDCA brand name] implemented by [name of manufacturer] . As a result of those reports, the ACM launched an investigation into abuse of an economic dominant position by [name of manufacturer] . Shortly thereafter, FTV requested the ACM to take enforcement action against [name of manufacturer] because of the price of [CDCA brand name] .

2.7. During this investigation, on August 10, 2020, [name of manufacturer] submitted an application to the ACM to declare a commitment binding. This application was rejected by the ACM on October 7, 2020.

2.8. The investigation ultimately led to the penalty decision and then, after objection, to Contested Decision I.

FTV's request for admission to the proceedings 6

3. The court did not admit FTV to the proceedings because it did not designate FTV as an interested party. To this end, the court considered the following.

3.1. An interested party is defined as: a person whose interest is directly affected by a decision.7 Pursuant to Article 1:2, third paragraph, of the Awb, the interests of legal persons include the general and collective interests which they promote by virtue of their objectives and as evidenced by their actual activities. For the determination of whether FVT is an interested party, the determining factor on appeal is whether its interest existed within the appeal period.8 Furthermore, the actual activities must have some scope and be related to the objective pursued by the legal entity.

3.2.In accordance with Article 2 of its Articles of Association, FTV's object is serve the public interest by endeavouring to ensure that medicines and other medical technologies are available on the in a sustainable and socially acceptable manner, in which connection it attaches importance to fair pricing and distribution in accordance with written and unwritten national, European and international legal standards. FTV endeavors to achieve its objective by all appropriate means, including the provision of advice, information and education, the conduct of legal proceedings as well as the performance of all further actions which are directly or indirectly related to the foregoing or which may conducive thereto, all in the broadest sense.

3.3. The court finds that on the basis of the factual activities it has put forward, FTV does not qualify as an interested party as referred to in Article 1:2 of the Awb. A large part of these activities relates to its conducting administrative law proceedings. According to established case law,9 such activities do not qualify as actual activities within the meaning of Section 1:2(3) of the Awb. Also, most of the activities cited date from well before the appeal period (period 2018-2022). The activities performed in 2023 are minor in scope. The court also took into account that some of the alleged activities were not undertaken by FTV but by persons who do not represent FTV (e.g., they serve on an advisory board of FTV) and that although FTV's board members are active, they do so in their own names and not recognizably in the name of FTV. The mere mention of the board position by their own name does not make it possible to assume that FTV is significantly involved in that work. Regarding the concrete interest put forward by FTV for participation in the proceedings, namely that FTV disagrees with a part of the contested Decision I, the Court further notes that there is no room for a third party admitted under Article 8:26 of the Awb to raise its own grounds against the contested Decision I.10

Assessment of appeals against contested decisions I and II

4. In this ruling, the court assesses whether the fine imposed on [name manufacturer] and the publication of the fine decision and Contested Decision I can stand. It does so on the basis of [name manufacturer's] grounds for appeal.

Appeal grounds

5. [name of manufacturer] argues that the ACM committed procedural errors. It further challenges - in brief - the ACM's (legal) characterization of abuse. It argues that the ACM misrepresented the factual framework. According to [name of manufacturer], the ACM's competition law analysis is based on descriptions of market dynamics and the drugs involved that misrepresent and ignore the relevant evidence. Furthermore, the ACM misrepresents the legal framework, the relevant market and dominance are wrongly established and there is no abuse thereof. [name of manufacturer] believes the ACM should have declared the commitment binding. It submits grounds against the (amount of) the fine and, finally, disagrees with the publication of the fine decision and of Contested Decision I.

6. [name of manufacturer] has explained the grounds of its appeal in great detail. However, it does not follow from Articles 8:69 and 8:77 of the Awb that the district court must address all the arguments presented separately in its ruling. Although the District Court has considered all arguments, it will limit itself in the following to the essence of the grounds put forward by [name of manufacturer]. To the extent the court leaves arguments of [name manufacturer] unaddressed, the court has considered those , but finds that they do not succeed. Where, in its grounds of appeal, [name manufacturer] suffices with a single reference to the grounds of objection which it regards as repeated and recalled and does not substantiate in what respect, in its view, the response of the ACM in Contested Decision I is inadequate, the court does not regard this as a ground of appeal to which it must respond.11

Table of contents review

7. Below, the court will address the following parts of [name of manufacturer]'s grounds of appeal :

- Procedural errors (8 - 8.10);
- Conclusion procedural errors (8.11);
- Qualification (what does it consist of) abuse of dominance (9 - 9.2);
- Misrepresentation of factual framework (10 - 10.23);
- Misrepresentation of legal framework (11);
- Relevant market and dominant position misidentified (12 - 12.10);
- Conclusion on market definition and dominance (12.11);
- Abuse (economic dominance) improperly found 13 - 22.5);

- Excessive price (16 - 19.3);
- Fairness of price (20 - 22.4);

- Conclusion finding of abuse of economic dominance (22.5);
- Binding commitment decision (23 - 23.3);
- Assessment (amount of) fine 24 - 24.32);
- Conclusion fine (24.33);
- Publication (25 - 25.6);
- Reasonable term (26 - 26.2);
- Conclusion court and implications (27 - 27.2).

Procedural errors

8. This ground of appeal falls into four parts: (1) the ACM violated the rights of defense by claiming too many documents and passages as confidential, (2) the ACM erred in not making available the correspondence within the European Competition Network (ECN),

(3) the ACM should have reimbursed the translation costs of the fine report and (4) there is a violation of the separation of functions requirement.

Violation of rights of defense and failure to make ECN documents available

8.1. The court considers that [name manufacturer's] rights of defense not been violated because [name manufacturer] can adequately represent its interests even with limited access to the documents. As regards the ECN documents, the interests of the ACM's cooperation within the network of competition authorities in the EU and the effectiveness of the supervision of competition rules outweigh [name manufacturer's] interest in access to information relating to it. In this respect, the Court notes that, as also indicated by the ACM, these ECN documents do not contain evidence about [name manufacturer's] conduct. [name manufacturer] can adequately represent its interests even with limited access to these documents.

Translation costs penalty report to be by the ACM?

8.2. Article 6(3(a) of the ECHR requires that any person against whom a prosecution (for the imposition of a punitive sanction) has been brought must be informed promptly, in a language she or he understands and in , of the nature and cause of the accusation against him.

8.3. The European Court of Human Rights (ECtHR) ruled in the case of Kamasinski v. Austria of December 19, 1989 (ECLI:NL:XX:1989:AD0982) ruled that any person threatened with the imposition of a punitive sanction and who does not understand the language of the competent court has the right to the free assistance of a translator for the translation of all written documents and statements, in so far as it is necessary for the requirement of a fair trial that those documents be understood by her or him or made accessible in the language of that national court.

8.4. The Board of Trade and Industry Appeals CBb) has considered in several decisions12 that it deduces from the Kamasinski ruling that in a criminal charge, a defendant does not have an unlimited right to written translation of all written evidence or other documents relating to the case. What matters is that the defendant understands what is happening in his proceedings and that he is sufficiently able to mount an effective defense so that there can be a fair trial.

8.5. The ACM provided the penalty report on August 11, 2020, and an English translation of the essential part of the penalty report to [name manufacturer] three weeks later, on September 4, 2020. The court finds that by providing this English translation, the ACM has satisfied the requirement that [name manufacturer] can understand what is happening in its proceedings and that it is sufficiently able to mount an effective defense. The court sees no reason for the ACM to reimburse [name manufacturer] for the costs of the translations made by [name manufacturer] on its own initiative, as requested by [name manufacturer].

8.6. [name fabricator], before its August 13, 2020 request to the ACM to English translations, or immediately thereafter, commissioned translations itself without waiting for a response from the ACM. Indeed, the ACM argues undisputedly that by August 17, 2020, a first tranche of translations by [name of manufacturer] had already been completed. Under these circumstances, the ACM is not obliged to reimburse the translation costs incurred by [name manufacturer].

Separation of functions requirement

8.7. According to [name of manufacturer], by requesting two documents from the Italian competition authority AGCM in the preparation of the supplementary fine report of April 22, 2021, the ACM violated the segregation of duties requirement of Article 12q of the Iw13. It argues - with reference to the CBb's decision of 30 August 2011, ECLI:NL:CBB:2011:BR6737, point 5.3 - that the Directorate of Legal Affairs (DJZ), by itself making such a specific and targeted request (requesting two documents), carried out an investigation that was actually aimed at establishing

the violation. The mere fact that DJZ had the actual query performed by the investigation team does not negate the fact that the specific investigative act was determined, organized and directed by DJZ. Thus, the separation of functions requirement was violated. This is a segregation of duties at the individual level, given the degree of specificity and identification of the documents DJZ wishes to obtain in order to complete what had hitherto been described as "meager" evidence. That there indeed a mixing of investigative and sanctioning functions, according to [name fabricator], finds confirmation in the documents that were made available to [name fabricator] on October 26, 2023, invoking the Open Government Act (Woo). An e- mail exchange dated November 9 and 10, 2022 between two ACM officials shows that documents were exchanged with AGCM on two occasions after the investigation was completed. The e-mail exchange concerns a question (Nov. 9, 2022) addressed by one official to another and focused on cooperation within the European Competition Network (ECN) that was useful to the ACM "for our [name of manufacturer] case": "If I wanted to ask someone what the cooperation within ECN contributed to our [name of manufacturer] case (I say something about this in response to [DELETED]), who would be the best person to discuss that with? Do you know, for example, or is it better to ask [DELAKT], or did this play more with JZ?" and a reply to that dated November 10, 2022 reads, "Hi, During the DZ phase, [DELAKT] has indeed been in regular contact with (mainly) colleagues from the Italian Competition Authority. Indeed, she can tell you most that first-hand. After completing the investigation, we additionally provided (, from my memory) information based on Article 12 of the Regulation from the [name of manufacturer] file to the Italian authority." [name of manufacturer] argues that it follows in any event that DJZ actively engaged in research and directed specific investigative actions. As a result, Contested Decision I is not based on a sufficiently objective and unbiased assessment.

8.8. The ACM argues that DJZ did not conduct an investigation in this case. Precisely the handlers from the investigation phase (DZ) made a request for information to AGCM, not the persons in charge of work related to the imposition of an administrative fine. This is consistent with the separation of functions requirement of Article 12q Iw. On the argument that the specific investigative act was determined, organized and directed by DJZ, the ACM argues that it does not see how handlers in the sanction phase would have so in violation of the separation of functions requirement. To the extent that [name fabricator] is referring to the April 9, 2021 email from one of the handlers in the sanction phase to a manager of the officials of the investigation team, this did not violate the segregation of duties requirement. On the contrary, this e-mail expressly leaves it up the manager in the investigation phase (DZ) to determine whether an investigative act should performed, and if so, how the investigation team views these documents in light of the report (since the handlers in the sanction phase had not seen the documents in question): "Can you consider with the investigation team whether these documents are sufficiently relevant to add to the case file and, if , put in writing how the investigation team views these documents in light of the report? If so, we will give [name of manufacturer] the opportunity to respond to them in accordance with Article 5:53 Awb."

8.9. In this regard, the ACM recalls point 5.5 of the CBb's ruling that if the handling team in the sanction phase comes to the conclusion that [...] the facts and circumstances stated in the report are insufficient to arrive at the conclusion with an objective and unbiased assessment that a violation has been committed, this does not exclude - of course with due observance of the principles of proper administration - that a new investigation is carried out and that a supplementary report is drawn up. Furthermore, none of the passages quoted by [name fabricator] from the e-mail exchange of November 9 and 10, 2022, show any steering of investigative actions by handlers in the sanction phase. The internal ACM email of November 10, 2022, cited by [name of fabricator] only mentions that information was requested from the Italian Competition Authority by DZ after the investigation was completed. It is not in dispute that employees of DZ did indeed so. They prepared a supplementary penalty report based on this information and handed it to the handlers in the sanction phase. The sanction phase handlers then provided this to [name of manufacturer] .

8.10. The court follows the ACM's position and sees no basis in the emails submitted for the opinion that the separation of functions requirement was violated. The ACM was free to conduct an additional investigation.

commissioned and it then gave [name of manufacturer] an opportunity to respond to the supplemental report.

Conclusion procedural errors

8.11. [name of manufacturer]'s argument about procedural errors does not succeed. Qualification (what does it consist of) abuse of dominance

9. In Contested Decision I, the ACM states that [name fabricator] relies on the incorrect premise that the abuse is based on - as [name fabricator] calls it - a triple allegation, a number of grounds for objection need not be discussed.

9.1. [name of manufacturer] disputes that it relies on an incorrect premise. It argues that the ACM relies on a triple allegation of abuse of dominance in both the fining decision and Contested Decision I. These are the allegations (A) that [name fabricator] had set the list price for [CDCA brand name] too high; (B) that [name fabricator] had not negotiated hard or fast enough to reach a lower net price and (C) that [name fabricator] , faced with failing to reach a negotiated solution, should have somehow paid money to the health insurers, even without gaining sustained market access, but that [name fabricator] had failed to make such payments. [name of manufacturer] argues that it was this combination of acts and omissions (including allegations B and C) that qualified the ACM as an abuse of a dominant position. That this was a triple allegation is confirmed, according to [name of manufacturer], by statements made by the ACM after the penalty decision.

