

COMPETITIVE MARKETS AND CONSUMER WELFARE

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EXCESSIVE PRICING IN PHARMACEUTICAL MARKETS

– THE DANISH CD PHARMA-CASE

Intervention against possible exploitative and excessive prices should always be considered carefully. However, the dynamics of pharmaceutical markets makes it particularly relevant for competition authorities to prioritise cases on unfair prices.

Recently the Danish Competition Appeals Tribunal upheld the Danish CD Pharma-case concerning the drug Syntocinon given to pregnant women during childbirth. This article explains the content of the case and the reasons why it was prioritised by the The Danish Competition Council (the DCC).

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Competition cases concerning excessive pricing under competition law have been rare in Europe for decades.

Excessive pricing is typically viewed as a temporary and self-correcting market failure, or, conversely, as a problem to be addressed through sector-specific regulation.¹

Parts of the legal and economic community have therefore occasionally raised the question whether competition authorities in the EU should be concerned with unfair pricing or whether it would be better to focus enforcement activities to exclusionary conduct only.

In the EU, the European Commission, competition authorities of Member States and the courts in the EU are all entrusted with the mandate to ensure effective enforcement where dominant undertakings are found to abuse their market power by imposing unfair prices.²

It may be particularly important to enforce this prohibition in pharmaceutical markets, since these markets have essential features, which significantly depart from the standard models for competitive markets.³

Box 1: Excessive prices and Competition Law

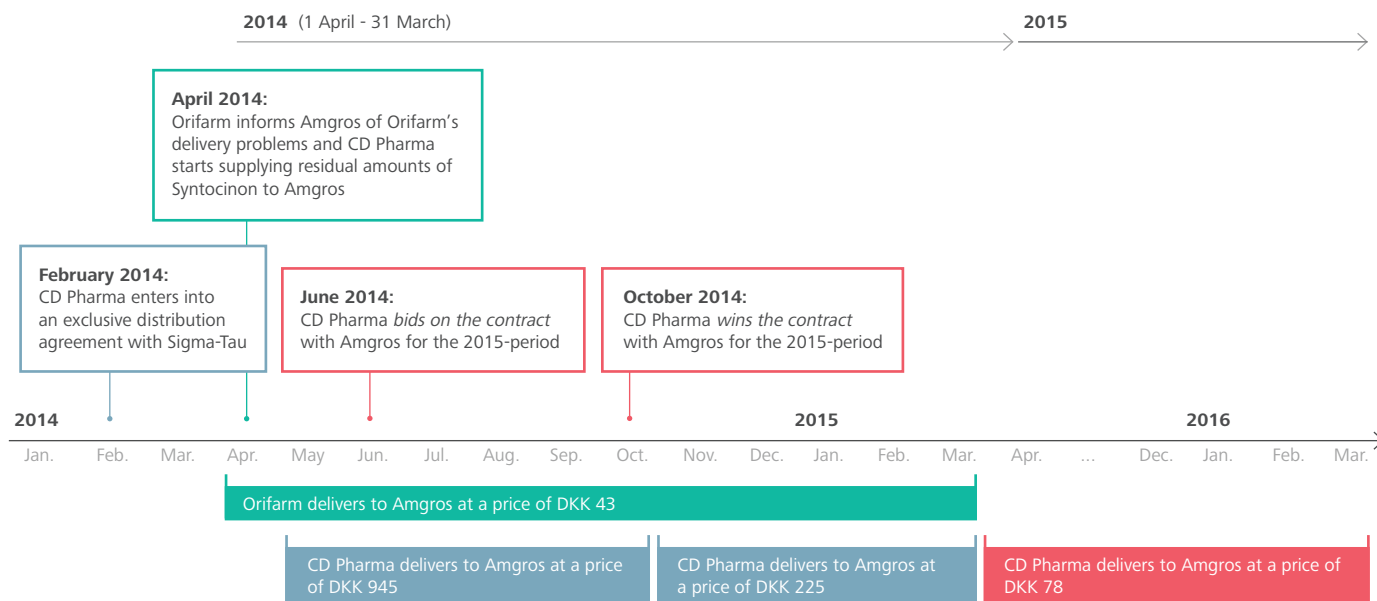
Article 102(a) of the Treaty on the Functioning of the European Union ("TFEU") provides that an abuse of a dominant position may, in particular, consist in "directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions".

This prohibition is generally understood to cover conduct such as charging excessive prices. In essence unfair pricing conduct concerns the extraction of excessive profits by imposing high, unfair prices to customers.⁴

An equivalent prohibition follows from section 11(3) (i) of the Danish Competition Act.

