Neutral citation [2023] CAT 52

Case No: 1419/1/12/21
1421/1/12/21
1422/1/12/21

IN THE COMPETITION APPEAL TRIBUNAL

Salisbury Square House
8 Salisbury Square
London EC4Y 8AP

8 August 2023

Before:

ANDREW LENON K.C.
(Chair)
TIM FRAZER
PROFESSOR MICHAEL WATERSON

Sitting as a Tribunal in England and Wales

BETWEEN:

HG CAPITAL LLP

(The Hg Appellant)

CINVEN CAPITAL MANAGEMENT (V) GENERAL PARTNERSHIP LIMITED
CINVEN (LUXCO 1) SARL
CINVEN PARTNERS LLP

(The Cinven Appellants)

MERCURY PHARMACEUTICALS LIMITED
ADVANZ PHARMA SERVICES (UK) LIMITED
MERCURY PHARMA GROUP LIMITED
ADVANZ PHARMA CORP LIMITED

(The Advanz Pharma Appellants)

- and –

COMPETITION AND MARKETS AUTHORITY

Respondent

Heard at Salisbury Square House from 27 September 2022 to 14 October 2022

APPEARANCES

Brian Kennelly K.C. and Daniel Piccinin K.C. (instructed by Linklaters LLP) on behalf of the HG Appellant.
Robert O'Donoghue K.C. and Ben Rayment (instructed by Clifford Chance LLP) on behalf of the Cinven Appellants.
Mark Brealey K.C. (instructed by Morgan, Lewis & Bockius UK LLP) on behalf of the Advanz Pharma Appellants.
Josh Holmes K.C., Ben Lask K.C., David Bailey, Hugo Leith and Jennifer MacLeod (instructed by the Competition and Markets Authority) on behalf of the Respondent.

Note: Excisions in this Judgment (marked "[…][✂]") relate to commercially confidential information: Schedule 4, paragraph 1 to the Enterprise Act 2002.

CONTENTS

A. INTRODUCTION

1. Liothyronine is a drug used to treat patients with a thyroid hormone deficiency. Between 2007 and 2017, a single undertaking consisting of Mercury Pharmaceuticals Limited, Advanz Pharma Services (UK) Limited and Mercury Pharma Group Limited ("the Mercury Pharma Companies") and, at various points, the Hg Appellant, the Cinven Appellants and Advanz Pharma Corp Limited ("Advanz Pharma Corp"), was the sole supplier of 20mcg liothyronine sodium tablets ("Liothyronine Tablets") in the UK. This single undertaking as it existed at any particular point is referred to in this Judgment as "Advanz".

2. In 2007, Advanz was selling Liothyronine Tablets at a price of £4.05 per pack. By January 2009, it had raised the price to £20.48 per pack and by August 2012 to nearly £46. By October 2015, the price had risen further to £190 and by July 2017 it reached £247.87. The cost to the National Health Service ("NHS") of purchasing Liothyronine Tablets rose from around £600,000 a year before 2007 to over £30 million a year by 2016 despite volumes remaining largely stable.

3. In 2016 the Respondent ("the CMA") commenced an investigation into the pricing of Liothyronine Tablets. By its decision dated 29 July 2021 ("the Decision"), the CMA decided that Advanz had abused its dominant position in breach of the prohibition set out in section 18 of the Competition Act 1998 by charging excessive and unfair prices for Liothyronine Tablets from at least 1 January 2009 to 31 July 2017 ("the Infringement Period"). The CMA imposed a total financial penalty of £101,442,899 on the Appellants in relation to the infringement.

4. The Appellants have appealed against the Decision on a number of grounds. They dispute the CMA's conclusion that the prices charged were excessive and unfair. They contend that the CMA made errors in assessing the relationship between their prices and their costs (the so-called "Cost Plus" assessment). They also contend that the CMA erred in failing to grant sufficient weight to three comparators, which they characterise as the "*real-world*" evidence of what would have constituted a fair price for Liothyronine Tablets. In addition, the Advanz Pharma Appellants ("Advanz Pharma") contend that Advanz lacked

dominance because the Department of Health and Social Care (and / or its predecessor, the Department of Health) ("DHSC") and / or the National Health Service ("NHS") (together the "DHSC/NHS") exerted countervailing buyer power to constrain prices during the Infringement Period and / or that the DHSC/NHS acquiesced in the prices charged for Liothyronine Tablets so that there was no abuse. Finally, the Appellants contend that the penalties imposed by the CMA should be quashed in their entirety or reduced in amount.

B. FACTUAL BACKGROUND

(1) Liothyronine Tablets

5. The primary use of Liothyronine Tablets is to treat patients whose thyroid does not produce enough thyroxine. Thyroid hormone deficiency, also referred to as hypothyroidism, causes a person's metabolism to slow, potentially resulting in weight gain, tiredness, sluggishness and depression as well as other symptoms. If hypothyroidism is left untreated, complications such as heart disease, or exceptionally, coma or death, may occur.

6. Liothyronine Tablets are a second-line treatment. This means that most UK patients who suffer from hypothyroidism are treated using UK-licensed levothyroxine tablets. However, a subset of patients who do not respond adequately to levothyroxine tablets are treated with Liothyronine Tablets.

7. Liothyronine Tablets consist of an active pharmaceutical ingredient ("API"), along with inactive substances. During the Infringement Period, liothyronine sodium ("Liothyronine") was licensed in the UK for supply as a 20mcg tablet, in packs of 28 tablets, although 5mcg and 10mcg strengths have subsequently been licensed.

(2) The manufacture of Liothyronine Tablets

8. Liothyronine Tablets are difficult to manufacture because of the low amount of active pharmaceutical ingredient or API in each tablet, and the potential sensitivity of Liothyronine to apparently minor changes in the processing

technology. Advanz itself had difficulty in supplying a consistently stable product over the Infringement Period, resulting in the Medicines and Healthcare products Regulatory Agency ("MHRA") requiring Advanz to apply for a batch specific variation in respect of each batch it supplied.

9. Advanz did not itself directly undertake the manufacture of Liothyronine Tablets. Advanz's business involved outsourcing product manufacture to third-party contract manufacturing organisations ("CMOs"). Distribution of Advanz's products was then outsourced to wholesalers and pre-wholesalers, as described below.

10. During the Infringement Period, Advanz outsourced the manufacture of Liothyronine Tablets to a third party CMO ("the CMO").

11. On 13 November 2007, Advanz and the CMO entered into a five-year manufacturing and supply agreement covering a range of products, including Liothyronine Tablets. This agreement was extended and then replaced in June 2014 by another five-year agreement. Under these arrangements, the CMO supplied Liothyronine Tablets exclusively to Advanz. Advanz was the CMO's largest single customer during the Infringement Period.

(3) The distribution of Liothyronine Tablets

12. Advanz does not carry out distribution of its products itself, but contracts with wholesalers and pre-wholesalers who store, distribute, and sell products in response to orders from pharmacies and hospitals.

13. At the outset of the Infringement Period, Advanz supplied Liothyronine Tablets through one of two wholesalers: Alliance Healthcare (Distribution) Ltd ("Alliance") or AAH Pharmaceuticals Ltd ("AAH"). From 20 December 2014 until at least the end of the Infringement Period, Liothyronine Tablets were only available from Alliance.

(4) Marketing authorisation

14. Pharmaceutical manufacturers and distributors operating in the UK are subject to a system of licensing and inspection. Unless exempt, a medicinal product must be covered by a marketing authorisation (an "MA") before being placed on the market in the UK. An MA will only be granted if the pharmaceutical product meets satisfactory standards of safety, quality, and efficacy in treating the condition for which it is intended.

15. A company that holds an MA may manufacture the pharmaceutical product itself or contract with a third-party to manufacture the pharmaceutical product on its behalf. The company which holds the MA (and not the third-party manufacturer) is primarily responsible for ensuring that the product complies with its licence and other applicable legislation.

16. In the UK, MAs are granted by the MHRA. MAs identify specifications relating to the manufacturing of the licensed product. Any changes in the manufacturing process or manufacturing organisation must be approved by the MHRA. If a particular batch of the licensed product does not comply with these specifications for any reason, the MA holder would need to seek approval from the MHRA if it wished to place the product on the market. If no alternative product is available, the MHRA may allow the product to be released following a review of the benefits and risks of placing such product on the market.

17. Obtaining a marketing authorisation is a lengthy process. According to a confidential memorandum issued by Advanz to lenders in September 2012, obtaining marketing authorisation:

> "… is costly and requires submission of a detailed dossier that may include toxicology, pharmacological, and clinical data. From start to finish (including dossier development and going through the marketing authorisation approval process), this can take around 3-4 years."

18. The memorandum stated that an entrant wishing to supply a copy of an existing product for which regulatory approval had been obtained in the past:

> "… must meet modern documentation standards to prove similarity against a product which might not get approval if it was to be re-submitted to the

> authorities in its current form. This can make it quite problematic for companies to be successful at copying old products, as the scrutiny threshold for these new approvals is higher than it was previously."