9.2. The court finds that the ACM - also already in the fining decision - establishes that [name manufacturer] abused its economic dominant position by asking and collecting an excessive price for [CDCA brand name] in the Netherlands. For example, in paragraph 219 of the contested Decision I, the ACM states *"Also in this decision on objection, the ACM is of the , that the conduct to be assessed for abuse consists of [name fabricant] asking and collecting an excessive and unfair price, and does not consist of, in short, its negotiating behavior."* Unlike [name fabricator] , the court does not see the part of paragraph 218 of Contested Decision I14 cited by [name fabricator] as part of the qualification of abuse but as a response to the argument raised by [name fabricator] that it wanted to arrive at a non-excessive price after negotiations. In response [name fabricator]'s argument in objection that the list price not be the price to be assessed for abuse because that price would be expected to be followed by negotiations to a lower price, the ACM argues in paragraph 221 of Contested Decision I that [name fabricator] unilaterally set this price and it could also - whether confidentially or not - ask for and collect a different price. Furthermore, what is stated in the penalty decision and in Contested Decision I is decisive. Therefore, the statements of (employees of) the ACM cited by [name fabricant] in an article, book or at meetings, leaving aside whether they confirm that it is a triple accusation, are irrelevant.

Misrepresentation of the factual framework

The factual framework according to the ACM

10. The ACM assumes the following factual framework. [name of manufacturer] the CDCA-based drug Chenofalk in 2008. In late 2009, [name of manufacturer] changed the name Chenofalk to Xenbilox and, after obtaining marketing authorization, to [CDCA brand name] . [CDCA brand name] contains the same active ingredient, CDCA, as Chenofalk and Xenbilox. The molecular drug is the same, containing the same active ingredient, produced in the same way by the same manufacturer for the same patients, and with no difference in efficacy and side effects. The close relationship between [CDCA brand name] and Xenbilox is also evidenced by the fact that the assessment of [CDCA brand name] as an orphan drug by the European Medicines Agency (EMA) relies significantly on

documentation of the efficacy of Xenbilox.15 No study was conducted with [CDCA brand name] prior to granting orphan drug status. The only difference between [CDCA brand name] and Chenofalk and Xenbilox is that [CDCA brand name] is an orphan drug and [name of manufacturer] has a marketing authorization for this drug for the treatment of CTX rather than the treatment of gallstones. CDCA has been safely and effectively prescribed and used off-label for decades for treatment of CTX, so the use of the registered drug [CDCA brand name] has few advantages for CTX patients in terms of quality, efficacy, safety and security of supply.

Magistral preparation CDCA by Amsterdam UMC

10.1. A drug with CDCA as the active substance can also prepared by a (hospital) pharmacy (magistral preparation), although relevant Dutch authorities16 in the field of medicines prefer as a main rule a registered drug over a compounded drug. Pharmaceutical compounding does not require a marketing authorization and pharmaceutical compounding is not affected by the exclusivity provision in the Orphan Drug Regulation17 . However, magistral preparation is subject to safety requirements. In order to prepare CDCA magistrally, it is necessary for the pharmacy to have a sufficiently pure raw material. Magistral preparation can be reimbursed by health insurers as an insured performance under health insurance.

10.2. At some point, several initiatives may have existed in the Netherlands to prepare CDCA magistrally, including the project to prepare magistrally prepared CDCA by the Amsterdam UMC (AUMC). In the fall of 2016, at least, concrete steps were taken to the active ingredient CDCA. On October 28, 2016, Euro-Chemicals B.V. (Euro-Chemicals)18 emailed Prodotti Chimici e Alimentari S.p.A. (PCA)19, also the CDCA supplier of [name of manufacturer], asking if it could supply the active ingredient CDCA. Euro-Chemicals informed PCA that several European hospitals had engaged it to obtain CDCA. PCA replied to Euro-Chemicals the same day that it not supply the raw material because of existing agreements. In 2008, [name of manufacturer] had entered into an agreement with PCA containing exclusivity agreements in favor of [name of manufacturer] .

10.3. Following the introduction of [CDCA brand name] at a price of 13,090 per 100 capsules, health insurer Menzis informed the distributor of [name of manufacturer] , Orly Pharma, in June 2017 that it would not change its plan to try to manufacture CDCA itself and that it might have been able to obtain a kilogram of the active ingredient. On July 11, 2017, shortly after the introduction of [CDCA brand name] in the Netherlands, an employee of Zorginstituut Nederland (ZIN) explored the possibilities for continuity of a CDCA-based drug for CTX patients. On October 17, 2017, Euro-Chemicals informed PCA that it had still managed to find another producer of CDCA. Around October 5, 2017, AUMC's board of directors approved the production of magistrally prepared CDCA.

10.4. In late 2017, health insurers and the Ministry of Health, Welfare and Sport (VWS) also became aware of the concrete steps toward magistral preparation by the AUMC. On December 29, 2017, the CbusineZ Foundation CbusineZ), an entity established with the help of health insurer CZ but independent, notified VWS that it was expected that magistrally prepared CDCA could be supplied to Dutch patients starting in February or March 2018.

10.5. In the fall of 2017, [name of manufacturer] received several signals that health insurers were considering discontinuing their reimbursement of [CDCA brand name] effective January 1, 2018. However, health insurers continued to reimburse [CDCA brand name] after January 1, 2018, until AUMC announced the launch of the magistrally prepared CDCA in early April 2018. Leading up to that launch, several parties (VWS, Healthcare and Youth Inspectorate (IGJ) and CbusineZ) talked about it. AUMC was also aware of the discontinuation of reimbursement for [CDCA brand name] . In March 2018, health insurers announced that as of April 1, 2018, they would stop reimbursing [CDCA brand name] out of leniency.

10.6. On April 5, 2018, AUMC announced the launch of the magistrally prepared CDCA. From April 27, 2018, dispensing to patients with CTX in the Netherlands took place from the AUMC pharmacy. The magistrally prepared CDCA was based on CDCA that the AUMC had

obtained through Euro-Chemicals, which in turn had the active ingredient from the manufacturer Panjin Hengchanglong. The magistrally prepared CDCA was sold for 20,000 to 25,000 per patient per year. In April and May 2018, according to [name of manufacturer] , virtually the entire Dutch patient population was successfully switched to this magistrally prepared CDCA from AUMC.

10.7. [name of manufacturer] requested the IGJ on May 7, 2018 to take enforcement action against the 's magistral preparation of CDCA. On June 12, 2018, the IGJ conducted an inspection visit to the . On July 23, 2018, the IGJ sent the AUMC a proposed order to stop dispensing the prepared drug due to the use of a raw material that was not sufficiently pure. On July 26, 2018, the AUMC decided to immediately stop the magistral preparation. Therefore, the IGJ subsequently refrained from imposing the intended order. CTX patients were again treated with [CDCA brand name] from then on, with [name of manufacturer] again requesting and collecting its price of 13,090 per 100 capsules.

10.8. A search for a supplier of a pure raw material then took place. During this search, several steps were taken, in response to the high price of [CDCA brand name] , to realize the alternative of magistral preparation. Different expectations existed about the resumption of compounding. AUMC stated to the ACM at various times that obtaining a pure raw material for CDCA was uncertain. Health insurers stated to the ACM that they were in favor of the AUMC's initiative in this case, but that its resumption was uncertain. On March 23, 2020, AUMC stated to the ACM that it had started dispensing magistrally prepared CDCA as of mid-January 2020. The price per patient per year became higher than in 2018 and was between 30,000 and 35,000. AUMC procured the active ingredient from a supplier from Asia. The process of selection and technical preparations lasted from August 2018 to January 1, 2020.

10.9. Also involved in the run-up to and preparations for the AUMC project for magistral preparation of CDCA have been the Pharmagister Foundation20 (founded on August 11, 2016 by Cbusinez), Cbusinez and a number of health insurers (including at least Zilveren Kruis and CZ). That involvement covers both the project of introduction and the project of reintroduction of compounding of CDCA.

Preference for registered drugs

10.10. Both the lead-up to and original introduction of magistrally prepared CDCA in April 2018, and the lead-up to and reintroduction of magistrally prepared CDCA in early 2020, took place against the backdrop of general dissatisfaction with high drug prices in general and of [CDCA brand name] in particular. In general, however, there was a broad-based preference among health insurers for registered drugs.

List price of [CDCA brand name].

10.11. [name of manufacturer] set the pharmacy purchasing price for [CDCA brand name] in the Netherlands at 14,000 and thus arrives at an annual price per patient of 153,300. This pharmacy purchase price includes a 6.5% distribution fee for the distributor of [CDCA brand name] , pharmaceutical wholesaler Orly Pharma. [manufacturer name] therefore receives a price of 13,090 euros per package (list price). This price is the maximum price for the sale of [CDCA brand name] in the Netherlands. [name manufacturer] sets this price itself within the systematics of the Medicines Pricing Act.21 Because of the reference system used in the Netherlands, but also in other countries, and because of the confidentiality of price agreements, the setting of the sales price by a drug manufacturer in one country can have consequences for the maximum price in other countries. Drug manufacturers, by setting their own sales price in each country, have some control over the maximum price in countries where a reference system is used. Thus, by setting the selling price of CDCA brand name], [name of manufacturer] has control over the maximum price it can charge in the Netherlands under the Medicines Pricing Act.

The different modes of reimbursement of CDCA

10.12. As a registered drug, [CDCA brand name] can be reimbursed by health insurance companies in the Netherlands. In the Netherlands, the ZIN assesses whether extramural22 drugs and expensive specialist intramural23 drugs are eligible for reimbursement from the basic health insurance package. [name of manufacturer] ultimately - although it is and remains of the opinion that [CDCA brand name] is a specialist, intramural medicine - submitted an application to ZIN on March 13, 2018 for inclusion of [CDCA brand name] in the Drug Reimbursement System (GVS) as an extramural medicine.

10.13. [CDCA brand name] was not yet included in the GVS (even at the end of the infringement period). In its advice to the Minister of VWS, the ZIN suggested first negotiating the price of [CDCA brand name] , because this drug was many times more expensive than the previous drug Xenbilox and magistrally prepared CDCA. Discussions with the Buro Financiële Arrangements of VWS did not lead to a negotiation result. Because [CDCA brand name] is not included in the GVS, health insurers are not obliged on that basis to reimburse this drug for CTX patients insured with them. Nevertheless, health insurers have reimbursed this drug either on the basis of their general legal duty of care, or out of a moral obligation. Health insurers are free to negotiate the price of a drug before or after its inclusion in the GVS, but these negotiations on [CDCA brand name] did not off the ground.

Negotiations with health insurers and VWS on reimbursement of [CDCA brand name] .

10.14. Each health insurer has had its own considerations and its own approach to reducing health care costs for its own insureds. Not every health insurer feels there is a legal obligation to reimburse [CDCA brand name], although every health insurer has felt a moral obligation to reimburse at the time when no alternative was available for CTX patients. Health insurers did not see compounding as a structural solution unless they had to pay an excessive price. However, discussions with [name of manufacturer] did not lead to an acceptable outcome for the various health insurers. There were several reasons for this. For one, health insurers clearly indicated in advance that they wanted to see a significantly lower price offer. Apart from a price proposal to CZ, a concrete proposal from [name of manufacturer] always failed to materialize. In addition, most health insurers were unwilling to a confidentiality agreement. However, [name of manufacturer] insisted on signing it before it wanted to start talks. The health insurers then adopted a wait-and-see attitude and also waited for the possible magistral preparation of CDCA, the advice of ZIN and the talks with VWS.

10.15. Even prior to the ZIN opinion, VWS was aware of the issues surrounding the high price of [CDCA brand name] combined with the absence of reimbursement status. In that context, in October 2017, VWS considered (i) contacting [manufacturer name], (ii) alerting health insurers to the Supreme Court ruling of December 19, 201424 or (iii) asking pharmacists whether they could prepare a CDCA-based drug. As of December 2017, there was contact between [name of manufacturer] and VWS. On December 13, 2017, VWS informed [name of manufacturer] that ZIN was awaiting a complete dossier. VWS urged [name of manufacturer] to quickly submit an application for inclusion of [CDCA brand name] in the GVS as an extramural drug. On December 20, 2017, [name of manufacturer] informed VWS that it would submit a dossier to ZIN in early 2018. In the meantime, the opinion of VWS was that [name of manufacturer] should approach health insurers to discuss the price of [CDCA brand name] .

10.16. Based on the file as submitted in March 2018, ZIN a draft opinion on August 3, 2018. In it, ZIN questioned cost-effectiveness. The health insurers were of the opinion that ZIN, in its final opinion, should urge VWS to enter into discussions with [name of manufacturer] because of the price and attitude of [name of manufacturer] , regardless of the method of reimbursement. Instead, to VWS, [name of manufacturer] complained about the attitude of the health insurers.

