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Summary of the decision on objection on abuse of dominance by Leadiant

Chapter 'Summary' of the decision on objection of the Netherlands Authority for Consumers and markets (ACM) adressed to Essetifin S.p.A., Leadiant Biosciences Ltd. and Leadiant GmbH ACM/UIT/590746.

Our reference : ACM/UIT/559405
Case number : ACM/21/053339
Date : 22 June 2023

General

1. In this decision on objection, the Netherlands Authority for Consumers and Markets (ACM) decides on the objections of Leadiant Biosciences Ltd., Leadiant GmbH and Essetifin S.p.A. (hereinafter jointly: '**Leadiant**') against the decision of 1 July, 2021, with reference number ACM/UIT/554938 (the '**fining decision**'). In the fining decision, ACM established that Leadiant had abused its dominant position by applying an excessive and unfair price in the sales of its prescription drug CDCA-Leadiant in the Netherlands from June 2017 through December 2019.

2. The objections are aimed at the description of the market dynamics as well as the description of CDCA-based drugs, at the legal assessment (including the definition of the relevant market, the determination of a dominant position and of the abuse), at the procedure, and finally at the fine itself.

Objections against the description of the market dynamics and CDCA-based drugs

3. According to Leadiant, the fining decision paints an incorrect picture of the negotiations with health insurers and other market participants. Leadiant argues that, since 2016, these market participants had already preferred the compounded CDCA, which, at the time, was not yet available, and that, given this preference, these market participants had thus never showed any intention of negotiating with Leadiant about the price of CDCA-Leadiant. As such, these market participants formed a collective boycott. Leadiant additionally argues that the fining decision wrongfully considers CDCA-Leadiant and its predecessors Xenbilox and Chenofalk to be the same product.

4. Upon review, ACM establishes that, in response to the unease in Dutch society over high prices of prescription drugs, market participants explored and sometimes also supported the opportunities for compounding CDCA. However, the choice of not negotiating with Leadiant was made by each health insurer individually, after prior discussions had not led to an acceptable outcome. A collective boycott has not been established. Furthermore, the choice of market participants of supporting or reimbursing compounded products is without prejudice to Leadiant's own conduct.

During the violation period, Leadiant consistently charged and collected the high price for CDCA-Leadiant. Taking into consideration the strong similarities between CDCA-Leadiant and its predecessors Xenbilox and Chenofalk (with the same active ingredient), ACM does not follow Leadiant's argument that CDCA-Leadiant should be considered a new product, meaning the price of which should not be compared with that of its predecessors. That is why ACM considers these objections to be unfounded.

Objections against the legal assessment

5. According to Leadiant, ACM failed to define the relevant market correctly. For example, ACM should have included the compounded CDCA in the relevant market. In addition, Leadiant argues that, during the entire violation period, it did not enjoy a dominant position. Therefore, Leadiant continues, no abuse (as a result of the charging of an excessive and unfair price) could have taken place either.

6. Upon review, ACM considers one of Leadiant's objections against the market definition to be founded. In its reassessment, ACM establishes that the compounded CDCA, as offered in the Netherlands from 1 April through 26 July, 2018, is part of the relevant market. During said period of approximately four months, a majority of CTX patients in the Netherlands first switched from CDCA-Leadiant to the compounded product and then back again to CDCA-Leadiant, after the Amsterdam University Medical Centers (Amsterdam UMC) stopped supplying its compounded product. During said period, Leadiant was thus unable to charge and collect CDCA-Leadiant's high price without any repercussions, and, as a result thereof, it temporarily lost its dominant position on the relevant market. To this extent, Leadiant's objection is considered to be founded. ACM further establishes that, from 1 June, 2017, through 1 April, 2018, and from 27 July, 2018, through 31 December, 2019, Leadiant enjoyed a dominant position. During said periods, it was the sole supplier on the relevant market. Patients were dependent on CDCA-Leadiant, which resulted in health insurers feeling compelled to reimburse CDCA-Leadiant.