The particularities in pharmaceutical markets follow from the nature of pharmaceutical products, the pharmaceutical product life cycle and the role of regulation throughout the product life cycle (research and development, commercia-

Figure 1
Timeline of the CD Pharma-case



Source: Case no.: 14/08469, CD Pharma's pricing of Syntocinon, p. 36

¹ "OECD: Excessive Pricing in Pharmaceutical Markets - Note by Denmark", p. 2

² "OECD: Excessive Pricing in Pharmaceutical Markets - Note by the European Union", pp. 2-3

³ "OECD: Background Note by the Secretariat", p. 4

⁴ "OECD: Excessive Pricing in Pharmaceutical Markets - Note by the European Union", p. 2

lization, production, pre-generic entry and post-generic entry). In addition, the demand for certain pharmaceuticals is highly price inelastic, which may make the pharmaceutical sector more prone to unfair pricing practices or concerns than other sectors.⁵

Furthermore, expected profits in a pharmaceutical market may be too small to attract (sufficient) entry, which can be very costly, for instance, when the market is relatively small, or the particularities of the market constitute barriers to entry.⁶

Recently, national competition authorities have adopted three cases concerning excessive pricing in the pharmaceutical sector:

1. The Italian Aspen-case (Sep. 2016), which was upheld by the Administrative Tribunal (July 2017) and is under review of the Council of State.
2. The Pfizer/Flynn-case from the UK (Dec. 2016), which was remitted by the Competition Appeals Tribunal (June 2018).
3. The Danish CD Pharma-case (Jan. 2018), which was upheld by the Danish Competition Appeals Tribunal (Nov. 2018).

The CD Pharma-case

On 31 January 2018, the Danish Competition Council (the DCC) adopted a decision concerning CD Pharma's abuse of dominance by charging an excessive and unfair price for the drug Syntocinon.⁷

When deciding whether to pursue the possible infringement, the DCC in particular emphasised:

- The very significant price increase
- Demand was price inelastic
- There were no generic or substitutable pharmaceuticals available on the Danish market
- There were high barriers to entry, and due to the size and particular characteristics, the market was less likely to attract new entrants
- Syntocinon was no longer patented and hence there was less need for protection of innovation. Furthermore, CD Pharma was a distributor and did not engage in any product innovation.

In addition to CD Pharma's behaviour being exploitative, the behaviour could lead to a permanently higher price level in the post-abuse period. As the contract with Amgros stated that a supplier was obliged to cover Amgros' loss in case of delivery failure, suppliers in the post-abuse period must take into account the risk of a significant claim for compensation, and CD Pharma's behaviour may therefore also have exclusionary effects.

Box 2: Key players in the CD Pharma-case

- CD Pharma: a pharmaceutical distributor, which started distributing Syntocinon in Denmark in April 2014
- Orifarm: a Danish pharmaceutical parallel importer and competitor to CD Pharma
- Amgros: the pharmaceutical procurement service for the five regional authorities in Denmark (including the Danish hospitals)
- Sigma-Tau: the producer of Syntocinon

Background

Syntocinon contains oxytocin, an active substance given to pregnant women during childbirth. This drug has been marketed since the 1950's and the patent expired several years ago.

From 2007-2014, the price of Syntocinon in Denmark was stable at approximately DKK 44 (EUR 5.9).

Amgros carried out a tender for Syntocinon for the period of 1 April 2014 to 31 March 2015, which Orifarm won.

During the contract period, Orifarm tried to supply Syntocinon in accordance with the contract, but could not procure a sufficient amount of Syntocinon in the relevant dosage from other EU-countries to cover Amgros' full demand.

It was therefore necessary for Amgros to buy the residual amount from CD Pharma, the only other approved supplier of Syntocinon on the Danish market.

From 28 April 2014 to 27 October 2014, during the period when CD Pharma acted as a residual supplier to Amgros, CD Pharma increased its price on Syntocinon from DKK 45 (approx. EUR 6) to DKK 945 (approx. EUR 127).

⁵ "OECD: Excessive Pricing in Pharmaceuticals - Summaries of Contributions (EU)", p. 10

⁶ "OECD: Excessive Pricing in Pharmaceutical Markets - Note by the European Union", p. 6

⁷ Case no.: 14/08469, CD Pharma's pricing of Syntocinon.