10.17. The Minister of Health invited [name of manufacturer] to a meeting in which he wanted to address [name of manufacturer] on the price for [CDCA brand name] , without wanting to anticipate an opinion from ZIN but requesting transparency. On November 22, 2018, ZIN

opinion and advised VWS to discuss the price of [CDCA brand name]. VWS officials subsequently discussed a number of possible options, including waiting for the resumption of . VWS has felt limited in its options because of the small macro amount required for central negotiation.
In addition, VWS considered the request of health insurers, the Canisius Wilhelmina Hospital (CWZ), AUMC and the Patient Association for Metabolic Diseases (VKS) to transfer CDCA-based drugs and designate them as inpatient care. In the meantime, VWS officials alerted [name of manufacturer] to the possibility of speaking with health insurers.

10.18. Ultimately, on July 2, 2019, the Minister of Health decided to [name of manufacturer] to a meeting in which VWS would indicate its desire to obtain an explanation of the costs, expect a reasonable price, and if , reject the application for inclusion in the GVS. The subsequent talks with VWS did not proceed energetically in large part because a justification of the high price by [name of manufacturer] failed to materialize.

10.19. On August 28, 2019, [name of manufacturer] informed VWS that it was willing to substantiate the price, but was concerned about confidential treatment of its business data. Although in the September 5, 2019 conversation with VWS, [name of manufacturer] appeared willing to provide access, [name of manufacturer] kept delaying it by demanding various conditions before providing the requested transparency. Instead, the minister wanted to be able to inform the House of Representatives. Further consultations on the conditions set by [name of manufacturer] and a signed non-disclosure agreement did not yield results. In the fall of 2021, VWS was still waiting to see the price structure of [CDCA brand name] . On October 6, 2021, [name of manufacturer] proposed to speak directly about the price. On July 14, 2022, VWS informed [fabricant name] that it did not want to enter into a confidential price agreement for [CDCA brand name] . After all, [name of manufacturer] still had not provided the requested information and compounding was available at a lower price.

Position of [name of manufacturer] on representation of factual framework

10.20. According to [name of manufacturer], the relevant facts described by the ACM contain a (large) number of omissions. For example, the ACM does not discuss the long-planned development and launch of compounding by AUMC and its impact on market dynamics. As a result, the ACM reaches four incorrect conclusions, namely that (1) the health insurers did not have a specific preference for 's pharmaceutical compounding, (2) there was no collective boycott by the health insurers to negotiate with [name of manufacturer], (3) the conduct of the health insurers does not detract from [name of manufacturer]'s decision to continue to charge the list price for [CDCA brand name], and (4) [CDCA brand name] is similar, even identical, to the drug Xenbilox® and that, even if the specifications did differ, that is immaterial because the marketing authorization process involved nothing more than "administrative effort." None of those conclusions, according to [name of manufacturer], can be by the evidence.

10.21. Instead, the ACM should have based its competition law analysis on the finding that the health insurers demonstrated a principled, universal and consistent preference for AUMC's compounding of CDCA throughout the study period. The health insurers acted in concert and aligned their conduct to achieve the building blocks necessary for the introduction and reintroduction of . The ACM also ignores the fact that [name of manufacturer] consistently and repeatedly offered a retroactive discount, but that the health insurers never made a credible counter-offer demonstrating their willingness to negotiate. For [name manufacturer] , faced with health insurers who consistently and fundamentally refused to negotiate with it, negotiations with VWS were the only route to sustainable reimbursement. However, VWS never even had any intention of negotiating with [name of manufacturer]. It wanted to "name and shame" [name manufacturer] and share its commercially confidential information with parliament and with the press. This did [name

fabricator] discovered through requests under the Open Government Act (Wob)/Open Government Act (Woo). This contextual information is crucial for the competition law assessment. Therefore, [name of manufacturer] concludes that Contested Decision I cannot stand because the competition law analysis is based on descriptions of the market dynamics and drugs involved that misrepresent and ignore the relevant evidence.

Opinion of court on representation of factual framework

10.22. The grounds of appeal relating to the representation of the factual framework do not succeed.

10.23. Central to the ACM's judgment is the price that [name manufacturer] charged and from the health insurers. Even if the health insurers would colluded and boycotted negotiations with [name manufacturer] on lower prices, that does not justify [name manufacturer] keeping its prices unchanged at a very high level. [name manufacturer] determined its own pricing policy and could also have seen in its alleged boycott of health insurers reason to lower its prices order to take wind out of the sails of possible alternatives, especially after the temporary introduction of a magistral preparation. This [name of manufacturer] did not so. It cannot therefore hide behind the alleged conduct of the health insurers to justify its own conduct in retrospect. The conduct of [name of manufacturer] and the alleged conduct of the health insurers are independent of each other and the ACM therefore did not have to include [name of manufacturer]'s assertions about the conduct of the health insurers in its assessment in this penalty case any further than it did.

Misrepresentation of legal framework

11. [name of manufacturer] argues in vain that the ACM applied the wrong legal framework. At issue in this case is not [name manufacturer's] right of exploitation and the resulting market exclusivity obtained through the designation of [CDCA brand name] as an orphan drug, but rather whether within that context the exercise of that right by [name manufacturer] is consistent with competition law. What [name manufacturer] argues about violations of standards of Union or national law25 by public and private parties other than itself or the ACM ignores the central question in this case, namely whether [name manufacturer] abused an economic dominant position with the price it charged for [CDCA brand name]. Therefore, the court will not further address those alleged violations. For that matter, even if (part of) those violations were established, they do not in principle detract from [name manufacturer]'s liability for its own conduct.

Relevant market and dominance misidentified?

Legal framework relevant market and dominance

12. Article 24(1) of the Mw provides that companies are prohibited from abusing a position of economic power. A position of economic power is defined in Article 1 opening words and under i of the Mw as a position of one or more undertakings which them to prevent the maintenance of effective competition on the Dutch market or part of it by giving them the ability to behave to an appreciable extent independently of their competitors, their suppliers, their customers or end users.

12.1. Article 102(a) TFEU provides that it incompatible with the internal market and prohibited, in so far as it may trade between Member States, for one or more undertakings to abuse a dominant position within the internal market or in a substantial part thereof. Such abuse may consist in particular in the direct or indirect imposition of unfair purchase or selling prices or other unfair contractual terms.

12.2. Economic dominance is established by first defining the relevant market26 and determining the market share in that market. It is then assessed whether the market share is high enough to indicate economic dominance.27 If that is the case

is, other factors potentially disciplining the behavior of the firm in are assessed. These include, in particular, the possible pressure from potential competition or countervailing buyer power.28

Relevant market

12.3. There is no dispute between the parties that the relevant market is the Dutch market for CDCA-based drugs against CTX. With Contested Decision I, the ACM - unlike with the penalty decision - also included CDCA magistrally prepared by AUMC in the relevant product market during the period that the product was available in the Netherlands for CTX patients. Relatedly, the ACM concluded that [name of manufacturer] had no economic market position on the relevant market during the period from April 1, 2018 to July 26, 2018, because the CDCA prepared magistrally by the AUMC then a substitute. Actual competitive pressure was temporarily exerted on [name of manufacturer] with this magistral preparation for a relatively short but still substantial period of time.

12.4. [name of manufacturer] has referred to the case law of the Court of Justice of the European Union () on "readiness", in particular to ECJ 30 January 2020, C-307/18, Generics (UK), ECLI:EU:C:2020:52, in support of its view that magistral preparation of CDCA by the AUMC belongs to the relevant product market throughout the infringement period. On this, the ACM correctly states that the conduct to be assessed here does not consist of an agreement entered into between an undertaking operating on a market and another undertaking not yet operating on it, and that potential competition should not be included in the market definition but in the assessment of economic dominance. Therefore, the ACM was right not to include the magistral preparation of CDCA by the AUMC in the relevant market throughout the infringement period.

Economic dominance

12.5. [name manufacturer] argues that the ACM has not demonstrated that [name manufacturer] was able to behave independently of competitors and customers, particularly from the potential - and subsequently actual - competitive threat posed by the pharmaceutical compounding combined with the purchasing power of the health insurers. [name of manufacturer] was never able to prevent competition from compounding and was unable to behave independently of its competitor (the AUMC) and its customers (the health insurers), who were their competitor's financial backers and provided the AUMC with a guaranteed customer base. The price of
13,090 is only a list price (not a negotiated price) and therefore cannot be to establish dominance. The ACM may not include the Dutch price for [CDCA brand name] in its assessment of [name of manufacturer]'s dominance. Indeed, the system of reference prices in other Member States29 implied that it could not reasonably reduce its public price in the Netherlands because of the downward impact that this could have on the price level that [name manufacturer] could achieve in other Member States.

12.6. This argument fails.

12.7. The court considers that [name manufacturer] - except for the period from April 1, 2018 to July 26, 2018 during which magistrally prepared CDCA was available on the market - had a dominant position because its market share in the relevant product market was 100%. Whatever [name manufacturer] has argued about not having the status of indispensable trading partner, being indeed heavily disciplined and forming a bloc by health insurers against it, does not alter the fact that [name manufacturer] had, throughout the entire infringement period for [CDCA brand name], the price of 13,090 continued to charge, actually charged and collected.

12.8. Precisely in light of the reference price system and [name of manufacturer]'s market exclusivity for [CDCA brand name] in Europe, [name of manufacturer] had a particular responsibility in setting the price for [CDCA brand name]. After all, a CDCA-based drug has been prescribed for many years to treat CTX patients, and these patients are constantly dependent on the availability of a CDCA-based drug (an alternative cannot be waited for). Linked to that dependency is also the dependency of physicians to prescribe that drug as well as health insurance companies to reimburse that drug.

In addition to the harm risk if they not do so, the health insurers also pointed to the Supreme Court's ruling of December 19, 2014, ECLI:NL:HR:2014:3679, which establishes the legal obligation to reimburse [CDCA brand name] even if this drug is not included in the GVS.

12.9. The court considers - unlike [name of manufacturer] - that, according to established case law of the Court of Justice,30 price behavior can be included as one of the relevant factors in the assessment. This is not "backwards reasoning" as [name manufacturer] argues. The Competition Appeal Tribunal decision to which [name manufacturer] refers in this regard also considers the company's pricing behavior as a relevant factor in establishing dominance.31 On the argument derived by [name fabricant] from the Servier ruling32 on assessment of [name fabricant's] price level as an element in the determination of its dominance, the ACM correctly states that the consideration to which [name fabricant] refers does not concern the determination of dominance and cannot detract from the jurisprudence of the Court Justice on the relevance of the firm's conduct in determining its dominance.

12.10. It also already follows from the fact that [name of manufacturer] always requested and collected the price of 13,090 that it not (sufficiently) disciplined. In any case, if there was any actual competitive pressure from the magistral preparation, [name of manufacturer] did not act accordingly. [name of manufacturer]'s argument that the price of 13,090 is only a list price and therefore cannot be used to establish a dominant position also fails since this price was actually charged and collected. To the extent that [name of manufacturer] argues that (partly) because of the absence of non-disclosure agreements it did not come to negotiated prices, the Court considers that the documents show that CZ and Menzis a non-disclosure agreement. There is therefore no reason to see why [name of manufacturer] could not have charged and collected (without the list price) a lower price than the list price. After all, the system of reference prices does not alter the fact that the manufacturer can give (usually secret) discounts on the pharmacy purchasing price (list price) on the basis of negotiations with the Minister for Health, Welfare and Sport, with health insurers and/or hospitals.

Conclusion on market and dominance determination

12.11. The ACM correctly determined the market and dominant position. The grounds of appeal against the market and dominance determination do not succeed.

Abuse (economic dominance) wrongly established?

13. An undertaking in a dominant economic position is not allowed to abuse that dominant position. The charging of unfairly high, excessive, prices, that is, prices that are not in reasonable proportion to the economic value of the service provided,33 constitutes abuse. In this regard, it must be determined whether there is an excessive (disproportionately) large difference between the actual costs incurred and the price actually charged.34 There are no exhaustive criteria for determining whether or not rates are excessive.

Evidence standard

14. The court considers that, contrary to [name of manufacturer]'s contention, the ACM does not have to prove here that a dominant company, by charging an excessive price, prevented competition by using means other than those customary in normal competition, or competition based on merit. This case involves exploitative abuse, not exclusion of competitors. [name manufacturer] refers for its claim to case law dealing with exclusionary abuses where the dominant firm engaged in conduct aimed at excluding competitors. The criteria cited by [name of manufacturer] are not at issue here.