7. Leadiant has objected to ACM's standard for establishing abuse. According to Leadiant, ACM had blamed Leadiant for having put in insufficient effort to reach a negotiated agreement with health insurers and the Dutch Ministry of Health, Welfare and Sports (VWS). Leadiant argues that it could not have known in advance that this would violate the prohibition of abuse of dominance. ACM considers that this objection is based on the incorrect assumption that, in the fining decision, ACM designated Leadiant's negotiating conduct as abuse (or as a part thereof). ACM therefore considers this objection to be unfounded. In this decision on objection, too, ACM is of the opinion that the conduct to be assessed for abuse consists of Leadiant's charging and collecting an excessive and unfair price, and not of its negotiating conduct.

8. In addition, Leadiant puts forward objections against the determination of excessiveness of the price in the fining decision. Leadiant levels criticism against the method used by ACM in its fining decision, and argues that ACM should have used a different method in these calculations. Furthermore, it argues that ACM used incorrect assumptions in its calculations. For example, in the fining decision, ACM should not have included Leadiant's revenues earned from the predecessor drug Xenbilox in its assessment of the excessiveness of CDCA-Leadiant's price. Also, ACM, according to Leadiant, underestimated the risks of its CDCA-Leadiant project, and overestimated the revenues thereof, which means excessiveness cannot be established.

9. ACM declares Leadiant's objections against the establishment of excessiveness of CDCA-Leadiant's price to be unfounded. For example, ACM does not follow Leadiant's argument that ACM should have used a different method. Although different methods can be used for making calculations, all of these methods result in the conclusion that the price was excessive. The outcomes of these calculations are primarily driven by the used assumptions, such as the inclusion of revenues earned from Xenbilox. In this case, it is logical to include Leadiant's revenues earned

from Xenbilox in the assessment, yet these revenues in themselves are not the deciding factor for the result. Upon review, ACM finds the assumptions made in the fining decision that form the basis for the calculations to be correct. These have been based on internal documents of Leadiant, and do justice to what actually happened. Conversely, the calculations suggested by Leadiant in its notice of objections contain assumptions that paint a distorted picture.

10. Leadiant further contends that ACM did not establish that the price was unfair. For example, in its fining decision, ACM, according to Leadiant, failed to appreciate certain advantages of CDCA-Leadiant for patients compared with its predecessors. According to Leadiant, these advantages are so considerable that they justify an excessive price. ACM considers these objections to be unfounded, and, considering the excessiveness and unfairness of the price, concludes that the fining decision correctly designates the application of the price of EUR 14,000 per package of 100 capsules of CDCA-Leadiant as abuse.

Objections against the procedure

11. Leadiant has raised several objections against the course of events during the procedure. ACM concludes that, in the case at hand, the procedure has been followed correctly. For example, ACM has provided sufficient English translations of documents, the presumption of innocence and the principle of impartiality have not been violated, and Leadiant has had sufficient access to the case file. Leadiant has thus been given the opportunity to defend itself extensively against the allegations laid down in the statement of objections and the fining decision. Also, ACM rejected a request by Leadiant to accept commitments on valid grounds. ACM believed commitments not to be appropriate in the case at hand, if only because of the nature and scope of Leadiant's conduct, as well as the late stage in which Leadiant offered the commitments.

Objections against the fine

12. Finally, Leadiant raises a number of objections against the fine. In its fining decision, ACM imposed a fine of EUR 19,569,500 on Leadiant. According to Leadiant, ACM should have refrained from imposing a fine altogether, and, instead, should have, as an alternative, accepted Leadiant's commitments or should have established a violation without imposing a fine, or should have imposed an order subject to periodic penalty payments. Additionally, Leadiant objects against the level of the fine of EUR 19,569,500. ACM does not follow Leadiant's argument that it should have accepted its commitments. Upon review, too, ACM finds that this would not have been effective. On one point, Leadiant's objection is well-founded, which is the point that, as a result of the designation of the compounded CDCA in 2018 to be part of the relevant market, ACM concludes that Leadiant did not have a dominant position from 1 April through 26 July, 2018, and that no violation of the prohibition of abuse of dominance in said period could be established. The shorter period of violation has implications for the level of the fine. ACM thus sets the level of the fine at EUR 17,044,000. ACM considers the imposition of this fine as well as the setting of its level to be appropriate and proportional because of the seriousness of the violation. ACM has found the level of the fine appropriate from a preventive (both general and special) point of view. In that context, ACM has also taken into account the profits earned by Leadiant from the violation.