19. Advanz's business has changed names several times since then but what remained constant throughout the period from 1992 until the end of the Infringement Period in July 2017 was that the business was the only licensed supplier of, and it was therefore a monopolist in the market for, Liothyronine Tablets.

(5) The prescribing and dispensing of Liothyronine Tablets

20. Treatment of hypothyroidism patients with Liothyronine Tablets is typically initiated in hospitals by a specialist, with subsequent prescriptions issued by primary care doctors. Liothyronine Tablets are not available for purchase without a prescription.

21. Patients who are established on Liothyronine Tablets who then transfer to another drug, such as levothyroxine tablets, may be exposed to clinical risks, and may experience a worsening of their condition or symptoms.

22. As Liothyronine Tablets are no longer sold as a branded product, prescriptions are generally "open" (which means that they specify only the generic name, dosage, and tablet strength) as opposed to specifying a specific manufacturer, supplier or brand. Within the parameters of the prescription, the dispensing pharmacist will then typically choose the cheapest version of the medicine, since the dispenser pays for the drug and is reimbursed for it by the NHS at a fixed level as set out below. During the Infringement Period, the funding was provided by the patient's local Clinical Commissioning Group ("CCG").

(6) The pricing framework for pharmaceutical products

23. Branded drugs are subject to price regulation by means of a voluntary scheme between the DHSC and the Association of the British Pharmaceutical Industry. Throughout the Infringement Period, this price regulation occurred through a voluntary agreement known as the Pharmaceutical Pricing Regulation Scheme

(the "PPRS") which applied to manufacturers and suppliers of branded medicines to the NHS from 2014 to 2018. Advanz was a member of the PPRS throughout the Infringement Period but, since Liothyronine Tablets were not a branded product after 2007, the PPRS did not apply to them during the Infringement Period.

24. The cost of prescriptions for "generic" drugs (i.e. drugs that are not branded and therefore not subject to the PPRS) is funded by the NHS via a reimbursement price payable to dispensing pharmacies. The reimbursement price for Liothyronine Tablets is set out in a list published monthly by NHS Prescription Services on behalf of the DHSC (the "Drug Tariff"). The Drug Tariff governs the price that is reimbursed to the dispenser for fulfilling NHS prescriptions, subject to any price concessions agreed between the DHSC and the Pharmaceutical Services Negotiating Committee (the "NHS Reimbursement Price" or "Drug Tariff Price").

25. Products covered by the Drug Tariff are assigned to one of three categories (A, C or M) which determine the Drug Tariff Price for the product. To be in Category A, drugs must be listed either (i) by two wholesalers, or (ii) by one wholesaler and by two manufacturers. Category C only applies to a product available as a branded product or as a generic product from one or two sources. Category M typically applies to commonly used generics that are available from several sources.

26. Between December 2007 and November 2010, Liothyronine Tablets were not listed in the Drug Tariff, and therefore the NHS Reimbursement Price was the list price, in accordance with Part II Clause 8C in the Drug Tariff. From November 2010 to April 2015, Liothyronine Tablets were listed in Category A. In May 2015, Liothyronine Tablets were moved to Category C, where they remained until March 2018 when they were moved back to Category A. In January 2019, Liothyronine Tablets were moved to Category M following determination that they met the relevant criteria.

27. During the Infringement Period, Scheme M was a voluntary scheme between the Secretary of State for Health and the British Generics Manufacturers Association

(the "BGMA") which applied to manufacturers and suppliers of generic drugs sold to the NHS, if they chose to join it. The stated objective of this negotiated agreement was to promote a competitive pharmaceutical market. Scheme M allowed its members to alter the price at which a medicine is sold to wholesalers or dispensing contractors without any requirement to discuss such changes with the DHSC in advance. Its members would then notify such price changes to the DHSC. The provisions of Scheme M specified that the DHSC could intervene to ensure that the NHS paid a reasonable price for the relevant medicines if it appeared that normal competitive conditions were not operating, so as to protect the NHS from significant increases in expenditure. The pricing of Liothyronine Tablets was subject to Scheme M during the Infringement Period.

28. The Secretary of State has certain powers to monitor and intervene in drug pricing in specific circumstances. These powers are set out in sections 261 to 266 of the National Health Service Act 2006 (as amended) (the "NHS Act"). These powers are considered in detail later in this judgment.

(7) Advanz's pricing of Liothyronine Tablets

29. Liothyronine Tablets were originally developed in the UK in the mid-1950s and sold under the brand name 'Tertroxin'. Advanz acquired Tertroxin in 1992, as one of a portfolio of 22 products acquired by Goldshield Pharmaceuticals Ltd from Medeva plc for a total purchase price of £1 million. Tertroxin was by then already long off-patent. Advanz continued to sell the product under the Tertroxin brand name until 2007.

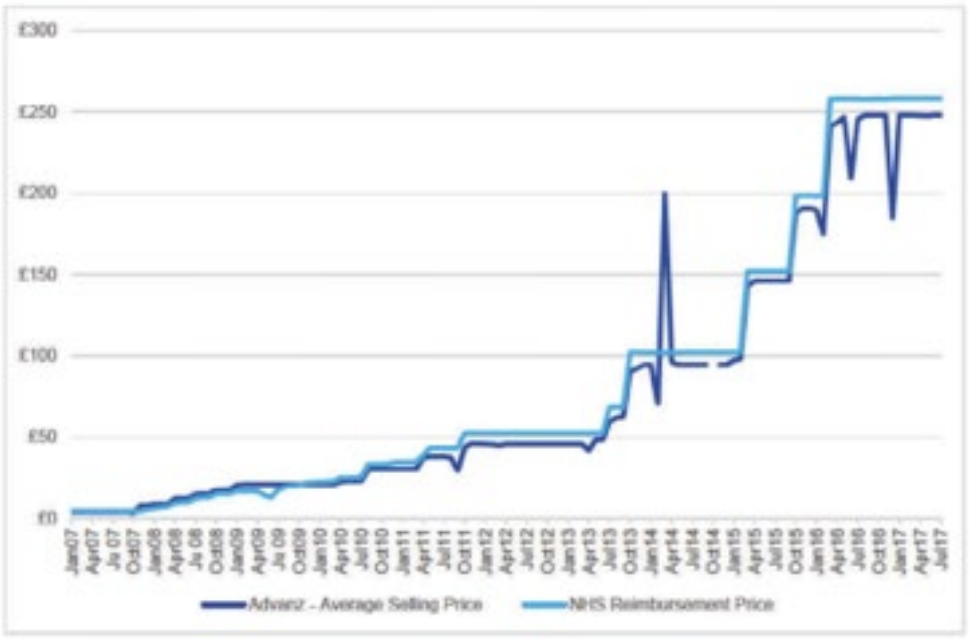
30. In 2007, the business decided to de-brand the product and to supply it instead as a generic drug. In practical terms, this meant that Advanz had to apply to amend the MA so as to remove the branded pharmaceutical name and give instead the generic name of the product, as set out in the British Pharmacopoeia, the government's list of medicinal drugs. Liothyronine Tablets were then sold under the generic name rather than Tertroxin. As noted in paragraph 22 above, prescriptions are generally open.

31. The decision to de-brand was part of a strategy by Advanz to drive an increase in profitability through price increases. By de-branding, products were removed from the PPRS scheme and hence from price regulation, as recognised in Advanz's UK business plan for branded pharmaceuticals in April 2007:

> "The way in which the PPRS scheme works means that price increases cannot be made easily on branded products. In order to drive price increases there is a strategy to move to the generic name and increase prices.
>
> …
>
> A range of products can be moved from branded to generic resulting in their removal from the current PPRS scheme and hence from price regulation. Prices on these products can be increased."

32. John Beighton, Advanz's former CEO, speculated in his witness statement about other possible reasons for the decision to de-brand (a decision which was taken several years before he joined Advanz), including the obsolescence of the Tertroxin brand name but these are not reflected in the contemporaneous documents. Advanz proceeded to implement a series of price increases in accordance with this strategy. Immediately prior to the de-branding of Tertroxin in October 2007, the average selling price ("ASP") for the drug was the equivalent of £4.05 per 28 tablet pack. It was Advanz's seventh most profitable product in its portfolio of 62 drugs. Having de-branded the drug, Advanz reduced the pack size from 100 to 28 and immediately increased its ASP to £8.05 per pack, in effect nearly doubling the price. A series of 63 individual price increases followed as shown in the Figure below.

Figure 1: Advanz's monthly ASP and average NHS Reimbursement Price of Liothyronine Tablets (January 2007 – July 2017)



Note: Advanz's price data for October 2014 unavailable.

Source: CMA analysis of data submitted by Advanz and PCA data for England[267]

33. In 2009, the business was acquired by the Hg Appellant ("Hg") in a management buy-out valuing it at £179 million. By this time, the price of a pack of 28 tablets had risen to £20.80. As part of the acquisition, Hg received a due diligence report from McKinsey & Company addressing the strategic focus of the business. The report commented on the Pharmaceutical Division as follows (Trojan being the code name given to the Advanz business which was the acquisition target):

> "The reason behind the extraordinary success of the pharmaceutical division in the difficult generics market in the UK is the efficacious management of its product portfolio within the regulation schemes in the UK: Trojan (i) manages to position its products in niches where competition is absent or very limited, (ii) optimally manages their products within the regulatory pricing schemes (branded and non-branded). Often their sales level stays under the radar screen of potential new entrants, thus protecting their business."