14.1. The ACM found in two steps that [name of manufacturer], with the price of 13,090 for [CDCA brand name], charged and collected an excessive price throughout the infringement period of almost 2.5 years. First, using a comprehensive price-cost test, the ACM concluded that that price excessive. Second, the ACM found that the price was unfair and that there was no legitimate reason for that (excessive) price. In doing so, the ACM stated that, in the case of an orphan drug, such a legitimate reason could be, for example, that the manufacturer needs to recover high costs, including the costs of developing drugs that prove ineffective or safe, or that

it involves an innovative drug with great benefits for patients. That is not the case here, according to the ACM.

14.2. [name of manufacturer] argues that the ACM has not met the applicable standard of proof. There is no evidence of harm to customers or consumers. Patients were not deprived of the drug (the uncertainty for patients was caused by the health insurers, not [name of manufacturer]) and the health insurers benefited financially, economically and politically from their refusal to negotiate with [name of manufacturer].

14.3. The District Court held that the ACM was correct in arguing that the buyers - the health insurance companies - had to pay an excessive price for [CDCA brand name] for almost 2.5 years. The benefits of registration as an orphan drug in return could not justify this price increase. Health insurance companies were thus . Because the number of CTX patients is small, the total spending by health insurers on [CDCA-brand name] was relatively small. That said, given the limited financial resources in the healthcare industry, there were fewer financial resources available to consumers with other care. Consumers of [CDCA brand name] , CTX patients, were also harmed because was uncertainty about the reimbursement and source of their CDCA drug. [manufacturer name] blames this on the health insurers and the AUMC, but ignores the fact that [manufacturer name]'s high price was at the root of their behavior.

14.4. In Contested Decision I, the ACM found that - contrary to [name of manufacturer]'s view - the determination of excessiveness of the price of [CDCA brand name] is not based on a comparison with the Aspen and Phenytoin cases.35 These cases are similar in some respects to the case against [name of manufacturer], since each of these cases concerns the excessiveness of the price of a drug and involves, among other things, the cost of the drug. But that does not mean that the ACM did not conduct its own investigation and assessment of the excessiveness of the price of [CDCA brand name] . This is not altered by the reference by [manufacturer name] to an article - written in a personal capacity - by an employee of the ACM.

14.5. The conduct that the ACM qualifies as abuse relates only to the price actually applied by [name of manufacturer] on the relevant market for [CDCA brand name] . The ground for appeal that the ACM did not in any way take into account that [name of manufacturer] - unlike the health insurers and VWS - negotiated in good faith and complied with the rules for proper negotiation36 therefore already fails. Whatever those arguments may be, they do not make the price applied could not constitute an abuse.

Lex certa principle

15. As the abuse is based on an excessive price, the court also does not follow [name of manufacturer] in its argument that there is an unforeseeable interpretation of law on the basis of which the conduct qualifies as abuse (lex certa). In several previous cases by the European Commission and national European competition authorities, (drug) prices have been assessed as excessive. The ACM mentioned several examples in the fine decision. This assessment took place on basis of a comparison of price with costs, so that, contrary to [name of manufacturer]'s argument, this methodology was also foreseeable for [name of manufacturer] .

Excessive price misrepresentation of Copenhagen Economics (CE) report and the risks taken by [name of manufacturer]?

16. To demonstrate the existence of excessiveness, there is no unique (economic) method or test that a competition authority must apply. The ACM rightly points out that it has a certain amount of latitude in determining which method or test to use for this purpose.37

The methodology used by the ACM

16.1. In this case, the ACM used a price-cost test to the reasonableness of the returns achieved. The premise of this method is that a price is excessive if it leads to an excessive or disproportionate (profit) margin compared to the cost price. This method is based on the idea that there is a price that guarantees an adequate margin in relation to costs, and that a higher price demanded by a company may excessive. Excessive return and excessive price exist when

the difference between the adequate price and the requested price is significant and sustainable.

16.2. In assessing the price-to-cost ratio of [CDCA brand name] during the infringement period, the ACM compares the return achieved with the standard return and considers the project risk for [name manufacturer's] price and registration project. In the excessiveness assessment, the ACM also considers [manufacturer name]'s investments in the project.38

16.3. As a basis for the price-cost test, the ACM uses the net present value method (NPV model). The ACM elaborates the price-cost test in two variants: comparison between internal rate of return (IRR) and weighted average cost of capital (WACC) as the norm return and comparison between the price paid and the lowest possible profitable price.

16.4. The ACM states that [name manufacturer's] project is characterized by low costs to revenues, low risks and very high returns. Moreover, [fabricator's name]'s project has no period of start-up losses. Also due to the very favorable ratio of negative to positive cash flows, the project had a very high internal rate of return. The project was characterized by very high upside potential and low downside risk for [name of manufacturer] . The ACM concludes that the results of the price-cost test all clearly show that the price of 13,090 euros charged and collected by [name fabricator] for [CDCA brand name] during the infringement period is excessively high. The same applies to a lower price of 7,000, [name fabricator] had as a possibility according to its accounts.

Should the ACM have used a different model?

16.5. [name manufacturer] objects to the ACM's use of the NPV model and believes that the ACM should have used the model of the consultants engaged by [name manufacturer] (Copenhagen Economics, CE) risk-adjusted net present value model, rNPV model). Although [name of manufacturer] does not deny that the NPV model is also regularly used in the pharmaceutical sector, it believes that an rNPV model is preferable because it allows for a more detailed calculation by assigning different risk factors to individual costs and revenues.

16.6. [name of manufacturer] does not dispute that calculating the net present value of cash flows is appropriate for determining excessiveness in this case. The point of contention concerns which model to use for this purpose.

16.7. The ACM first notes that an rNPV model is always about ' ex-ante assessment of investment options, not the excessiveness assessment. The ACM does not dispute that the rNPV model is a suitable model for investment decisions and that it is regularly by investors. But so is the NPV model that [name manufacturer] itself used in 2014. In practice, the suitability of a method for making investment decisions is not equivalent to the suitability of the method for a competition assessment. On the contrary, an rNPV model is in principle less suitable for an excessiveness assessment. In this model, costs and revenues are recalculated by multiplying them by the probability that they would materialize. This often introduces considerable uncertainty because it is difficult to determine these probabilities robustly. In addition, it ignores the actual cash flows realized, which must be determined whether they excessive. For the NPV model it used, the ACM was able to match the risk estimate incorporated in the WACC by [name manufacturer] itself. The ACM also tested this WACC against the WACCs applied by other pharmaceutical companies. This shows that given the relatively low risk of the project, this WACC is on the high side and thus in favor of [name manufacturer] .

16.8. About the rNPV model submitted by [name of manufacturer] and prepared by CE, the ACM states that the probability estimates are not robust and much more negative than estimated by [name of manufacturer] itself preparing the project. They represent a significant overestimation of the project risks. This overestimation is reinforced by the fact that the rNPV model multiplies the various partial probabilities by each other to arrive at a success rate for the project as a whole. With this, according to this model, the project would succeed only one out of four times, which is not credible. The ACM further states that the rNPV model submitted by [name of manufacturer] is also not suitable for the

assessment of excessiveness, because CE's rNPV model is built for the global revenues of [CDCA brand name] through 2027 (the end of the exclusivity period), while the ACM assesses the price of [manufacturer name] in the Netherlands through 2020. Also, this model incorrectly does not include revenues from Xenbilox's 2014 price increase, despite the fact that it was part of the project and intended to fund start-up costs.

16.9. According to [name of manufacturer], investors have a strong preference for the rNPV model, in which context it refers to the Valuation Survey, and many reports by economists confirm that the rNPV model is leading in the pharmaceutical sector. The ACM disputes this. The Valuation Survey relies on a survey by CE and the ACM questions the expertise of the respondents (of most respondents, CE could not indicate whether they had experience in the pharmaceutical sector). Furthermore, according to the ACM, there are several shortcomings in the implementation of the survey. For example, it involves only stated preferences in response to hypothetical stylized projects that say little about choices made in practice. Further, according to the ACM, the survey's questions were prescriptive and unclear. [name of manufacturer] did not address these shortcomings at all. The general reference by [name of manufacturer] to some reports by economists prepared in the context of regulatory exclusivity of medicines is insufficient support for its claim.

Conclusion used model

16.10. The court - in view of the ACM's rebuttal thereof - sees no reason in what was argued by [name of manufacturer] for the opinion that the NPT model could not have been used by the ACM as a basis for its decision-making.

Application of incremental approach

17. An excessiveness assessment involves the actual costs incurred and revenues received. This is necessary to do justice to the actual advantage enjoyed by the dominant company and the disadvantage suffered by its customers. This is also evident from case law.39 The court is of the opinion that the ACM was therefore right - also already in the penalty decision - not to apply the incremental approach40 .

Applied WACC correct?

18. [name of manufacturer] further argues that the ACM continues to underestimate the risks of the CDCD- [name of manufacturer] project. The CE Review explained why the WACC of 15% applied by the ACM probably the actual risk of the project. These include that smaller biotech and pharma companies are known to underestimate risks, that the peer group chosen by the is not representative, and that the ACM failed to assess individual risk components.

18.1. The ACM claims to have used the 15% WACC as a starting point because [fabricator name] itself used this WACC in 2014 when deciding to start the project. This was because, at the time, [name fabricator] had an interest in assessing the risk as realistically as possible since it was going to invest in the project. [name fabricator] used a WACC of 12% as its "base case" and a WACC of 15% as its "best case." The ACM took the highest and thus most favorable figure for [name fabricator] from this (after all, with a higher WACC, the difference with a higher realized return is smaller and thus less likely to be excessive). The ACM then tested this WACC of 15% against the WACCs used by other companies in the pharmaceutical and biotechnology sector. This showed that the 15% WACC is higher than the WACCs of the vast majority of these . This confirms that this WACC is on the high side, and thus favorable to [name of manufacturer] . In doing so, the ACM has assumed a large and diverse group of companies (more than 80 in the pharmaceutical sector and just under 150 in the biotechnology sector). Even if some of these - and [name manufacturer] does not indicate which number it concerns - would underestimate the risk, this does not mean that a WACC of 15% is too low given that only a few of this large group of companies have a higher WACC than [name manufacturer]. Furthermore, within this large group, the peer group constitutes a subset of companies with a similar Research & Development (R&D) profile as [name manufacturer] . This group represents only a small minority of the companies used by the ACM. Also

therefore, even if [fabricator name]'s argument were true, it does not change conclusion based on the WACCs of all companies used.

18.2. The court followed the ACM's considerations. As an extension of its argument as to why the WACC was correctly determined, the ACM indicated why, in its view, the risks for the [name of manufacturer] CDCA project were not underestimated. What is important here is not only that [name manufacturer] itself estimated the risks lower at the time the project was started than the CE review afterwards. Also important is that the CE review does not substantiate why a higher risk percentage is chosen than in the studies, so that there is no reason to assume those higher risk percentages.

Conclusion WACC

18.3. The court finds that the ACM correctly applied a WACC of 15% and that there is no concrete evidence that the ACM underestimated the risks of the [name of manufacturer] CDCA project.

Arithmetical error corrected

19. The ACM acknowledged that, as [name of manufacturer] argued on appeal, there was a calculation error related to interest income and foreign currency gains. In the defense submission, the ACM corrected its return calculations.41 The ACM argues that this changes the results only very slightly. Even after the correction, the IRR remains infinitely high and the return on (ROI) remains very high. Based on the IRR, the ACM after correcting the aforementioned calculation error that a price of 4,110 would still be profitable. Using the ROI, the ACM determines that a price of 4,500 would still more than profitable. With that price, the (necessary) upfront investments would be recovered with a return of at least 15%. Here the ACM uses the WACC of 15% to calculate the net present value of costs and revenues and also as a limit for determining the price of 4,500, which is in favor of [name manufacturer] . Each of these prices is much lower than the price of 13,090 that [name fabricator] actually charged and collected for [CDCA brand name]. This calculation considers only the infringement period. If the full ten years of market exclusivity were considered, the price would be at a significantly lower level (dropping toward 3,000), because the start-up costs could be recovered over a much longer period.

19.1. According to [name of manufacturer], a second "calculation error" was made by not Xenbilox's production costs. The ACM argues that this not an error, but a deliberate and justified choice. After all, Xenbilox's production costs do not arise from the project and are not necessary for the production of [CDCA brand name] . [fabricator name] gives no reason why these production costs should be included. Nor did the ACM include Xenbilox's revenues in its excessiveness assessment insofar as they are not attributable to the project. This means that the ACM only included the revenues from Xenbilox's price increase, as this a first step of the . If production costs were included, Xenbilox's entire revenues would also have to be . That would amount to a spillover effect of 100%, which [name manufacturer] itself (rightly) criticizes.