Figure 2
Price development for Syntocinon on the Danish market during the period 2009-2017



Source: Case no.: 14/08469, CD Pharma's pricing of Syntocinon, pp. 105-6 and 158

Contrary to the parallel importer, Orifarm, CD Pharma was guaranteed supply due to an exclusive distribution agreement with the producer of Syntocinon, Sigma-Tau.

CD Pharma had entered into the exclusive agreement with Sigma-Tau with effect from February 2014.

Before February 2014, Sigma-Tau had an exclusive distribution agreement with another distributor in Denmark. From at least 2009 to 2014, the distributor having the exclusive distribution agreement with Sigma-Tau held a monopoly-like position in Denmark with a market share of 100 percent.

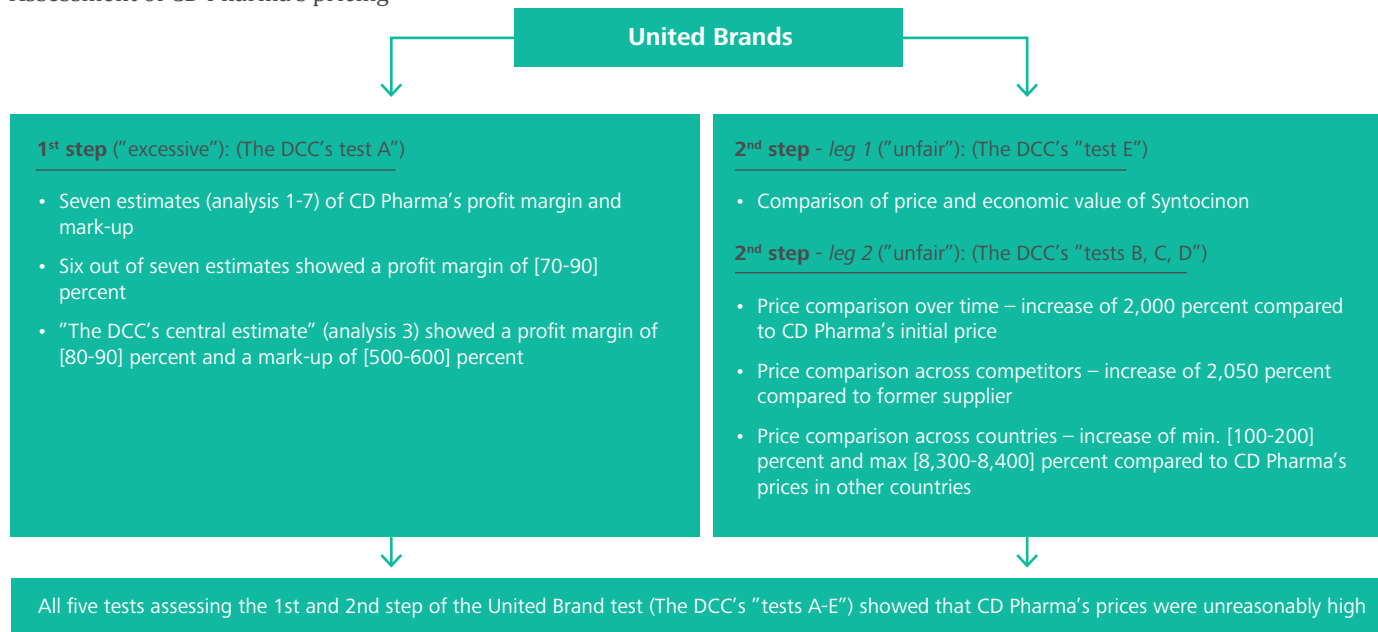
The assessment of CD Pharma's pricing

The DCC found that CD Pharma held a dominant position on the Danish market for the sale of oxytocin during at least the period from 1 April 2014 to 31 March 2015, but also in the subsequent period from 1 April 2015 to 31 March 2016 where Amgros carried out a new tender. This was primarily caused by CD Pharma's special position on the market given the exclusive distribution agreement with Sigma-Tau.

In the assessment of CD Pharma's pricing, the DCC followed the test set out by the Court of Justice in *United Brands*⁸, cf. box 3.

⁸ Case 27/76 *United Brands and United Brands Continental v Commission* ("United Brands") [1978] ECR 207.

Figure 3
Assessment of CD Pharma's pricing



Source: Case no.: 14/08469, CD Pharma's pricing of Syntocinon, p. 170

Box 3: The United Brands Test

The United Brands test consists of two steps:

1. Whether the difference between the costs actually incurred and the price actually charged is excessive, and,
2. if the answer to this question is affirmative, whether a price has been imposed which is either unfair in itself or unfair when compared to competing products.⁹

In practise, it may be difficult to assess excessive pricing conduct. Especially the first step of the test, where the profit margin of the undertaking involved is assessed, can be challenging, as it requires a solid basis for assessing the relevant costs, e.g. access to internal information about actual costs of producing or selling the specific product in question.