34. Following the acquisition, Hg replaced senior management and appointed Mr Beighton as CEO. Hg continued with Advanz's strategy of increasing the prices of unbranded niche generics. At a meeting on 21 July 2010, shortly after he had joined, a meeting took place attended by Mr Beighton and others at which it was decided to raise the price of Liothyronine Tablets by 32%. By August 2010 the

price of Liothyronine Tablets had reached £34.65 per pack and by August 2012, when the business was sold to Cinven for £465 million, it had risen to £46.

35. At around the time of the sale to Cinven, a number of reports and presentations were generated addressing, amongst other things, the pricing of Liothyronine Tablets, the scope for further significant price increases with no negative effect on volumes, the absence of competitors, the high barriers to new entrants and the favourable regulatory environment.

36. In May 2012, a report was produced by IMS Consulting Group entitled "Project Glacier Final Report" (Glacier being the code name for Mercury Pharma). IMS had been retained to produce an independent expert report providing external validation of the management forecasts for key products. The Report noted that, as the price of Liothyronine Tablets had more than doubled over the previous three years with no negative impact on volume, a price of £60 per pack was thought to be sustainable, with sales forecast to increase, in the expectation that there would be no competitors because the product was difficult to manufacture.

37. A confidential memorandum entitled "Project Glacier" dated June 2012 prepared by Jefferies, a financial services company, for Hg stated that the business was "uniquely positioned in the UK off-patent market, focusing on small to mid-sized off-patent products with lower levels of competition", including:

> "niche products that fall under the radar of large players but above the size threshold of small generic companies. Furthermore, these products are difficult to manufacture thereby reducing the risk of new competitors."

38. The same point about the market size putting off competitors was made in the information memorandum:

> "**Sales potential**: The Company's products are niche medications with existing revenue typically under £5-10 million, falling below the radar of large generics companies. Given the sales potential of these products for a new competitor, it is not economically viable for new entrants to invest resources to develop these products."

39. At a meeting of the Investment Committee of Cinven on 2 July 2012, an initial Investment Recommendation was presented. In summarising the investment attractions, the Recommendation drew attention to the beneficial regulatory

environment and minimal competition in the market for low volume niche products:

> "Mercury's products are generally old and low volume and therefore fall below the reimbursement radar.
>
> In the UK such branded/niche low volume products benefit from a particularly beneficial reimbursement mechanism which, whilst effective for high volume products (which is what the NHS cares about) does allow for niche players to achieve good margins.
>
> […]
>
> A key point is that the payor (NHS), prescriber (physician) and customer (wholesaler/pharmacy channel) **are all different for Mercury** – and the customer has no ability to prevent the prescriber from choosing a particular drug as long as it is reimbursed (which for Mercury's low volume, old, relatively cheap generic products is always the case) and in any case Mercury products are a tiny proportion of the relevant spend
>
> […]
>
> Reimbursement for drug manufacturers is controlled by a small group within the DoH, who aim to minimise the NHS' £11bn drug bill whilst ensuring drug availability
>
> The focus is on high volume drugs (patent and off-patent) as this is where the absolute quantum of savings is higher: niche products are typically below the radar
>
> […]
>
> Some of Mercury's products display price inelasticity, with no volume response from successive price increases."

40. Under the heading "Market overview" the Recommendation noted as follows in relation to the pricing of generics:

> "Approximately 40% of the generics market in the UK is unbranded [...] The pricing of these unbranded products is not regulated because competition suppresses pricing across the market as a whole [...]
>
> However, for smaller, niche formulations, the competitive forces may not work to suppress prices as efficiently as for larger volume products and create room for price growth.
>
> Mercury's sales in the UK are £70m which is just **0.6%** of the NHS' total spend on drugs
>
> […]

> Mercury therefore operates below the radar and capitalises on opportunities to achieve volume and pricing growth even in such a heavily regulated market"

41. Specifically in relation to Liothyronine Tablets, the Recommendation commented as follows:

> "Very strong market position. Planned price increase of circa 12% per annum over forecast (with flat volumes) supported by de-branding of some [units] for price optimisation"

42. In an internal email exchange on 19 July 2012 during the due diligence process, a query was put to Advanz's finance department as to how some products carried an extremely high gross margin, including Liothyronine Tablets at 98%. The following explanation was given, emphasising Advanz's ability, as exclusive marketer, to raise prices:

> "All these products are life saving products and exclusively marketed by Mercury Pharma only. There is no other substitute in UK market for these products. After de-branding ... we have increased the prices continuously in last 3 to 4 years. We have also changed the pack sizes of the products without reducing the prices. Few of the examples are like ... Liothyronine, where we have reduced the pack size from 100 to 28 ... we could continue increasing the prices [year on year] subject no other company introduces these molecules. Since these are de-branded therefore they do not have any PPRS liability also."

43. The final Project Glacier due diligence report dated 10 August 2012, prepared by Deloitte for Cinven, drew attention to the ability of Mercury Pharma to increase prices, subject to the possibility of new generic entry or DHSC intervention:

> "As Glacier is the exclusive or semi-exclusive supplier for much of this portfolio, price increases are possible, although the threat of a new generic competitor or intervention from DH means price increases need to be managed carefully."

44. In relation to Liothyronine Tablets, the report stated that the threat of a new entrant was limited given the difficulty of manufacturing the drug. There were currently no other suppliers of Liothyronine Tablets in the UK which allowed Glacier to control the price under Category A of the Drug Tariff; between 2010 and 2012 Glacier achieved a price increase of c36%; the low volumes and lack of alternatives allowed for "good pricing power"; an endocrinologist was quoted as saying that the drug was not common enough for pricing to be an issue. There was some risk that growing the market would attract competition from Europe however the difficulty of manufacturing the product coupled with the relatively

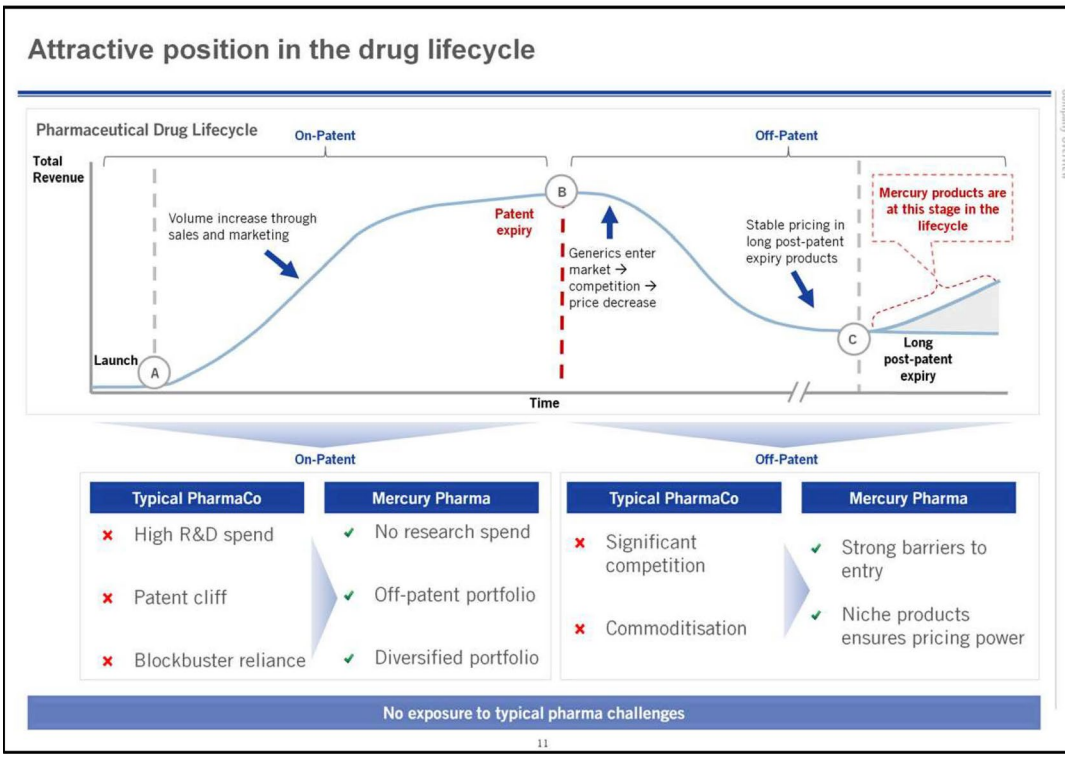
small market size would be likely to deter any new competition; underlying demand was good as there were few alternative therapies for patients who were intolerant of levothyroxine.

45. The final recommendation for Cinven to acquire the Mercury Pharma and Amdipharm groups gave as an "investment thesis" for the acquisition the ability to continue the exploitation of Amdipharm's portfolio of unbranded generic drugs where there was little or no risk of price competition:

> "Drive growth in the UK through optimisation of the Amdipharm UK portfolio in an identical manner to what Mercury have done in the last 2 years – a low risk value lever which we believe can deliver in excess of £20m of additional EBITDA under our ownership."