19.2. At issue here is how the return calculation of [CDCA brand name] should take into account the sales of Xenbilox in the period before [CDCA brand name] entered the market, namely from the start of the project in 2014 until June 2017. CEs calculation of [CDCA brand name]'s return assumes a so-called "spillover effect" of Xenbilox of 20%. This means that in the period before [CDCA brand name] entered the market, CE includes 20% of Xenbilox's costs and revenues in the return calculation. [name of manufacturer] believes that this does justice to the advantage that it, as the manufacturer of Xenbilox, might have had in marketing [CDCA brand name] . The ACM states in its excessiveness assessment that it did not adopt this spillover effect. This is because [manufacturing name] does not make clear why it considers 20% of all costs and all revenues of Xenbilox. In doing so, [name fabricator] ignores what its own internal documents show, namely that Xenbilox's price increase from 660 to 2,900 was part of the project. The ACM assumed the demonstrated reality and included the revenues from this price increase

included in its excessiveness assessment. The ACM did not include Xenbilox's costs. The price increase was not necessary to these costs, as Xenbilox was already profitable before this price increase ([name fabricator] does not dispute this). Thus, by assuming the spillover effect, [name fabricator] paints a distorted picture of reality, with higher costs (20% of Xenbilox's costs) and lower revenues (based on 20% of the price of 2,900 instead of the amount of the price increase, which amounts to 77% of that price).

Conclusion yield calculation

19.3. The District Court finds that the ACM conducted the yield calculation in a careful manner, correctly assuming the actual course of events within [name of manufacturer]'s CDCA project that was aimed at incremental (steep) price increases. The criticism directed against it by [name of manufacturer] ignores this reality and gives no reason to disqualify the calculation followed by the ACM.

Fairness of price

20. The ACM then the fairness of the excessive price. An excessive price may be fair if it reflects the economic value of the product. The fairness or of the price can be assessed both absolutely and in comparison to competing products.42 [name of manufacturer] directed several grounds against the ACM's assessment. These will be presented with the ACM's response to them for each section.

What price should be ?

20.1. [name of fabricator] first argues that the list price is the wrong target for assessing the unfairness of the price. It was never [name of fabricator]'s intention charge the list price. Its indisputable goal was to charge a lower, negotiated price. However, it did not do so because health insurers and VWS imposed restrictions on negotiations. For the maximum price that [name of manufacturer] was expected to charge (i.e., after applying a 50% discount), Contested Decision I contains no analysis of unfairness.

20.2. [manufacturer's name] further argues that no cost-effectiveness analysis is available and that, in a case where the ZIN has refused to the normal cost-effectiveness assessment, it is not for the ACM to substitute its own judgment on the cost-effectiveness or value of [CDCA brand name] for it. The ACM has no authority to make judgments on the therapeutic value or cost-effectiveness of orphan drugs.

20.3. The ACM states that cost-effectiveness concerns the relationship between the value of the product (in this case the effective and safe treatment of the patient) and the costs incurred to realize this value (in this case the price of the drug). ZIN did not do a cost-effectiveness analysis because this was a drug that had been on the market for a long at a much lower price, so the (much higher) price of [CDCA brand name] was obviously unacceptable in ZIN's view and therefore no comprehensive pharmacoeconomic analysis necessary. In assessing the price of [CDCA brand name], the ACM therefore examined whether it is a drug that adds so much added value for patients that the price can therefore be justified. The ACM concludes that this not the case. One of the relevant considerations in that regard is that the active ingredient in [CDCA brand name] and in the other CDCA-based drugs, Xenbilox and magistrally prepared CDCA, is virtually the same. In doing so, the ACM did not itself assess the added therapeutic value of [CDCA brand name]. For the determination that [CDCA brand name] has no therapeutic added value compared to Xenbilox, the ACM referred to the expertise of the ZIN and medical specialists involved in the treatment of CTX.

20.4. The court finds that these two arguments by [name of manufacturer] do not . The ACM was right to rely on the list price because [name manufacturer] actually charged and collected that price. The alleged intentions of [name manufacturer] are not relevant when assessing the actual conduct of [name manufacturer] . Furthermore, the ACM was allowed to

agree with the ZIN's assessment that a cost-effectiveness analysis was not necessary in this case because the active ingredient has been used successfully for many years, but at a significantly lower price, to treat the condition for which [name of manufacturer] has now registered it.

Did the ACM adequately consider the benefits of registration and the efforts of [name of manufacturer]?

21. [name of manufacturer] argues that in assessing unfairness per se, the ACM ignores the complexity of the regulatory system and the benefits made available by "repurposing" medicines. Also, according to [name of manufacturer], the ACM ignores the benefits of applying modern standards, including the latest requirements on proving safety, efficacy and quality (updated production methods, including those for the active substance). In addition, the EMA and the MEB both confirmed that medicines with marketing authorization (MA) should not be compared with medicines without an MA. Off-label use, according to the General Court of the European Union (the General Court), is not a "satisfactory method of treatment. "43 Furthermore, according to [name of manufacturer], the MEB explicitly stated that it compare Xenbilox to [CDCA brand name] because Xenbilox has never been authorized on the Dutch market. Furthermore, according to [name of manufacturer], downplaying the innovative value of [CDCA brand name] amounts to downplaying the importance and rationale of the Orphan Drug Regulation and the marketing authorization system itself.

21.1. In this regard, the ACM states that it recognizes that the registration and prior efforts of [name of manufacturer] are not without value, but that as far as [CDCA brand name] is concerned, the benefits of registration and the efforts of [name of manufacturer] should be put into perspective. With CDCA having been used for decades for the effective and safe treatment of CTX, the benefits of registration cannot justify the excessive price of [CDCA brand name]. As for [name of manufacturer]'s efforts, according to the ACM, it relied entirely on data obtained in two studies using Xenbilox and a pharmacy preparation, respectively, to obtain marketing authorization and orphan drug status. [CDCA brand name] was not developed by [name of manufacturer] and was itself never studied in clinical trials. The ACM explains that the reference to innovation in Contested Decision I, unlike [name of manufacturer] makes it appear, is made in the specific context of a comparison with two other drugs (Kolbam and Orphacol) that were already authorized in the European Union for the treatment of CTX. To that extent, there is an innovation because treating CTX with CDCA compared to treatment with those drugs provides a significant benefit to patients, as the EMA also ruled. However, those drugs were not used in the Netherlands for the treatment of CTX because doctors preferred the (long-established) off-label treatment of CTX with CDCA. Also, at the time of the project, [name of manufacturer] itself felt that Kolbam was not a real alternative to CDCA. Thus, the practical value of this innovation is limited. The ACM states that this does not represent a value judgment on the rationale for orphan drug protection and the marketing authorization system. It further states that [manufacturer's name]'s references to certain statements by the EMA and the MEB do not make it impossible to compare the price of [CDCA brand name] with the price of Xenbilox. The MEB also believes that the price increase of [CDCA brand name] is disproportionate to the efforts made by [name of manufacturer].

21.2. The court finds that the ACM correctly considered that as far as [CDCA brand name] is concerned, the benefits of registration and the efforts of [name of manufacturer] should be put into perspective. Because CDCA has been used for decades for the effective and safe treatment of CTX, the benefits of registration cannot justify the excessive price of [CDCA brand name]. As for [name manufacturer's] efforts, [name manufacturer] did not dispute that it relied entirely on data obtained in two studies using Xenbilox and a pharmacy preparation, respectively, to obtain marketing authorization and orphan drug status. [CDCA brand name] was not developed by [name of manufacturer] and was itself never studied in clinical trials. Nor is there any innovation because the active ingredient is already

used safely in the Netherlands for decades to treat the condition for which [name of manufacturer] had that substance registered.

Is the price unfair in comparison?

22. [name of manufacturer] argues, in the context of unfairness of price compared to other products, that the ACM wrongly compares the price of [CDCA brand name] with the price of off-label products Chenofalk and Xenbilox and with the price of the magistral preparation of CDCA. Comparison with Xenbilox, according to [manufacturer name], is not possible because it is not an orphan drug. The price of Xenbilox was set decades ago for a mass product for millions of patients and does not depend on reimbursement negotiations. Comparison to the magistral preparation is not possible because that preparation has no MA, is not subject to any independently reviewed procedure or product standard, does not meet the same quality and safety requirements as [CDCA brand name] , is reimbursable without negotiation and, as the evidence shows, was sold below cost. According to [name of manufacturer], the most logical measures of comparison are : (i) the prices of other orphan drugs and (ii) the prices of [CDCA brand name] in other member states of the European . Such comparisons can be used on their own to show that the price of [CDCA brand name] was not in violation of Article 102 TFEU.44 According to [name of manufacturer], the ACM does not meet the legal standard that it must give due consideration to comparables put forward by the investigated company that are prima facie valid, and the ACM was only allowed to reject them with a reasoned justification.45 In addition, comparison measures should be selected according to objective, appropriate and verifiable criteria and should be sufficiently similar (not identical) to the remedy in question to allow for meaningful comparison. Comparisons should be made consistently and the figures compared should comparable.

22.1. The ACM argues against this that the fact that off-label use was classified by the General Court as "not a satisfactory method of treatment" does not mean that there can be no comparison at all between (the price of) [CDCA brand name] and (the price of) its predecessors. At most, the orphan drug status of [CDCA brand name] may justify a difference in price from its predecessors.

22.2. The ACM further states that it carefully weighed whether the comparisons offered by [name of manufacturer] were valuable and concluded that they not. For a meaningful comparison, both the products themselves and the prices actually charged must comparable. Neither condition was met with respect to the other orphan drugs cited by [manufacturer name]. Indeed, [CDCA brand name] deviated from the usual situation for orphan drugs in that the risks, development costs and degree of innovation were much smaller than for other orphan drugs. A comparison with the list price of other orphan drugs is also not meaningful because - as [name of manufacturer] itself points out - it is common for manufacturers to give discounts on list prices. Thus, the list prices of the orphan drugs mentioned by [name of manufacturer] are probably (considerably) higher than the prices actually charged and do not lend themselves to a comparison with the (list) price actually charged by [name of manufacturer]. [name of manufacturer] no substantiated arguments against this. The general claim that there are many more orphan drugs with high prices nothing. Indeed, for truly innovative drugs, a high price may justified. In the case of [CDCA brand name], this is not the . Furthermore, the ACM argues that a comparison between prices of [CDCA brand name] in other Member States is of limited value, because due to the EU-wide market exclusivity for the marketing of [CDCA brand name] for CTX, there was in principle no competitive pressure from other suppliers.

22.3. The ACM finds that the comparison measures it has selected meet the criteria raised by [name of manufacturer]. The ACM has selected these comparison measures according to objective, appropriate and verifiable criteria, and the comparison measures are sufficiently similar to the resource in question to make a meaningful comparison. The comparison of the prices of Chenofalk, Xenbilox and [CDCA brand name] is substantiated. These drugs each other in time and have been supplied by [name of manufacturer] from the time [name of manufacturer] acquired Chenofalk in 2008. They are essentially the same drug under three different

designations. The fact that [CDCA brand name] , unlike previously Chenofalk and Xenbilox, is indicated for the treatment of CTX and has acquired orphan drug status does not mean that the prices of these drugs cannot be compared. While this registration may justify a difference in price, it does not justify the difference at here. The comparison of the price of [CDCA brand name] with the price of AUMC's magistral preparation is also substantiated, according to the ACM. That magistral preparation replaced [CDCA brand name] for several months during the infringement period and after its expiration. Given the substitutability of these drugs, which are also part the same product market, a price comparison is . The arguments put forward by [name of manufacturer] for its claim that the price of the magistral preparation cannot compared with the price of [CDCA brand name] , rather seem to fit with the contention that the difference in price is justified, but do not make a impossible. Moreover, according to the ACM, these arguments cannot be convincing in any case: as indicated, the benefits of registration and the efforts of [name of manufacturer] cannot explain the huge difference in price.

22.4. The court endorses this refutation by the ACM of [name of manufacturer]'s argument .

Conclusion finding of abuse of economic dominance

22.5. The court finds that the ACM carefully and objectively assessed the excessiveness and fairness of [CDCA brand name]'s price. In doing so, the ACM correctly based its assessment on the list price that [name of manufacturer] has consistently charged and collected. Together with the ACM, the District Court considered that registration of [CDCA brand name] as a drug for the treatment of CTX does offer advantages that may a certain price increase, it is absolutely evident that a price that, with intermediate steps, has increased from 46.00 to 13,090.00 per package is
gone, in the absence of sound substantiation is beyond all limits. This is even more so when considering the fact that [name of manufacturer] used older studies in the registration process that did not use [CDCA brand name], but a compound preparation and a predecessor with a different brand name but the same active ingredient. The active ingredient had been successfully used for decades for the treatment of CTX, and all [name of manufacturer] did was take advantage of the opportunity to register the drug administratively for that decades-old method of treatment in order to an exclusive right. The exorbitant price increase subsequently applied is a textbook example of abuse of an economic dominant position. This abuse is even more insistent because it takes place on the backs of vulnerable patients who cannot do without this medicine. [name of manufacturer] took advantage of this for its own financial gain. The ACM has therefore properly established that [name of manufacturer] has abused its position of economic power. The grounds of appeal against this do not succeed.