This difficulty also arose in the CD Pharma-case when assessing CD Pharma's profit margin on Syntocinon. The DCC was unable to obtain documentation of the relevant costs and had to rely on cost estimates based on other

information. The DCC set up seven estimates of CD Pharma's profit margin in order to test the overall robustness of the conclusions.

With regard to the first leg of the second step of the test, the DCC compared CD Pharma's price and the economic value of Syntocinon. The DCC did not find any non-cost related factors that could justify the high price.

With regard to the second leg of the second step the DCC found that CD Pharma's price was significantly higher than:

- historical prices,
- CD Pharma's competitors prices and
- CD Pharma's prices of Syntocinon in other countries.

CD Pharma was unable to justify the price increase with, for instance, increased costs or special considerations related to research and development. All tests conducted by the DCC confirmed that CD Pharma's price on Syntocinon was excessive and unfair.

Against this background, the DCC found that CD Pharma had exploited its dominant position by making Amgros (i.e. the Danish hospitals) pay an excessive and unfair price on Syntocinon. Consequently, the DCC ordered CD Pharma to terminate the infringement if it had not already done so and refrain from similar abusive behaviour in the future.

⁹ Case 27/76 United Brands, paragraph 252.

The appeal

On 29 November 2018, the Danish Competition Appeals Tribunal (the DCAT) ruled in the appeal concerning CD Pharma's pricing.¹⁰ The DCAT upheld the DCC's decision.

The DCAT considered a number of arguments, including

- whether the relevant period for dominance constituted a "significant period of time"¹¹, and
- whether CD Pharma's pricing behaviour was "temporary or episodic", and the pricing conduct therefore could not constitute abuse¹².

The dominant position

The DCAT found that there is no general minimum period of dominance. The DCAT emphasized:

- CD Pharma had held a market share in volume of [60-70] percent in the period from 1 April 2014 to 31 March 2015 (2014) and 100 percent from 1 April 2015 to 31 March 2016.
- CD Pharma had a significant competitive advantage through the exclusive distribution agreement with Sigma-Tau, while Orifarm, as a parallel importer, was not guaranteed a stable access to Syntocinon.
- During the period, CD Pharma was the only other player on the market.¹³
- Amgros' demand was price inelastic.
- Competition from potential new players on the market was limited by the requirements of marketing authorizations, which could take more than six months to obtain.
- CD Pharma's ability to raise the price with 2,000 percent.

Under these circumstances, and in view of the special competitive structure of the pharmaceutical market, in particular the duration of the tender period and the pricing structure of the spot market, the DCAT found that CD Pharma's market influence lasted for a period that was significant in that market.¹⁴

CD Pharma's abusive behaviour

Based on the information on CD Pharma's profit margin of [80-90] percent and a mark-up of [500-600] percent, the DCAT found that there existed an unfair relationship

between CD Pharma's price of DKK 945 per package Syntocinon and CD Pharma's costs associated with the sale of Syntocinon during the 2014-period.¹⁵

The DCAT emphasized that the price increase had only been possible because of an inelastic demand in a competition-shielded market and that the price had been maintained for six months in a market where prices were frequently adjusted.

The DCAT found, that in such a case, CD Pharma's price increase could not be considered episodic or temporary.

The DCAT therefore agreed with the DCC that CD Pharma had imposed an unfair price increase on Amgros and found that CD Pharma has abused its dominant position.¹⁶

Next steps

Following the decision from the DCAT, the DCC has submitted the case to the Danish State Prosecutor for Serious Economic and International Crime for criminal assessment.

In January 2019, CD Pharma appealed the case to the Maritime and Commercial High Court. At the time of writing this article, the case is pending before the Maritime and Commercial High Court.

¹⁰ Case no.: KL-2-2018, CD Pharma vs. The DCC

¹¹ Communication from the Commission — Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, (2009/C 45/02), footnote 6

¹² Case 117/16 AKKA/LAA [2017], paragraph 55 og 56

¹³ Case no.: KL-2-2018, CD Pharma vs. The DCC, pp. 12-13

¹⁴ Case no.: KL-2-2018, CD Pharma vs. The DCC, p. 13

¹⁵ Case no.: KL-2-2018, CD Pharma vs. The DCC, p. 13

¹⁶ Case no.: KL-2-2018, CD Pharma vs. The DCC, p. 14