46. In September 2012, shortly after Cinven's acquisition of the business, representatives of Advanz including Mr Beighton gave a presentation to lenders, describing Advanz's business and prospects. One of the slides depicted Advanz's advantageous position in the drugs lifecycle, highlighting that with its off-patent portfolio there was no research spend, strong barriers to entry and pricing power in relation to niche products:

Figure 2: Advanz Presentation PowerPoint Slide (September 2012)



47. Mr Beighton's speaking notes accompanying this slide read as follows:

> "Attractive position - niche off-patent products insulated from key pharma risks
>
> - No R&D spend or patent cliff
>
> - Little/no competition - pricing/margin power
>
> - Strong entry barriers mean position sustainable"

48. Another of the slides, headed "Differentiated product portfolio benefits from high barriers to entry", identified the following barriers to entry:

> "**Manufacturing Process**
>
> • Products require complex manufacturing process and have difficult to determine formulations
>
> **Regulatory Approval**
>
> • Competitors entering market need to obtain new marketing authorisations
>
> • Process is costly and can be time-consuming (c.3-4 years)
>
> **Sales Potential**

> • Niche medications with sales under £5-10 million fall below the radar of large, global generics companies"

49. Mr Beighton's speaking notes commented on this slide as follows:

> "• Illustrate 3 key barriers
>
> - Complicated manufacturing process
>
> - Regulatory approval process
>
> - Sales potential
>
> • Overall leads to no economic incentive for new entrant
>
> • Stable competitive dynamics over a significant period of time attest to the strength and sustainability of these barriers."

50. A further slide described the regulatory environment. Mr Beighton's speaking notes pointed out that on-patent drug cost control was the focus of the Department of Health with limited resources. With unbranded drugs, the NHS encouraged competition to drive down the prices of unbranded drugs.

> "[…] However, on an individual drug basis where there was no/little competition allows drug producers to increase prices and margin - this is the key element for Mercury with its niche portfolio."

51. Mr Beighton's speaking notes made the same point in relation to the slide describing drug pricing regulations:

> "• Non-PPRS products not subject to formal price control - limited competitive pressures mean Mercury can drive price increases."

52. Mr Beighton's speaking notes in relation to the slide headed "Well positioned to address niche UK opportunities" commented on Mercury's "unique position":

> "- Niche products do not provide economic incentive for large multi-national companies to enter
>
> - Smaller UK generics companies do not have firepower/capabilities to compete with Mercury- also difficult for them to in-license given limited capabilities"

53. Mr Beighton's speaking notes accompanying the slide headed "High barriers to entry limited and stable competitive dynamics around key products" commented on Mercury's top ten molecules including Liothyronine, noting that there were

significant and sustainable barriers to entry and there was no foreseeable reason for this to change.

54. A confidential information memorandum signed by Mr Beighton in September 2012 for the purposes of raising additional finance following the acquisition of the business by Cinven drew attention to Liothyronine Tablets' niche position:

> "Mercury Pharma has a strong market position as the only supplier of Liothyronine tablets in the UK market […] Through its position as sole market provider in the UK, Mercury Pharma has strong pricing power. Over the last 3 years, Mercury Pharma has doubled the price of Liothyronine. Continued stable growth in historical volumes demonstrates the inelasticity of demand to the price increases, with volumes growing from FY2010 to FY2012 at a CAGR of 2%."

55. Following Cinven's acquisition of Advanz, the business was restructured. The Mercury Pharma group was merged with another group of pharmaceutical companies, Amdipharm, which was acquired for £367 million, to create Amdipharm Mercury or AMCo. Cinven's plans for the combined group were explained in a Financial Times article of 15 October 2012 as follows:

> "Cinven is hoping to exploit the stable growth of these cheap off-patent medicines that are sold in low volumes and with limited risk of price competition.
>
> These relatively neglected drugs, which Cinven partner Supraj Rajagopalan dubbed 'little jewellery boxes', can still attract strong sales ...
>
> Such drugs include Liothyronine, a treatment for underactive thyroid glands ...."

56. A presentation to a rating agency by Advanz in November 2012 included an explanation of the business's "De-branding Strategy", the stated purpose of which was to free the product from the PPRS pricing regime:

> "• Products not covered by the PPRS which are essentially non-branded products have free pricing due to NHS's approach to allow competition to check prices which is indeed the best approach to optimise pricing across the £11bn drug budget
>
> – Management actively identifies branded products where the Company has exclusive or semi-exclusive positions and deliberately "de-brands" them thus freeing the product from the PPRS pricing regime
>
> – Because the Company has exclusive or semi-exclusive positions, there is no/limited competition for its products"

57. Advanz continued to increase the price of Liothyronine Tablets. By September 2013 the price was £63.08 and a further 50% increase to £94.62 was planned. In late 2014 Cinven launched a project to market the business to potential bidders, producing a presentation document entitled "Project Asclepius". As with the reports and presentations at the time of the sale to Cinven, this highlighted the scope for price increases, the absence of competition and freedom from regulatory restraints. The document described the company as "the market leader in identifying and optimising niche off-patent prescription pharmaceutical drugs". Advanz's "systematic identification of attractive niches" was said to be based on the following three characteristics:

> "– High visibility of revenue opportunity – AMCo's portfolio consists of off-patent drugs with well-established safety profiles and stable revenue streams. It is also typically free from pricing limitations imposed by Payors (e.g. NHS in UK)
>
> – Strong competitive position including high technical barriers and regulatory complexity. Typically AMCo drugs have a complex manufacturing process and a tough and long drawn-out regulatory approval process
>
> – Volume below focus threshold of global Gx competitors - Niche medications with sales typically under £2m"

58. Its pricing and reimbursement expertise was said to benefit from free pricing in the UK:

> "AMCo utilizes its deep expertise in niche market segments to optimize pricing for its portfolio …
>
> AMCo's UK portfolio is majorly non-PPRS which favors its pricing optimization strategy
>
> • 77% of AMCo sales in UK are non-PPRS; for these drugs there **is no regulatory price ceiling**, similar to many aspects of the US market, so that pricing is largely governed by **competition, which for the majority of AMCo's drugs is very low**"

59. Disruption in pricing levels was said to be unlikely. The NHS was unlikely to change the current pricing set-up, which worked well for the NHS, price controls for products with few players was risky given the risk of players withdrawing. The niche market "may be too small for future interest from NHS", and further that "[c]urrent pricing levels are not high enough to attract unwanted attention."

60. Liothyronine was put forward in the presentation as a case study. It had delivered a 20-50% year on year price increase since 2010, with no price ceiling, being a non-PPRS drug. AMCo was the exclusive marketer, and the drug was difficult to manufacture due to low dosage and an insoluble hormone making it difficult to create a homogenous blend for tableting. The presentation document proposed a further 50% price increase.

61. By March 2015, the notified trade price of Liothyronine Tablets was £152.18. Over the course of 2015 there were two further large increases taking the price at the end of 2015 to £191, double the level at the start of that year. Advanz was aware that its price rises would provoke competitive entry relatively soon but planned nonetheless to maintain price increases and indeed to increase them immediately before the anticipated generic entry. A presentation document headed "UK key molecules" forecast loss of volumes in 2017 offset by increased prices, achieving year on year revenue gains in the period 2015 to 2018. This was consistent with the strategy adverted to in an email dated 31 May 2013, some two years earlier, in which Mr Beighton advocated a price increase in relation to another drug (Prednisolone):

> "… because I am pretty sure that we are going to get competition within the next year or so. I know of at least [one other supplier] that are developing. Therefore we should take what we can from it now. I think Liothyronine may be a similar story…"

62. In October 2015 AMCo was purchased by Concordia Health Corporation, (subsequently renamed Advanz Pharma Corp), in a deal valuing the enterprise at £2.3 billion. As with the previous acquisitions, there was a due diligence process. A report by consultants L.E.K. dated August 2015 identified liothyronine as AMCo's second highest revenue-generating molecule. As with previous reports and presentations, this noted that generic drugs had freedom of pricing in the UK and that whilst high levels of competition for most molecules ensured that generic prices were kept low, there were "niche scenarios" where generics with limited competition had been able to obtain premium pricing, of which liothyronine was an example.

63. By November 2015 a further price increase was planned from £148.40 to £198.90 and from March 2016 the price was increased to £258.20.

64. A company review document prepared by Concordia following its acquisition of the business identified Liothyronine Tablets as one of its top ten products:

> "… protected by manufacturing processes, stable market dynamics (limited appeal to new entrants) and no need for innovation (strong efficacy and safety)."

65. Under "key barriers to entry" in relation to Liothyronine, the Review identified the difficulty of manufacture, requiring a dedicated and segregated hormone production suite.