<u>Binding commitment decision</u>

23. The power to declare a commitment binding is located in Section 12h(1) of the Establishment Act of the Consumer and Market Authority (Iw). With the decision of October 7, 2020, the ACM rejected [name of manufacturer]'s application to declare a commitment binding. This decision could not be directly appealed by [name of manufacturer].46 However, [name of manufacturer] could raise the rejection of the application to declare the commitment binding in the context of the fine imposed.47 It did so.

23.1. Section 12h(2) of the Iw provides that the ACM may take a decision to declare a commitment binding if it considers it more effective than imposing an administrative fine. The power to declare commitments binding is therefore a discretionary power.

23.2. The ACM did not consider declaring the commitment offered by [name of manufacturer] to be more effective than imposing a fine. In short, the ACM points to the gravity and scope of the conduct (imposing and collecting excessive prices over an extended period of time), the phase of submission of the application, [name manufacturer's] view of the violation ([name manufacturer] could not agree with any reproach made against it as responsible for the excessive price), the lack of actual initiative by [name manufacturer] to arrive at a lower price

in negotiations with health insurers, and the amount of the price proposed by [name of manufacturer] about which there was uncertainty whether it was sufficient for health insurers. The ACM emphasizes that after transmission of the penalty report48 it does not consider accepting a commitment to be effective in , unless there are special circumstances. There are none in this case. In this case, [name of manufacturer] submitted the commitments by letter on the day of the (announced) signing and sending and thus transfer of the report. Therefore, declaring the commitment binding could not bring efficiency gains in terms of time of investigation or by deployment of fewer resources by being able to stop the investigation early. The ACM also takes into account the effect of such a commitment on other companies. A commitment is not intended to allow companies that have committed serious violations to escape a sanction by a commitment at the moment the regulator has virtually completed its investigation. The ACM therefore stands by its October 7, 2020 rejection of the application to a commitment binding.

23.3. In the court's opinion, the ACM could reasonably decide to reject the application, given the reasons it gave for doing so.

Assessment (amount) fine

24. Pursuant to Article 56 of the Mw, when the ACM violates the prohibition on abuse of a dominant economic position, it can choose to impose a fine or an order subject to periodic penalty payments - or both - or it can choose to establish a violation only. The ACM has chosen to impose a fine.

24.1. The ACM has explained why it chose to impose a fine and not (also) an order under penalty or a mere finding of the violation. It pointed to the difference in objectives between an administrative fine (a punitive (punitive) sanction) and an order under penalty (an reparative (remedial) sanction). An order under penalty was not at issue in the circumstances of the case. At the time of the imposition of the fine on July 1, 2021, the market situation had already changed to such an extent that remedial measures were no longer opportune, either as an alternative to or in addition to a fine. The ACM considers [name of manufacturer]'s violation to be a very serious violation of competition rules. It does not consider the mere finding of a violation in this case sufficient and considers a fine to be the appropriate and appropriate remedy.

24.2. The court also believes that the imposition of a fine is appropriate in this case.

Principles establishing fine

24.3. In the specific case, the ACM must not only correctly apply Article 56 of the Mw and its fining policy rules, but also observe the proportionality requirement set out in Article 5:46 of the Awb. This means that when setting the fine, the ACM must assess whether the fine determined under the fine policy rules is proportionate to the intended purpose, taking into account all the circumstances of the case. Those circumstances include at least the nature and gravity of the violation, the extent to which it can attributed to the violator and the circumstances under which it was committed. The offender's ability to pay may also a circumstance to be considered. Article 6 of the Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR), which applies to the fine imposed, implies that the court tests without restraint whether the decision regarding the fine meets these requirements and results in a proportionate sanction.

24.4. Under Section 57(1of the Mw, the fine shall not exceed 900,000 or 10% of the 's turnover, whichever is higher.

24.5. The ACM determined the fine on the basis of the Fines Policy Rule ACM 201449 (the Fines Policy Rule). Under the Penalty Policy Rule, the ACM determines the turnover involved on the basis of the revenue that an offender earned in the last full calendar year of the violation from the supply of goods and services directly or indirectly related to the . The turnover involved also the duration of the violation.

The ACM then sets a basic fine between 0 and 50% of the violator's affected turnover. In determining the basic fine, the ACM takes into account the seriousness of the violation and the circumstances under which the violation was committed. The severity of the violation is determined by the gravity of the violation in conjunction with the economic context in which it occurred. In assessing the economic context, the ACM takes into account, among other things, the nature of the products or services involved, the size of the market, the size of the offender and the offender's market share. In addition, the ACM takes into account the prejudice or potential prejudice to the normal competitive process and the impact on the economy in general of the conduct in question. The ACM then possibly adjusts the amount of the fine based on penalty increasing and decreasing circumstances. Finally, the ACM tests against the principle of proportionality.50

The manner in which the ACM determined the (base) fine in this case

24.6. To calculate the turnover involved, the ACM considered the turnover achieved by [name of manufacturer] in 2019 from the sale of [CDCA brand name] in the Netherlands, 8,416,870. That turnover was divided by twelve and multiplied by the number of months the infringement lasted.51 The turnover in question was adjusted to 18,938,000.00 in Contested Decision I because of the change in the infringement period (27 months instead of 31 months). The ACM considers a severity factor of 45% appropriate and sets the basic fine at 8,522,080.88. In the context of specific prevention, the ACM can increase the turnover involved in view of the weight of the offender, expressed in terms of the total annual turnover of this offender in the financial year preceding the fine decision.52 The ACM did so in this case and doubled the basic fine so that the basic fine comes out at rounded 17,044,000. The ACM did not consider any fine-reducing or -increasing circumstances present in this case.

24.7. In determining the statutory fine maximum (10% of the 's turnover), the ACM based itself on the company's worldwide turnover in the most recent financial year for which it has financial statements available.53 The ACM based itself on [Manufacturer 3]'s 2020 consolidated turnover of 251,127,000, so the maximum fine the ACM can impose is 25,112,700.

24.8. [name of manufacturer] argues that the ACM wrongly applied the Penalty Policy Rule. It should have used the derogation power of Article 4:84 of the Awb given the existence of special circumstances. [name manufacturer] points to the cigarette case in which the ACM reduced the fine because of sector-specific regulations and because that was the first case in which the ACM imposed a fine for indirect information exchange. Furthermore, [name of manufacturer] compares the fine imposed on it with the actual turnover achieved by it during the infringement period and believes that the fine imposed on it in relation to turnover would the highest fine ever imposed by the ACM.

24.9. The ACM countered that the cigarette case does not entail granting such a reduction in every case involving industry-specific regulation. In addition, each case has elements that distinguish it from previous cases. That does not make every new case a new interpretation of the competition rules. There are several previous cases in which a competition authority has fined a company for an excessive price. The ACM further disputes that this is the highest fine it has ever imposed. It imposed several higher fines in the past, including individual fines higher than the fine imposed on [name of manufacturer].

24.10. The Court follows the ACM's argument that this case cannot simply be contrasted with other cases in which the ACM has imposed a fine. A fine is always tailored to the circumstances of the case itself in which a variety of factors play a role, such as the duration, context and seriousness of the violation and the size of the company. This case is therefore not comparable to the examples cited by [name of manufacturer]. In what [name of manufacturer] argues, the court sees no basis for the opinion that the ACM should have deviated from the Penalty Policy Rule applied.

Need for general or specific prevention

24.11. [name of manufacturer] argues that the fine imposed adds nothing to the overall deterrent effect. It argues that the overall deterrent effect is even stronger because companies are no longer launching their products in the Netherlands. The mere fact that the ACM has fined an orphan drug manufacturer for the list price of a newly authorized drug and tolerated its removal from the market by a pharmacy preparation developed by health insurers has raised concerns worldwide. Combined with the behavior of health insurers and VWS against four other (expensive) drugs, the fine imposed on [name of manufacturer] (regardless of amount) has already had the effect of making it known worldwide in the industry that the Dutch market is permanently closed to any repurposed or pharmacy-prepared drug. [name of manufacturer] further argues that specific prevention no longer necessary in this because [name of manufacturer] has been permanently removed from the Dutch market, and, by the time Contested Decision I was , had been removed from the Dutch market for 3.5 years.

24.12. The court considers ACM's general premise that the level of the fine must be such that it deters the offender from committing new offenses (special prevention) and also in general terms has a deterrent effect for other potential offenders (general prevention) to be correct. The court follows the ACM's position that the global concern outlined by [name of manufacturer] as a result of the fine imposed on [name of manufacturer] is in line with the deterrent effect of the fine envisaged by the ACM and that general prevention is also not only aimed at preventing excessive prices among companies in the pharmaceutical industry, but is aimed at potential violators in . The contentions of [name of manufacturer] that the fine imposed (and the action of health insurers and VWS against four other (expensive) drugs) has led to worldwide publicity that the Dutch market is permanently closed and that this has had negative effects on the introduction of drugs on the Dutch market are not substantiated. The ACM is therefore justified in saying that it has no reason to believe that the fine imposed on [name of manufacturer] has had negative effects on the introduction of medicines on the Dutch market.

24.13. Contrary to [name of manufacturer]'s contention, the fact that [name of manufacturer] has since ceased activities on the Dutch market does not mean that specific prevention would no longer an issue. The subsequent permanent absence of [name manufacturer] from this market does not make the committed infringement any less serious. That absence is not related to the fine imposed by the ACM, but is a consequence of [name of manufacturer]'s own actions that qualify as abuse. Therefore, there is no reason for the court to include this circumstance (ex nunc) in its assessment of the contested Decision I.

Revenue involved

24.14. [name of manufacturer] argues that the turnover in question was wrongly based on the list price and that the ACM should have reduced the turnover in question by 50% for the purpose of calculating the fine. It points in this regard to the 50% provisions it allegedly included in its books and argues that it always intended to repay 50% of the price received.

24.15. The court does not follow [name manufacturer] in this. Since [name manufacturer] always asked and collected the price of 13,090 per package during the infringement period and did not apply a discount to it, the ACM was able to take this (actual) price as the basis for its assessment of turnover involved. The ACM correctly states that the alleged intention to charge a lower, negotiated price not relevant. In any case, this does not make a lower by [name of manufacturer] in the relevant period. Therefore, the ACM did not need to see any reason to reduce the relevant turnover by 50% for the calculation of the fine.

24.16. [name of manufacturer] argues that the (by adjusting the infringement period) adjusted turnover (18,938,000) is higher than the total turnover actually achieved by [name of manufacturer] (17,865,540) and that that leads to a disproportionate outcome.

24.17. The court does not follow [name of manufacturer] this respect. It is not in dispute that the ACM acted in with its Penalty Policy Rule by basing the calculation of the turnover involved on the turnover in the last calendar year in which the violation was committed. The turnover involved is determined by dividing that turnover by 12 and then multiplying it by the number of months the violation lasted. It is inherent in such an approach that the

actual turnover achieved over the period in question may differ from the turnover in question. However, that in itself does not have to preclude the calculation method used. As the CBb has repeatedly considered, the turnover involved is not about determining the exact turnover achieved with the violation, but about determining the economic value of the product or service in question for the individual undertaking.54[name of manufacturer] does not make clear why this actual economic value of the fined conduct is incorrectly reflected in the turnover involved taken into account by the ACM.

Severity factor

24.18. The ACM marks [name of manufacturer]'s violation particularly serious because, beginning in June 2017, [name of manufacturer] charged and collected an excessive price for a drug that indispensable to patients. [name manufacturer] set a price for [CDCA brand name] in 2017 that was more than 4.5 times higher than the price of its comparable drug Xenbilox earlier in 2017, and nearly 20 times higher than the price of Xenbilox before [name manufacturer] began its project in 2014. This was not by commensurate benefits for patients: those benefits were very limited. However, [name of manufacturer] thus realized a very high return that ultimately came at the expense of Dutch society, in particular the Dutch health insurers that reimbursed the drug in question and the insured in their role as premium and tax payers. Due to the small number of CTX patients, total expenditures on [CDCA brand name] were small compared to total healthcare costs. That said, the healthcare system has limited financial resources to the health of patients, so that even an excessive price for a limited-use drug results in crowding other healthcare spending. Even though health insurers were not obliged to reimburse [CDCA brand name], they felt (morally) obliged to do so in the situation that their insureds could not otherwise obtain this drug that was essential to them. [name of manufacturer] has disadvantaged Dutch CTX patients with the excessive price, because as a result they have experienced uncertainty about the continuity of availability of the drug on which they depend for their health. [name of manufacturer] failed to observe its special responsibility as a company in a dominant position. It made insufficient efforts to a non-excessive negotiated price for [CDCA brand name] with health insurers or the Minister. The ACM therefore deemed a severity factor of 45% appropriate.55

24.19. [name fabricator] argues that in doing so, the ACM did not adequately justify a 45% severity factor. It never intended [name fabricator] to have the list price actually be the final price, and it also repeatedly offered a discount and recorded only 50% of the amounts received as revenue. It further argues that the comparison with the sales prices to Xenbilox is because Xenbilox (which was never registered in the Netherlands and was never registered for CTX) and [CDCA brand name] cannot be compared. The ACM also incorrectly states that the benefits to patients were of very limited value. [CDCA brand name] is a registered orphan drug that offers added value from both regulatory and medical perspectives. Efficacy, quality and safety have been established by an independent authority. [manufacturer name] was the first company to provide evidence of a favorable risk-benefit profile. The ACM also provides no evidence to support the claim that patients have been disadvantaged by the uncertainty surrounding the reimbursement of [CDCA brand name] . That the health insurers felt obliged to reimburse [CDCA brand name] is also incorrect because the health insurers never obliged to do so. The claim that [name manufacturer] did not observe its special responsibility is also not valid, because it implies that [name manufacturer] should have negotiated in any way more diligently with the health insurers. Finally, [name of manufacturer] argues that it is not true that an excessive price for a limited-use drug leads to displacement of other health care expenses. The total sales of [CDCA brand name] were well below the threshold of €10 million per year that applies to put drugs in the lock56 (€10 million is considered low risk).