66. The 2015 price increases led to an attempt to limit prescribing of Liothyronine Tablets. An NHS funded not-for-profit body called PrescQIPP works to identify areas for potential changes in prescribing practice. It produces a list of Drugs to Review for Optimised Prescribing (or "DROP list") which includes drugs that CCGs consider to be poor value for money. In July 2015 PrescQIPP added Liothyronine Tablets to the DROP-List with the recommendation that levothyroxine be used as an alternative on the basis that it was cost-effective and suitable for once daily dosing due to its long half-life.

67. The price increases also attracted adverse scrutiny in the press. An article in the Times dated 5 June 2016 reported that doctors had been encouraged to stop prescribing Liothyronine after the price of a tablet shot up from 16p to £9.22. The article was forwarded within Advanz, prompting concern that the change of guidance might impact on sales. In response to an internal enquiry as to what was meant by the reference in the article to the NHS encouraging doctors to stop prescribing Liothyronine, and whether there would be a big impact, the answer was as follows:

> "Business as usual. We have seen a very small volume decline over the last 18 mths but it is very small (1-2%). So we characterise the market and volumes as flat!"

68. A subsequent internal email dated 29 June 2016 commented as follows:

> "[…] In short -- nothing new. The most important thing about this is the date. [The] ... DROP-List is published every year. It was published a year ago and our volumes remain flat. Thus it has had no impact on the sales volumes."

69. Advanz's General Counsel Robert Sully forwarded a claim in a draft Times article that "NHS BSA officials challenged AMCo" over some price increases in an internal email to Advanz staff dated 9 August 2016:

> "AMCo employees regularly submitted large price increases via the NHS In-Demand system [i.e. the NHS-BSA]. These were then implemented in the next Drug Tariff and became the new NHS reimbursement price […] NHS BSA officials challenged AMCo over some of these increases [not related to Lio], on one occasion, on April 28, 2015, noting that there was 'quite a large difference' between the old and new prices. However, they did not seek explanation or justification and ultimately approved the changes."

70. The view of Advanz staff, recorded in another internal email on 9 August2016, was that the checks carried out by the NHS on price increases were not substantive:

> "As regards Times's claim is concerned regarding "NHS CHALLENGING to AMCo" on large price increases, I have attached a mail from […] where you will find a confirmation from NHS that computer picks up at random price changes, which they seek confirmation from the manufacturer not challenging the manufacturer decision on pricing.
>
> It is never a challenge from NHS, it is just a confirmation from NHS to be doubly sure about the price changes in DM+d."

71. Following an NHS Clinical Commissioners ("NHSCC") consultation in 2017, guidance was issued to CCGs that the prescribing of Liothyronine Tablets should be reduced because of the cost. As a result of the revised prescribing guidance issued by the PrescQIPP and subsequently by the NHSCC, some patients who had previously been prescribed Liothyronine Tablets had their treatment withdrawn. Some patients were able to obtain supplies of Liothyronine Tablets privately. A witness statement was provided to the CMA in the course of the investigation by Lynda Mynott, the Chief Executive and Chair of the Board of Trustees of the charity Thyroid UK that some patients were unable to find an alternative source and found that their symptoms returned. This evidence was not accepted by Mr Beighton who could not accept that doctors would cease to prescribe Liothyronine if a patient needed it.

72. Following the publication of the June 2016 Times article, Jeremy Hunt, the then Secretary of State for Health, asked the CMA to look into whether drugs companies had been guilty of excessive pricing.

(8) Price of Liothyronine in other EU Member States

73. The Decision included the prices of Liothyronine Tablets at the end of the Infringement Period in a number of different EEA States. Advanz's prices both during the Infringement Period and after the entry of Morningside and Teva were significantly higher than those prices. The Decision also contained details of the regulatory restraints to which these prices were subject in all of the states mentioned apart from the Czech Republic where, according to the Decision, prices were not regulated:

Table 1: Prices of Overseas Liothyronine where licensed (2017)

Country	Tablet strength (mcg)	Number of tablets per pack	Sales volumes	Price per pack (local currency)	Price for 28 tablets equivalent (£)
UK	20	28	**74,859**	£247.77	£247.77
The Czech Republic	25	30	3,915	50.91 CZK	**£1.58**
France	25	30	110,199	2.46 EUR	**£2.01**
Germany	20236	50 , 100	2,454 ,002	10 .55 EUR,	**£5.18, £4.85**
	20238	50 , 100	660,784	19.75 EUR 9.27 EUR **16.34 EUR**	**£4.55, £4.01**
Malta	25	30	**24,750**	3.55 EUR	£2.95
The Netherlands	25	30	406,630	23.50 EUR	**£19.23**
Norway	20	100	735,180	276.6 NOK	**£7.28**
Sweden	20	100	32,636	**229.04 SEK**	**£5.84**

Source: CMA analysis of responses to information requests

(9) Other entrants

74. Until June 2017, Advanz was the only holder of an MA for Liothyronine Tablets. Since then, two MAs for Liothyronine Tablets have been granted and additional applications have been made. On 15 June 2017, the MHRA granted Morningside an MA in respect of Liothyronine Tablets. Morningside had commenced development in 2012 and submitted its application for the MA on 13 July 2015, following which it received a number of deficiency letters from the MHRA. Morningside stated that "the process for obtaining [an MA] was also

challenging", despite receiving "tremendous support from the MHRA." Morningside subsequently submitted further data which the MHRA reviewed in January 2017 and considered satisfactory.

75. Morningside commenced supplying Liothyronine Tablets on 21 August 2017 with a weighted average sales price of […][✂] per pack. […][✂].

76. On 14 August 2017, the MHRA granted Teva an MA in respect of Liothyronine Tablets. Teva first contacted the MHRA regarding an MA application for the manufacture of Liothyronine Tablets in November 2014 and submitted an application on 16 December 2016. Teva began supplying Liothyronine Tablets on 29 September 2017, with a weighted average sales price of £[…][✂] per pack. By February 2021 Teva's weighted average sales price […][✂] per pack.

77. Since then, Accord-UK, which initiated a development project for Liothyronine Tablets in 2012 and submitted an MA application in June 2020, and Sigmapharm, which submitted an application in 2019, have both obtained MAs.

78. The CMA does not have access to the ASP of Liothyronine after February 2021 but for the purposes of the appeal it obtained evidence of subsequent price movements from two sources, (i) WaveData, a commercial data provider, showing the wholesale prices for Liothyronine Tablets paid by pharmacies and dispensing doctors and (ii) publicly available information from the NHS setting out the NHS reimbursement prices for Liothyronine Tablets under Category M of the Drug Tariff for the period from July 2021 to July 2022.

79. As set out in greater detail at paragraph 257 below, both metrics indicated that the ASPs of Liothyronine Tablets had fallen significantly since February 2021 to around £36 - 41. Cinven produced a further update based on the Drug Tariff price for October 2022 suggesting ASPs for Liothyronine Tablets had fallen further to around £34-39.

C. THE DECISION

80. The CMA formally commenced its investigation on 25 October 2016, having determined that it had reasonable grounds for suspecting that Advanz had infringed the Chapter II prohibition and Article 102 of the Treaty on the Functioning of the European Union ("TFEU"). As set out in the Decision, following the end of the transition period implemented by the European Union (Withdrawal Agreement) Act 2020, EU law is no longer applicable in the UK, and thus the Decision does not consider whether Article 102 TFEU has been infringed.

81. The key findings in the Decision for the purposes of these appeals are, in broad outline, as follows:

    (1) The relevant market was Liothyronine Tablets for sale in the UK, in which market Advanz was dominant from at least 1 November 2007 to 31 July 2017.

    (2) Advanz abused its dominant position in the market for Liothyronine Tablets in the UK by imposing unfair selling prices during the Infringement Period (i.e. from at least 1 January 2009 to 31 July 2017), when prices were between £20.48 and £247.87 per pack.

    (3) In accordance with the legal test set out in the Court of Justice's judgment in *United Brands*, referred to in detail later in this judgment, such prices were excessive and unfair and bore no reasonable relation to the economic value of Liothyronine Tablets.

82. The CMA's conclusion that Advanz was dominant in the relevant market from at least 1 November 2007 to 31 July 2017 was based on the following:

    (1) Advanz's 100% market share throughout that period.

    (2) Advanz's pricing behaviour and financial performance as reflected by the fact that Advanz was able consistently to raise prices profitably.

(3) The lack of sufficient constraint from potential entry owing to high barriers to entry. Liothyronine Tablets are difficult to manufacture and are subject to strict regulatory standards.

(4) The absence of countervailing buyer power on the part of its customers.

83. The CMA found as follows:

(1) From 2007 and throughout the Infringement Period, Advanz developed and implemented a strategy to exploit the absence of effective regulatory and competitive constraints on its market power in respect of Liothyronine Tablets, in order to impose inflated selling prices on the NHS and on patients.

(2) This strategy was effected by identifying suitable products, removing them from the PPRS price controls through de-branding, and then implementing sustained price increases, without any investment or improvement with respect to the product in question.

(3) This strategy did not comprise a benefit to the NHS or to patients but resulted in the NHS paying "significantly more" for Liothyronine Tablets than it would have if the parties had not infringed the Chapter II prohibition. Ultimately, the NHS changed its prescribing guidance to restrict access to Liothyronine Tablets, and some patients were therefore no longer able to access them through the NHS.