24.20. The court does not follow this argument of [name of manufacturer]. The intent of [name of manufacturer] and offering a retroactive discount does not negate the fact that [name of manufacturer]

continued to charge and collect an excessive price throughout the infringement period of nearly 2.5 years. Contrary to [name of manufacturer]'s contention, the comparison of the price of [CDCA brand name] with the price of Xenbilox is justified and the benefits of registration in the case of [CDCA brand name] must be put into perspective, as also considered above. That, as [name of manufacturer] rightly argues, health insurers were not obliged to reimburse [CDCA brand name] does not alter the fact that they did feel morally obliged to do so because patients had no alternative and would suffer serious health damage without this drug. Furthermore, it is up to [name of manufacturer], as a company in a dominant position, to carefully consider the consequences of its choices in its pricing. The fact that the lock criteria are not met does not mean that it cannot be a (very) expensive drug whose costs must be met from the limited financial resources of the healthcare system.57 [name of manufacturer] does not make clear why the ACM's assertion "that due to the small number of CTX patients the total expenditure on [CDCA brand name] is small in relation to the total healthcare costs, but that does not negate the fact that the healthcare system has limited financial resources to the health of patients, so that even an excessive price for a limited-use drug leads to a crowding out of other healthcare expenditures" would incorrect. Given the ZIN data, the cost of [CDCA brand name] per patient is 153,500 per year, which is more than three times the amount that counts as a very expensive drug under the lock-in criteria (50,000 per).

24.21. The court therefore finds that the ACM could have set the severity factor at 45%.

Doubling base fine

24.22. The ACM finds that in this , despite the relatively (high) severity factor of 45%, doubling the relevant turnover with a severity factor does not result in a deterrent fine. This is due to the unusually high excess profit by [name of manufacturer]. In the case of [name manufacturer], the basic fine would have resulted in it still being able to enjoy the "commercial benefit" of its infringement. That is what the ACM wanted to avoid, which is why the ACM doubled the basic fine. The calculation of the excess profit realized by [name manufacturer] clearly follows from Contested Decision I and is not contradicted by [name manufacturer].

24.23. There is no dispute between the parties that under Article 2.3(6of the Fines Policy Rule, the ACM can increase the proportion of the turnover involved to be taken into account in view of the weight of the offender. According to [name of manufacturer], this does not mean that the basic fine can be increased. Furthermore, according to [name of manufacturer], the ACM incomprehensibly argues that doubling the basic fine would have the same effect as doubling the relevant turnover.

24.24. The court considered that the ACM set the base fine at 45% of the affected turnover. The ACM then doubled that part of the turnover involved to be taken into account. The basic fine and the part of the turnover to be taken into account are therefore equal to each other. Therefore, the ACM correctly takes the position that doubling the basic fine has the same effect as doubling the part of the turnover concerned to be taken into account. [name of manufacturer]'s reference to a Competition Appeal Tribunal judgment of August 8, 202358, where a "deterrent multiplier" was declared unfounded, misses the point. The circumstances of that case are not similar to the circumstances in this case where, without doubling the basic fine, the fine would be less than the commercial advantage by [name of manufacturer]'s conduct. Thereby, the fine would have no punitive and deterrent effect. The ACM was right to prevent that by doubling it.

Fine-reducing circumstances

24.25. [name of manufacturer] argues on appeal that the ACM wrongly ignores the circumstances cited by it that it has been the subject of extensive and concerted "naming and shaming" campaigns, that - in short - it is no longer active on the Dutch market, and that the health insurers and VWS never seriously considered [CDCA brand name] as an alternative to their own product and they did not negotiate in good faith, partly through their collective boycotts. The health insurers contributed significantly to the problem for which the ACM a fine, namely the fact that the health insurers continued to pay the list price of [CDCA brand name].

24.26. The court finds that the ACM was justified in finding no mitigating circumstances in the circumstances alleged by [name of manufacturer]. Whatever the conduct of health insurers, it has always been [fabricator name]'s own choice to charge and collect an excessively high price for [CDCA brand name] and this conduct was also the sole reason for imposing the fine.

Take into account fines from other European competition authorities

24.27. [name manufacturer] argues that, under the Silver Onion Case Law59, the ACM should take into account the fact that the Italian competition authority, AGCM, [name manufacturer] 3.5 million on May 31, 2022 and the Spanish competition authority, CNM, fined [name manufacturer] 10.25 million on November 14, 2022. Thus, in total, [name of manufacturer] has been fined nearly 31 million.

24.28. The court considers that the ACM did not have to take into account the fines imposed by the Spanish and Italian competition authorities. As indicated in Contested Decision 1, the fine imposed by the ACM relates only to the conduct of [name manufacturer] in the Dutch market. It does not follow from the ruling cited by [name of manufacturer] that the ACM, when reassessing the fine, should have aligned it with the fines imposed by the Spanish and Italian competition authorities after the penalty decision, but before Contested Decision I. In that ruling, it was held that the ACM had rightly included turnover achieved outside the Netherlands in calculating the turnover in question. This included the fact that the ACM had coordinated this with other national competition authorities. In this case, however, the ACM only included the turnover achieved by [name of manufacturer] in the Netherlands when calculating the turnover involved. The cited ruling is therefore irrelevant.

Statutory penalty maximum

24.29. Contrary to [name manufacturer]'s contention, in the court's opinion there is no reason to [manufacturer 3]'s group turnover in 2022. Relevant for the fine is the consolidated turnover of the parent company of [name fabricant] , [fabricant 3] , in the year prior to the imposition of the fine (2020). The fact that the consolidated turnover of [fabricant 3] in 2022 (93.6 million) was lower than in 2020 (251.2 million) does not make the fine imposed on [fabricant name] too high.

24.30. [name of manufacturer] further argues that the ACM should not have taken into account the operations of [name of company] , which had been sold at the time of imposition of the fine and were therefore not included in the financial statements of [manufacturer 3] The net turnover of [manufacturer 3] for the 2020 financial year without Unikeris was only 147,408,000, and the fine imposed exceeds the fine maximum.

24.31. This argument does not succeed. The purpose of the fine cap is to prevent the imposition of a fine in an amount that exceeds the financial capacity of the liable undertaking at the date on which it is held liable for an . It follows from the Gascogne judgment60 that, when assessing the financial resources of an undertaking to which an infringement of the competition rules of Union law is imputed, the turnover of all companies over which the undertaking concerned can exercise decisive influence is taken into . For the purpose of calculating the statutory maximum fine, that turnover reflects the size and economic power of the undertaking to which the fine decision relates.61

24.32. Therefore, the ACM correctly states that [manufacturer 3's] turnover in 2020 also includes the turnover of [name company] for the period when it was still an indirect subsidiary of [manufacturer 3]62 [name manufacturer] has not disputed that the latter the case in 2020, which is also evidenced by [name company's] entry in [manufacturer 3's] financial statements for 2020.

Conclusion fine

24.33. The ACM correctly determined the fine. Published

25. On July 2, 2021, the ACM issued a decision to publish Chapter 1 (summary) of the fining decision and a news release (publication decision). In Contested Decision I, the ACM addressed [name of manufacturer]'s objections to this publication decision and indicated that it saw no reason to revoke the publication decision.

25.1. The ACM decided on June 26, 2022 (Contested Decision II) to publish the "Summary" section of Contested Decision I.

25.2. [name of manufacturer] maintains its objections to the publication decision as set forth in its supplemental objection and argues that those objections apply equally to Contested Decision II.

25.3. The ACM has already addressed the objections raised by [name manufacturer] against the publication in Contested Decision I. Since [name manufacturer] does not substantiate in what respect the ACM's analysis and reasoning in Contested Decision I was inadequate, as the ACM also notes - this mere comment is insufficient to constitute a ground of appeal for the court to address.63

25.4. Both the publication decision and the publication of Contested Decision I have their basis in Section 12v of the Iw. Pursuant to this article, the ACM is obliged to publish these decisions unless, in the opinion of the ACM, publication is or could be in conflict with the purpose of the supervision assigned to it. The ACM has indicated that it does not consider this exception applicable.

25.5. If there is an obligation to publish a sanction decision - as is the case here - this obligation will only lapse if the sanction decision is - in essence - found to be unlawful. According to established case law, the criterion in this respect is whether the entire fine ultimately does not stand up in court and the (legal) person involved has been wrongly portrayed publicly as the violator.64 The circumstance that the amount of the fine changes does not provide grounds to suspend publication.65

25.6. Since the fine decision and the subsequently issued Contested Decision I are not essentially unlawful, the obligation to publish the primary decision and Contested Decision I does not lapse.

Reasonable term

26. [name of manufacturer] argued at the hearing that the reasonable time limit had been exceeded. In response, the ACM argued that the complexity of the case and [name of manufacturer]'s procedural conduct (such as (the timing) submitting an enforcement request and the submission of very extensive documents) warranted extending the reasonable time limit.

26.1. In the opinion of the District Court, the charge moment as referred to in Article 6, paragraph 1, of the ECHR started with the issuance of the first report on August 12, 2020.66 Between this moment and the delivery of the judgment by the District Court lies a period of approximately 4.5 years. According to established case law in cartel cases, a period of 3.5 years for the administrative phase and the court phase together can in principle be considered reasonable.67 This means that this period has been exceeded by more than 12 months. However, there may be reason to extend the reasonable period if the delay is due to the conduct of the company involved or because of actions related to their defense interest.68 The court sees no reason to do so in this case. The complexity of cartel cases is already factored into that (longer) time limit, so that no reason is found therein to assume a longer time limit. Furthermore, the procedural conduct of [name of manufacturer] has not been such that grounds can be found therein for a longer term.

26.2. In cartel cases, the CBb applies a reduction of the fine of 5% for each half year or part thereof that the reasonable period is exceeded, with a maximum of 5,000 for each half year exceeded.69 Given this, the court will apply a reduction of 15,000 (3 x 5,000) to the fine. This means that [name manufacturer] will have to pay a fine of 17,029,000 (17.044.000 - 15.000). In this way, the court will provide its own.

Conclusion and implications

27. The ACM rightly imposed a fine on [name manufacturer] but the amount of the fine is reduced due to exceeding the reasonable time limit. Applying Article 8:72a of the Awb, the court will settle the case itself by setting the amount of the fine at 17,029,000. The appeal against Contested Decision 2 is unfounded.

Reimbursement of court fees

27.1. Having correctly mitigation for exceeding the reasonable time limit, the ACM must reimburse the court fee to [name of manufacturer].

Litigation Fee

27.2. The Court further finds cause to order the ACM to pay 226.75 in procedural costs. In doing so, the Court takes as its starting point that an appeal for mitigation on account of the reasonable term being exceeded is a procedural act to which 1 point is awarded, with a value per point of 907, and application of a weighting factor of 0.25 (very light) as provided in the appendix to the Administrative Costs Decree.

Decision

The court:

- Declares the appeal against Decision 1 well-founded insofar as it concerns the amount of the fine imposed;
- Annuls Contested Decision 1 insofar as it relates to the amount of the fine and sets the fine at 17,029,000;
- determines that this ruling supersedes the quashed portion of Contested Decision 1;
- Declares the appeal otherwise unfounded;
- determines that the ACM must reimburse [name of manufacturer] the court fee of 365;
- Orders the ACM to pay 226.75 in litigation costs to [name of manufacturer] .

This judgment was rendered by Mr. A.C. Rop, chairman, and Mr. E. Lunenberg and C.J. Wolswinkel, members, in the presence of M. Traousis-van Wingaarden, Registrar. Judgment was pronounced in public on Feb. 13, 2025.

registrar chairman

A copy of this ruling was sent to the parties on:

Appeal information

If parties disagree with this ruling, they may send a notice of appeal to the Board of Business Appeals explaining why they disagree with this ruling. The notice of appeal must be submitted within six weeks of the day this ruling was sent. If they cannot wait for the hearing of the appeal because the case is urgent, they may ask the interim relief judge of the Trade and Industry Appeals Tribunal to grant a preliminary injunction (a temporary measure).