84. The CMA referred to the first limb of the *United Brands* test ("the Excessive Limb") which asks whether the difference between the cost actually incurred and the price actually charged is excessive. The CMA split the total costs involved in the supply of Liothyronine Tablets into direct costs, indirect costs and a reasonable rate of return. Based on its assessment of these costs, the CMA's Cost Plus calculation ranged from £2.08 per pack of Liothyronine Tablets to £9.87 per pack during the Infringement Period, with a simple average of £4.94.

85. The CMA compared Advanz's selling price with these costs. It found that in 2009 (the first year of the Infringement Period), the differential was 900% per pack, rising to about 2,450% per pack in 2017 and 2,500% at other points in the Infringement Period. The differential in each year is set out in the Table below:

Table 2: Comparison of the ASPs of Liothyronine Tablets with the Differential

Value	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017***
Liothyronine Tablets ASP (£)	20.80	25.66	37.73	45.52	61.84	94.63	146.42	229.23	247.77
Cost Plus (£)	2.08	2.10	3.12	2.75	3.99	5.11	5.63	9.87	9.78
Differential (£)	18.72	23.56	34.61	42.77	57.85	89.52	140.79	219.36	237.99
Differential (%)	900%	1119%	1110%	1554%	1449%	1751%	2501%	2222%	2434%
Revenue differential (£m)	2.66	3.33	5.25	6.13	8.79	13.24	21.08	33.89	17.82
Note: ASPs are annual averages; the 2017 figure is the average to July 2017.									

86. The Decision recognised that the value of "Product Rights" (that is, the manufacturing know-how and the MA required for the supply of Liothyronine Tablets, and the most material asset to those who sold Liothyronine Tablets), the approach to common cost allocation and the appropriate return on capital were the main areas of judgement within the CMA's Cost Plus assessment and the main areas of difference between the CMA and the Appellants. The CMA applied a series of sensitivities (i.e. alternative approaches) to the data used in its Cost Plus analysis, specifically to the allocation of common costs, to the valuation of Product Rights and to the weighted average cost of capital or "WACC", to assess the effect of using alternative methods as set out below. These sensitivities were intended to function as cross-checks to the results of the CMA's Cost Plus analysis above. The cumulative application of these sensitivities resulted in a Cost Plus with a sensitivities range between £4.88 and £12.08 over the Infringement Period.

87. The CMA concluded that the scale of the differential between Advanz's prices and its Cost Plus was material throughout the Infringement Period even when the sensitivities were applied. The differential ranged from above 300% in 2009 to almost 2,000% by 2017. The CMA concluded that Advanz's prices during the Infringement Period were excessive.

88. The CMA then went on to consider the second limb of *United Brands* ("the Unfairness Limb"), which asks whether an excessive price is unfair "in itself" or "when compared to competing products".

89. The CMA first concluded that there were no demand-side factors which would add (or materially add) to the economic value of Advanz's Liothyronine Tablets. The price was unrelated to its therapeutic value. In any event, the therapeutic value of Liothyronine Tablets is likely to be no higher than that of levothyroxine tablets, which were priced significantly below the Cost Plus of Liothyronine Tablets during the Infringement Period.

90. Given that Liothyronine was a very old, unbranded generic drug, its characteristics could not be expected to create enhanced value from the consumers' perspective. There was no evidence that the DHSC/NHS or private patients were ready and willing to pay a premium for Liothyronine Tablets.

91. The CMA concluded that Advanz's prices for Liothyronine Tablets were "unfair in themselves". In coming to this conclusion the CMA had regard to the following:

    (1) The substantial disparity between Advanz's prices and the economic value of its Liothyronine Tablets (taking account of the age of Liothyronine Tablets, their therapeutic value and the lack of any evidence that the NHS was readily willing to pay a premium for Liothyronine Tablets).

    (2) The absence of alternative Liothyronine Tablet suppliers, lack of regulatory constraint, high demand inelasticity and high barriers to entry,

which enabled Advanz to sustain prices that bore no relationship to the economic value of Liothyronine Tablets.

(3) The commercial purpose of Advanz's pricing strategy, which was to exploit the lack of pressure on its pricing resulting from these competitive conditions.

(4) The significant increases in price, namely a 6,021% increase in Advanz's prices between 2007 and 2017, and a 1,110% increase over the Infringement Period with no material increase in costs or innovation.

(5) The significant adverse impact that Advanz's price increases had on the NHS and patients.

(6) The lack of any independent or objective justification for the conduct.

92. The CMA went on to assess various comparators put forward by the parties. These included in particular:

(1) the prices of Liothyronine Tablets following entry in 2017 by Morningside and Teva ("Post Entry Prices");

(2) the prices at which competitors were incentivised to enter the market ("Entry Incentivising Prices");

(3) the prices forecast by new and potential entrants in the market ("Forecast prices");

(4) the prices that would have been charged in a competitive market with multiple suppliers needing to recover their fixed costs over lower volumes ("Multi-Firm Prices").

93. The CMA concluded that Post Entry Prices were in principle capable of acting as a meaningful comparator but that they were still contaminated by the abusive prices charged during the Infringement Period and were therefore not a valid comparator. The CMA rejected the other comparators on the basis that they were

not prima facie valid as a measure of competitive pricing for Liothyronine Tablets. The CMA's reasons for rejecting these comparators are considered later in this judgment.

94. The CMA also rejected Advanz Pharma's contention that there can have been no abuse of a dominant position as it did not act unilaterally, but rather that the prices of Liothyronine Tablets were the outcome of agreement between Advanz and the DHSC/NHS. Advanz Pharma had argued that there was explicit approval of its price notifications, and further that the DHSC/NHS had an opportunity to object to its prices, but nevertheless paid them and that this amounted to acquiescence by the DHSC/NHS. The CMA found that the evidence did not support this argument and that Advanz's own internal documents showed that, in the case of Liothyronine Tablets, Advanz was deliberately raising prices for a niche drug that was "below the radar" of DHSC/NHS attention. In any case, the CMA considered that the argument that there can be no breach of the Chapter II prohibition where there is acquiescence is wrong in law.

95. The CMA found that Advanz infringed the Chapter II prohibition intentionally, or at the very least negligently, and imposed a total financial penalty of £101,442,899, with the various parties being liable for the following amounts:

(1) HgCapital was liable for a penalty of £8.6 million;

(2) The Cinven Appellants were liable for a penalty of £51.9 million; and

(3) The Advanz Pharma Appellants were liable for a penalty of £40.9 million (after adjustment in order to prevent the penalty exceeding the statutory maximum).

96. In setting the fines at these levels, the CMA took into account that Advanz made a total profit of over £92.3 million from the Infringement, of which:

(1) £5.7 million dated from the period when Advanz was controlled by HgCapital;

(2) £34.1 million dated from the period when Advanz was controlled by the Cinven Appellants; and

(3) £52.5 million dated from the period when Advanz was controlled by Advanz Pharma Corp.

D. THE APPEALS

97. Hg filed an appeal under section 46 of the Competition Act 1998 on 28 September 2021. Cinven and Advanz Pharma each filed their appeals on 14 October 2021. A case management conference took place remotely on 21 January 2022 at which the Tribunal ordered that all appeals of the Decision be case managed and heard together.

(1) Factual witnesses

98. The Tribunal heard evidence from two factual witnesses called by Advanz Pharma: Mr John Beighton and Mr Robert Sully. The CMA did not put forward any factual witnesses.

99. Mr Beighton has worked in the pharmaceutical industry for many years – including thirteen years at Teva UK Limited, where he was the Managing Director. In May 2010, Hg invited Mr Beighton to join Advanz as its CEO. Following the merger with Amdipharm in March 2013, Mr Beighton was CEO of the combined undertaking between March 2013 and the end of 2015. Mr Beighton then served as President of Concordia Healthcare Corp until 1 January 2017, when he stepped back from executive involvement with Advanz. Since then, Mr Beighton has taken various non-executive roles in the pharmaceutical industry and provides consultancy and non-executive advisory services for various pharmaceutical companies, including Advanz. Mr Beighton has also been involved in various roles with the BGMA.

100. Mr Sully joined Advanz as Legal Director (of the Goldshield Group) in 2011, and was appointed Global General Counsel of Advanz in August 2018. Mr Sully maintained this position until 10 May 2022 when he left Advanz to set up a legal

and ethical investment services provider of which he is a director. Mr Sully gave evidence in relation to the compliance and training initiatives he introduced and implemented at Advanz, as well as legal advice obtained from external competition lawyers regarding Advanz's non-branded drugs pricing strategy, and how that advice was understood and implemented by the business.

101. We consider that the factual witnesses were all seeking to assist the Tribunal with their evidence. This was not, however, a case that turned on oral evidence. The factual background was largely evidenced by Advanz's internal documents.