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[1] Violation of Article 24 of the Competition Act (Mw) and Article 102 of the Treaty on the Functioning of the European Union (TFEU).

[2] Pursuant to Article 8:29(1) and (3) of the General Administrative Law Act (Awb).

[3] In doing so, the German marketing authorization for Chenofalk for 750,000 and the stock of Chenofalk for 9.15 excluding VAT per package of 100 capsules transferred to the legal predecessor of [name of manufacturer] .

[4] Physicians, based on their own responsibility and expertise, may also prescribe for indications other than those for which the marketing authorization has been . This is referred to as off-label use of drugs. Conditions are that this is done on the basis of "informed consent" from the patient and only in accordance with guidelines and protocols applicable within the profession.

[5] [fabricator 2] , a wholly-owned subsidiary of [fabricator 1] ., is the holder of the orphan drug status and of the marketing authorization for [CDCA brand name] . Although [manufacturer 2] is the only group entity that sold [CDCA brand name] in the Netherlands, [manufacturer 1] . was also involved in the sale of [CDCA brand name] in the Netherlands.

[6] Pursuant to Article 8:26 of the Awb.

[7] Article 1:2(1) of the Awb.

[8] See, for example, CBb Sept. 12, 2014, ECLI:NL:CBB:2014:348, and CBb March 30, 2021, ECLI:NL:CBB:2021:350.

[9] For example, the decisions of the Administrative Law Division of the Council of State (the Division) of October 1, 2008, ECLI:NL:RVS:2008:BF3911, and March 18, 2020, ECLI:NL:RVS:2020:808.

[10] Having regard to Section 8:69(1) of the Awb.

[11] See CBb of March 16, 2021, ECLI:NL:CBB:2021:293, para. 6.1 (citing its rulings of October 4, 2017, ECLI:NL:CBB:2017:391, para. 3 and April 21, 2015, ECLI:NL:CBB:2015:132, para. 3).

[12] For example, CBb Feb. 12, 2010, ECLI:NL:CBB:2010:BM1689, para. 2.1.

[13] Article 12q Iw states that without prejudice to Article 10:34) of the Awb, the work in related to the imposition of an administrative fine shall not be carried out by persons who have been involved in the preparation of the report referred to in Article 5:48, 1, of the General Administrative Law Act and the prior investigation.

[14] Paragraph 218: "(...) Also, the penalty decision finds that if [name of manufacturer] had actually wanted to come to a negotiation result with a price lower than EUR 13,090, it should have taken energetic and serious steps to achieve negotiations leading to a negotiated price, so as to prevent the list price from also being and remaining the collected price."

[15] [manufacturer's name] submitted pre-existing literature and two retrospective cohort studies to the EMA submitted. The cohort studies mainly concern the application of the drug Xenbilox to Dutch patients ("pivotal clinical study") and in support the application of an Italian magistral preparation of CDCA to Italian patients ("supportive clinical study").

[16] Medicines Evaluation Board CBG), Healthcare and Youth Inspectorate (IGJ) and the Ministry of Health, Welfare and Sport (VWS).

[17] Regulation (EC) No 14 1/2000 of the European Parliament and of the Council of 16 December 1999 on orphan drugs.

[18] An Oldenzaal-based distributor of raw materials for the pharmaceutical and other .

[19] An Italian-based company engaged in the development and production of active ingredients.

[20] According to its bylaws, the purpose of the Pharmagister Foundation was "to promote magistral preparation of (biological) medicines in the Netherlands".

[21] Under the Drug Pricing Act, the maximum price for drugs is set by ministerial regulation determined based on the average of the selling price of the drug in question in four countries. Drug manufacturers can take into account the price they charge in the four reference countries when setting the Dutch asking price, so that the Dutch asking price does not exceed the average of the asking prices in the reference countries.

[22] Extramural drugs (pharmaceutical care) are prescribed by a physician and dispensed by a pharmacy. Extramural drugs listed in the GVS are reimbursed to patients by health insurance companies.

[23] Intramural drugs are an integral part of treatment.
Health insurance companies reimburse inpatient drugs (medical).

[24] Supreme Court Dec. 19, 2014, ECLI:NL:HR:2014:3679 (Bosentan) on whether or not it is compulsory Reimburse drugs for care the insured basic package.

[25] Article 8 of the ECHR, Articles 34 to 36 of the TFEU and Council Directive 89/105/EEC of December 21, 1988 on the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the national health insurance systems (Transparency Directive).

[26] ECJ Feb. 13, 1979, ECLI:EU:C:1979:36 (Hoffmann-La Roche).

[27] on Court of Justice case law : ECJ February 13, 1979, ECLI:EU:C:1979:36 (Hoffmann-La Roche) and ECJ July 3, 1991, ECLI:EU:C:1991:286 (AKZO), para. 60, where there is a significant market share (50% or higher) there is a presumption of an economic dominance. This also applies to an undertaking that has been granted an exclusive right for a certain period of time (inter alia: ECJ 18 June 1991, ECLI:EU:C:1991:254 (ERT).

[28] ECJ Feb. 14, 1978, ECLI:EU:C:1978:22 (United Brands); European Commission Communication: Guidelines on the Commission's Enforcement Priorities in Applying Article 82 EC Treaty to Abusive Exclusionary Conduct by Undertakings; OJ 2009, C45, no. 10-22.

[29] By the system of reference prices, [name of manufacturer] refers to the fact that for the drug it markets in the Netherlands independently determines the pharmacy purchasing price but is bound by maximum prices under the Medicines Pricing Act Wgp). These maximum prices are based on the average of prices for similar drugs in Belgium, France, the United Kingdom and, until December 18, 2019, Germany.

[30] ECJ Feb. 14, 1978, ECLI:EU:C:1978:22 (United Brands) and General Court Dec. 12, 1991, ECLI:EU:T:91:70 (Hilti).

[31] Competition Appeal Tribunal Sept. 18, 2023, [2023] CAT 56, Hydrocortisone, para. 291.

[32] General Court December 12, 2018, ECLI:EU:T:2018:922 (Servier).

[33] ECJ Feb. 14, 1978, ECLI:EU:C:1978:22 (United Brands) and ECJ Sept. 14, 2017, ECLI:EU:C:2017:689 (AKKA/LAA) para. 35, referring to ECJ December 11, 2008, ECLI:EU:C:2008:703 (Kanal 5 and TV 4), para. 28 and case law cited therein.

[34] ECJ Sept. 14, 2017, ECLI:EU:C:2017:689 (AKKA/LAA) para. 36.

[35] European Commission decision of February 10, 2021, case AT.40394 (Aspen) and revised decision of the UK Competition and Markets Authority of July 21, 2022, Case 50908 (Phenytoin).

[36] She refers to General Court 25 October 2023, ECLI:EU:T:2023:669 (Bulgartranz) and the judgment of the UK Court of Appeal in CA-2021-003153 Apple v. Otis, [2022]EWCA Civ 1411, para. 74, , according to [name of manufacturer], upheld the obligation of health insurers (and by analogy the Ministry) to negotiate in good faith as expressed in the Sisvel-Haier II judgment of the Federal Court of Appeal. [name of manufacturer] also refers to the ENVI Committee's report on the proposed Medicines Directive of October 3, 2023, paragraph 58.

[37] Cf. ECJ 14 September 2017, ECLI:EU:C:2017:689 (AKKA/LAA) para. 49: "It is for the relevant competition authority to conduct the comparison and the framework for it, understanding that it has a certain latitude and that there no single appropriate method."

[38] Relevantly, with respect to [CDCA brand name], there is an assessment of price that is partly intended to previous investments.

[39] The Court of Justice stated in the judgment of February 14, 1978, ECLI:EU:C:1978:22 (United Brands) in para.
252: "That this would involve whether there is an excessive disproportion between the actual costs incurred and the actual price charged." For example, the European Commission's decision of February 10, 2021, case AT.40394 (Aspen) and the UK Competition and Markets Authority's revised decision of July 21, 2022, case 50908 (Phenytoin) also do not apply an incremental approach (e.g., paragraphs 4.6-4.7).

[40] This means that a choice between two scenarios that a company makes is automatically means that Option A revenues are considered opportunity costs for Option B and vice versa.

[41] Table 1 in the defense brief shows the adjusted results and is a correction to Table 1 in Contested Decision I. The calculation of these figures can be found in the spreadsheet that the ACM attached as Exhibit 1 to the Statement of Defense.

[42] ECJ Feb. 14, 1978, ECLI:EU:C:1978:22 (United Brands), para. 252.

[43] General Court September 23, 2020, ECLI:EU:T:2020:444 (Medac Gesellschaft für klinische Spezialpräparate)
item 66.

[44] [fabricator name] argues that United Brands is only one of several keys that can be used to establish a breach of Article 102 TFEU. See, e.g., ECJ 13 July 1989, ECLI:EU:C:1989:319 (Ministère Public v. Tournier) para. 38; ECJ 14 September 2017, ECLI:EU:C:2017:689 ("Latvian Copyright").

[45] [name of manufacturer] refers to the case law referred to in paragraph 4.28 of the UK CMA order of July 21, 2022 in Case 50908 - Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK.

[46] Article 8:5(1) of the Awb, in conjunction with Article 1 of the accompanying Jurisdictional regulation of administrative law.

[47] See the Explanatory Memorandum to the Iw (House of Representatives, session year 2012-2013, 33 622, no. 3, p. 64).

[48] Within the meaning of Article 5:48 of the Awb.

[49] Policy Rule of the Minister of dated July 4, 2014, No. WJZ/14112617, regarding on the imposition of administrative fines by the Consumer and Market Authority (ACM 2014 Fines Policy Rule), Government Gazette 2014 No. 19776, amended by Policy Rule of the Minister of Economic Affairs of June 28, 2016, No. WJZ/16056097, amending the ACM 2014 Fines Policy Rule, Government Gazette 2016 No. 34630.

[50] articles 1.1, 2.2, 2.3, 2.4 and 2.8 of the Penalty Policy.

[51] Article 1.1 of the Fine Policy.

[52] Article 2.3(6) of the Penalty Policy.

[53] Article 12o, first paragraph, of the Establishment Act ACM. For this purpose, net turnover is relevant, as referred to in
Article 2:377(6) of the Civil Code.

[54] CBb 6 April 2021, ECLI:NL:CBB:2021:372 item 26.8, and CBb 23 October 2018, ECLI:NL:CBB:2018:52 section 8.3.2.

[55] Article 2.3(1): In case of violation of Articles 6(1) or 24(1) of the Competition Act, 101 or 102 TFEU (), the ACM sets the basic fine based on the turnover involved and Article 2.4: The ACM sets a basic fine between 0 to 50% of the offender's turnover involved.

[56] The lock for expensive drugs is for drugs and treatments that are very expensive per patient or that are going to cost a lot in total per year because many patients need them. It is also often unclear how well the drugs work and in whom exactly they work. The Minister of Health, Welfare and Sport can temporarily keep new, expensive drugs used in hospitals out of the basic health insurance package. The medicine is then in the lock for expensive medicines. Zorginstituut Nederland then advises the minister whether or not to reimburse the drug. The minister can also

negotiate the price with the manufacturer.

[57] In its GVS opinion, the ZIN specifies the financial impact of [CDCA brand name] on the Dutch healthcare system compared to Xenbilox and . We are talking about a difference of (several) millions of euros.

[58] CAT [2023] 52, casenumbers: 1419/1/12/21, 1421/1/12/21 and 1423/1/12/21.

[59] CBb March 24, 2016, ECLI:NL:CBB:2016:56 section 4.9.3.

[60] ECJ Nov. 26, 2013, ECLI:EU:C:2013:770 (Groupe Gascogne).

[61] General Court March 27, 2014, ECLI:EU:T:2014:160 (Saint-Gobain) and Court of Rotterdam July 18, 2023, ECLI:NL:RBROT:2023:6240.

[62] Unikeris Ltd was sold on Nov. 23, 2020.

[63] See, inter alia, CBb 16 March 2021, ECLI:NL:CBB:2021:293 item 6.1, citing CBb 4 October 2017, ECLI:NL:CBB:2017:391 point 3, and CBb 21 April 2015, ECLI:NL:CBB:2015:132 point 3.

[64] See, for example, CBB April 22, 2015, ECLI:NL:CBB:2015:126, Section 5.2.

[65] See, for example, CBb May 7, 2014, ECLI:NL:CBB:2014:163, section 4.4.4.

[66] For example, CBb July 9, 2008, ECLI:NL:CBB:2008:BD6629, para. 7.18, and CBb March 17, 2011, ECLI:NL:CBB:2011:BP8077, para. 9.27.

[67] For example, CBb July 9, 2008, ECLI:NL:CBB:2008:BD6629, para. 7.20, and CBb March 17, 2011, ECLI:NL:CBB:2011:BP8077, para. 9.27.

[68] CBb 8 July 2015, ECLI:NL:CBB:2015:191, section 5.2, concluding section.

[69] For example, CBb April 30, 2024, ECLI:NL:CBB:2024:316, section 8.3.2.