(2) Expert witnesses

102. The Tribunal heard evidence from a total of six experts. Five experts gave evidence generally on matters relevant to the substance of the alleged infringement: Professor Tommaso Valletti and Mr Greg Harman, on behalf of the CMA, Dr Avantika Chowdhury (on behalf of the Cinven Appellants), Ms Diana Jackson (on behalf of the Hg Appellant), and Dr Matthew Bennett (on behalf of the Cinven Appellants). The Advanz Pharma Appellants did not put forward an economic expert. Mr Richard Williams and Mr Warwick Smith (both on behalf of Advanz Pharma) addressed discrete issues, namely: the extent of the powers of the DHSC to intervene in the pricing of Liothyronine Tablets, as well as the reasonableness of Advanz's profitability across its entire portfolio during the Infringement Period, and the genesis and purpose of Scheme M, respectively, on behalf of Advanz.

103. The CMA called:

(1) Professor Tommaso Valletti, who is a Professor of Economics and Head of the Department of Economics and Public Policy at Imperial College Business School. Professor Valletti was previously the Chief Competition Economist of the European Commission (Directorate General for Competition) between 2016 and 2019, and has written extensively on industrial organisation, regulation and competition policy, including in relation to the pharmaceutical industry.

(2) Mr Greg Harman, who is Managing Director of the Berkeley Research Group, and a Fellow of the Institute of Chartered Accountants in England and Wales. Mr Harman was previously a partner at FTI Consulting and has worked on a range of matters involving economic and financial analysis, damages, valuation, pricing, regulation and competition in a variety of industries. Mr Harman's evidence was mainly focused on the Cost Plus calculations.

104. The Cinven Appellants called:

(1) Dr Avantika Chowdhury, who is a partner at Oxera Consulting LLP ("Oxera") and has been involved in many competition and regulatory matters including in relation to the pharmaceutical industry. Dr Chowdhury, in her capacity as a partner at Oxera, previously led a study into the supply of generic medicines in the UK commissioned by the BGMA. Her evidence was mainly concerned with the CMA's interpretation and use of the findings and data in that study. Dr Chowdhury was not cross-examined.

(2) Dr Matthew Bennett, who is a Vice President at Charles River Associates, and a professional economist. Prior to joining CRA, Dr Bennett was the Director of Economics at the Office of Fair Trading ("OFT") where he was responsible for the economic policy, financial analysis and statistics and econometric teams within the OFT. Dr Bennett's evidence dealt both with the suitability of the comparators relied on by the Appellants and the Cost Plus calculation.

(3) Hg called Ms Diana Jackson, who is a Vice President at Charles River Associates and a professional economist with over 20 years' experience providing advice on competition policy matters across various industries. Ms Jackson, like Dr Bennett, addressed both the suitability of the comparators relied on by the Appellants and the Cost Plus calculation.

105. The Advanz Pharma Appellants called:

(1) Mr Richard Williams, who is a Chartered Accountant and Fellow of the Institute of Chartered Accountants in England and Wales. Mr Williams's expert report dealt with the statutory powers of the Secretary of State for Health to intervene in the pricing of Liothyronine Tablets, as well as Advanz's level of profitability across its entire portfolio of medicine sales to the Department of Health, and the reasonableness of those profits. Mr Williams was not cross-examined by the CMA.

(2) Mr Warwick Smith, who was formerly the Director General of the BGMA between 1995 and 2020. Mr Smith's short expert report dealt exclusively with the genesis and purpose of the Scheme M framework from its inception.

106. The Tribunal found all the economic experts to be impressive, giving clear and cogent evidence both in their written reports and in their oral evidence. The Tribunal held one 'hot tub' session of contemporaneous expert evidence, in which the Tribunal's examination was led by Professor Waterson, which was helpful in enabling each of the economic expert witnesses to respond immediately to the others on the main issues. The Tribunal has formed its own views of the issues covered by the experts after weighing up their competing arguments. The evidence of Mr Williams and Mr Smith was less central to the issues and was largely uncontentious.

E. THE LEGAL FRAMEWORK

(1) Abuse of dominant position

107. Section 18(1) of the 1998 Act provides, insofar as material, as follows:

> **Abuse of dominant position**
>
> (1) Subject to section 19, any conduct on the part of one or more undertakings which amounts to the abuse of a dominant position in a market is prohibited if it may affect trade within the United Kingdom.
>
> (2) Conduct may, in particular, constitute such an abuse if it consists in—
>
> (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;

108. Section 18(1) was modelled on what is now Article 102 of the TFEU. In accordance with section 60A of the 1998 Act, the Tribunal, when determining any question arising under section 18, must act

> "… with a view to securing that there is no inconsistency between
>
> (a) the principles that it applies and the decision that it reaches in determining that question and
>
> (b) the principles laid down by the TFEU and the European Court before [31 December 2020], and any relevant decision made by that Court before that date so far as applicable immediately before [31 December 2020] in determining any corresponding question arising in EU law."

109. It was submitted on behalf of Hg that section 18 is primarily concerned with the protection of competition as an institution, rather than with the welfare of consumers. The cases relied on in support of this submission, *Hoffmann La Roche & Co AG v Commission* EU:C:1979:36 and *British Airways plc v Commission of the European Communities* Case C-95/04 [2007] 4 C.M.L.R. 22 do not, however, support the proposition that protection of consumers from direct harm through unfair pricing is only a secondary objective of the legislation. In *British Airways plc v Commission of the European Communities* Case C-95/04 [2007] 4 C.M.L.R. 22 the Court of Justice held (at paragraph 106) that Article 102 is aimed both at practices which may cause prejudice to consumers directly as well as the protection of competition. In *London & South Eastern Railway Ltd and others v Gutmann* [2022] EWCA 1077 Green LJ explained why the law relating to abuse of dominance is concerned with consumer unfairness:

> "[93.] The law relating to abuse is concerned with consumer unfairness because when an undertaking is dominant it is, by definition, freed from the competitive shackles which otherwise incentivise and discipline it to maximise consumer welfare and benefit. This is why most laws worldwide which prohibit abuse of dominance include within the prohibition the imposition of some form of "*unfair*" terms and prices. These are often described as "exploitative" abuses."

(2) The United Brands test

110. It was common ground that section 18 is to be construed by reference to the judgment of the Court of Justice in Case C-27/76 *United Brands v Commission* EU:C:1978:22 ("*United Brands*") in which the Court of Justice set out criteria for determining whether a dominant undertaking has imposed unfair prices and

gave guidance as to the methods and evidence that might be relevant to proving unfairness.

111. *United Brands* was an appeal from a decision by the European Commission that United Brands ("UBC") had abused its dominant position in the banana market by, amongst other things, charging its customers in certain Member States unfair prices which the Commission considered to be "excessive in relation to the economic value of the product supplied". The Commission had reached its decision as to excessive pricing on the basis of a comparison between the prices charged in the Member States in question and the prices which UBC charged to customers in Ireland. The core statement of principles, referred to in subsequent cases as the *United Brands* test, is set out in the following paragraphs:

> "248. The imposition by an undertaking in a dominant position directly or indirectly of unfair purchase or selling prices is an abuse to which exception can be taken under Article [102] of the Treaty.
>
> 249. It is advisable therefore to ascertain whether the dominant undertaking has made use of the opportunities arising out of its dominant position in such a way as to reap trading benefits which it would not have reaped if there had been normal and sufficiently effective competition.
>
> 250. In this case charging a price which is excessive because it has no reasonable relation to the economic value of the product supplied would be such an abuse.
>
> 251. This excess could, inter alia, be determined objectively if it were possible for it to be calculated by making a comparison between the selling price of the product in question and its cost of production, which would disclose the amount of the profit margin; however the Commission has not done this since it has not analysed [United Brands'] costs structure.
>
> 252. The questions therefore to be determined are whether the difference between the costs actually incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products.
>
> 253. Other ways may be devised – and economic theorists have not failed to think up several – of selecting the rules for determining whether the price of a product is unfair."

112. The Court of Justice went on to note that, despite the difficulties and complexities in working out production costs, doing so for bananas did not seem to present any insuperable problems. The Commission was at least under a duty to require

UBC to produce particulars of all the constituent elements of its production costs, which it failed to do. Nor had the Commission refuted evidence adduced by UBC that the Commission had miscalculated UBC's profits; furthermore, UBC's prices were only 7% higher than those of its principal competitors which could not automatically be regarded as excessive and consequently unfair. The Court of Justice concluded that in these circumstances, the Commission had failed to adduce adequate legal proof of the facts and evaluations underlying its finding that that UBC had infringed Article [102] by imposing unfair selling prices and annulled the relevant part of the Commission's decision.

113. The *United Brands* test and the European and domestic case law applying the test were reviewed by the Court of Appeal in *CMA v Flynn Pharma* [2020] EWCA Civ 339 ("*Phenytoin*"). Like this case, *Phenytoin* was an appeal against a decision by the CMA that pharmaceutical companies had abused their dominant position by charging the NHS unfair prices for a de-branded drug. The case raised some fundamental issues concerning the correct approach to be adopted by a competition authority when investigating unfair prices and the extent to which the Tribunal is bound by a competition authority's findings. The Court of Appeal's judgment established a number of principles which are set out below. The judgment was issued in the course of the investigation in this case, and prompted changes to the CMA's approach, as acknowledged in the Decision. The judgment had a significant bearing on the way the arguments on this appeal were developed.

114. In its decision in *Phenytoin,* the CMA had concluded that Pfizer's and Flynn's prices for phenytoin sodium capsules were excessive and that they were "unfair in themselves" for the purposes of the *United Brands* test because they bore no reasonable relation to the economic value of the capsules. Having reached that conclusion, the CMA considered that the *United Brands* test did not require it to address comparator evidence adduced by Flynn and Pfizer as part of their defence and concluded that there had been infringements of the Chapter II prohibition and Article 102.

115. On appeal by Pfizer and Flynn, the Tribunal held that the CMA had misapplied the *United Brands* test and set aside the part of decision relating to abuse. With

regard to the Excessive Limb of the test, the CMA had been wrong to restrict its assessment of whether the prices were excessive to a Cost Plus approach. It should instead have identified a benchmark price or range of prices which realistically would have applied in conditions of normal and effective competition. It should then have compared that price (or range) with the price that had been charged in practice and determined whether that was excessive. As to the Unfairness Limb of the test, the CMA had erred by basing its assessment of unfairness solely by reference to whether prices were unfair in themselves. It should instead have conducted a full investigation into prima facie valid comparators put forward by the undertakings.

116. There were five main issues in the CMA's appeal to the Court of Appeal. The first concerned the Unfairness Limb in *United Brands* and whether the "in itself" test and "competing products" tests were true alternatives, as the CMA contended. On this issue, the Court of Appeal rejected the CMA's argument, based on paragraph 252 of the *United Brands* test, that, if it established that prices were "unfair in themselves", there was no need for it to consider evidence of competing products. It upheld the Tribunal's conclusion that the tests were not strict alternatives. After reviewing the caselaw, Green LJ, with whom Sir Geoffrey Vos V-C and Sir Stephen Richards agreed, summarised the relevant principles as follows:

> "97. …
>
> (i) The basic test for abuse, which is set out in the Chapter II prohibition and in Article 102, is whether the price is "*unfair*". In broad terms a price will be unfair when the dominant undertaking has reaped trading benefits which it could not have obtained in conditions of "*normal and sufficiently effective competition*", i.e. "*workable*" competition.
>
> (ii) A price which is "*excessive*" because it bears no "*reasonable*" relation to the economic value of the good or service is an example of such an unfair price.
>
> (iii) There is no single method or "*way*" in which abuse might be established and competition authorities have a margin of manoeuvre or appreciation in deciding which methodology to use and which evidence to rely upon.
>
> (iv) Depending upon the facts and circumstances of the case a competition authority might therefore use one or more of the alternative economic tests which are available. There is however no rule of law requiring competition authorities to use more than one test or method in all cases.

> (v) If a Cost-Plus test is applied the competition authority may compare the cost of production with the selling price in order to disclose the profit margin. Then the authority should determine whether the margin is "*excessive*". This can be done by comparing the price charged against a benchmark higher than cost such as a reasonable rate of return on sales (ROS) or to some other appropriate benchmark such as return on capital employed (ROCE). When that is performed, and *if* the price exceeds the selected benchmark, the authority should then compare the price charged against any other factors which might otherwise serve to justify the price charged as fair and not abusive.
>
> (vi) In analysing whether the end price is unfair a competition authority may look at a range of relevant factors including, but not limited to, evidence and data relating to the defendant undertaking itself and/or evidence of comparables drawn from competing products and/or any other relevant comparable, or all of these. There is no fixed list of categories of evidence relevant to unfairness.
>
> (vii) If a competition authority chooses one method (e.g. Cost-Plus) and one body of evidence and the defendant undertaking does not adduce other methods or evidence, the competition authority may proceed to a conclusion upon the basis of that method and evidence alone.
>
> (viii) If an undertaking relies, in its defence, upon other methods or types of evidence to that relied upon by the competition authority then the authority must fairly evaluate it."

117. The second main issue considered by the Court of Appeal was as to the extent of the duty on competition authorities to investigate competing evidence adduced by an undertaking. The Court held that a competition authority has a margin of manoeuvre or discretion as to the method(s) it uses and the evidence it relies upon. How it goes about evaluating the evidence will be fact and context specific and will take into account the evidence adduced by a defendant undertaking:

> "116. In short, the authority has a duty to conduct a fair evaluation of the evidence. It has a margin of manoeuvre or discretion in how it goes about meeting this obligation. This might, depending upon the facts, involve the taking of proactive steps, such as the issuance of requests for information to third parties, but it will not inevitably do so. The extent of the duty will be affected by the nature, extent and quality of the evidence adduced by the defendant undertaking which has an evidential burden."

118. Sir Geoffrey Vos V-C held as follows:

> "270. In such a situation, in my judgment, the CMA is obliged to evaluate the arguments and evidence advanced by undertakings under the CMA Rules 2014 fairly and impartially. It may reject comparators so advanced, but should give reasons for doing so. In my judgment, however, the obligation that the CAT imposed on the CMA at [379] and [391] was not correct in law. The CMA does not have any duty actively to investigate in every case, in the sense of obtaining evidence about, any comparators put forward by the undertakings. It may do so, of course. It may even be desirable for it to do so (or even necessary in some

> cases), but it has a considerable margin of manoeuvre and it may decide how it wishes to deal with the comparators put forward by an undertaking. If it rejects the comparators wrongly or without giving appropriate reasons, its infringement decision will be more vulnerable, if and when the matter comes before the CAT on appeal."

119. The third issue on the appeal was whether the CMA was required to create a hypothetical benchmark price, as the Tribunal had held. The Court of Appeal allowed the CMA's appeal against the Tribunal's conclusion on this issue. The Court of Appeal held that the authority has a margin of manoeuvre or discretion as to how it goes about proving its case. As to the choice of benchmark, Green LJ held as follows:

> "125. In my view by the nature of the abuse in issue there needs to be "a" benchmark. But, in the first instance at least, the choice of benchmark is for the competition authority to choose and can be based upon the costs of the undertaking being investigated or it can be based upon comparables such as the prices charged by the same or different undertakings in the same or different geographical markets or indeed any other benchmark or combinations thereof capable of providing a "sufficient" indication that the prices charged are excessive and unfair. It follows from the above that assuming the Tribunal was mandating the use in all cases of a hypothetical benchmark price which did not include the costs of the undertaking or some other benchmark related to the undertaking, then I respectfully disagree with the Tribunal. I would allow this Ground of Appeal."

120. Sir Geoffrey Vos V-C held as follows:

> "252. In my judgment, the first step in the analysis for the excessive limb is likely in most cases to be for the competition authority to consider whether the costs of production or the costs actually incurred in relation to the product in question, including of course a reasonable rate of return, can be ascertained. In some cases, that simply cannot be done, and in others, it may provide an inappropriate counterfactual. But, where it can be done, there is no reason, based on the applicable authorities, why the authority should not use that methodology to ascertain an appropriate counterfactual for the excessive limb of the analysis. In other cases, it may be necessary to determine the excessive limb by other methods.
>
> 253. It is true that the cost plus calculation must take some account in the 'plus' part of the calculation of the economic value of the product, but once again, I do not think that the CMA is required to adopt any particular approach to the determination.
>
> 254. I agree, therefore, with the CMA that the CAT fell into legal error when it held at [310(1)] and [443(1)] that it had to establish a benchmark price or a range of prices, beyond a cost plus calculation, in order to determine whether the prices charged by Pfizer and Flynn were excessive. I, therefore, agree with Green LJ's analysis under his section on the CMA's Second Ground of Appeal."

121. The fourth main issue on the appeal was as to the extent to which the Tribunal was bound by the CMA's margin of manoeuvre or discretion in exploring factual matters. Green LJ noted that the CMA had a "*margin of manoeuvre*" (the terms used by the Court of Justice in *Latvian Copyright*) or "*appreciation*" or "*discretion*" which flowed from the fact that the legal test under Section 18(2)(a) CA 1998 and Article 102(a) is broad brush and necessarily confers a significant latitude upon a competition authority as to the methods and evidence bases that it resorts to in order to prove an abuse of unfair pricing. He continued as follows:

> "136. But this is quite different in principle to the question whether the Tribunal, as a supervisory judicial body, must pay deference to that exercise of judgment. Under the CA 1998 the Tribunal has a merits jurisdiction as to both law and fact and upon the basis of established case law it is not bound to defer to the judgment call of a competition authority. It is empowered under the legislation to come to its own conclusions on issues of disputed fact and law and can hear fresh evidence, not placed before the CMA, to enable it to do so."

122. Green LJ held that the conferral of a merits jurisdiction upon the Tribunal flows from important legal considerations relating to the rights of defence and access to a court, under fundamental rights such as Article 6 of the European Convention on Human Rights, competition law being treated as a species of criminal law as a recognised in numerous cases. Green LJ summarised the case law as follows.

> "140. From case law it is possible to draw various conclusions about the role of judicial bodies in relation to the margin of appreciation of a competition authority: (i) for a (non-judicial) administrative body lawfully to be able to impose quasi-criminal sanctions there must be a right of challenge; (ii) that right must offer guarantees of a type required by Article 6; (iii) the subsequent review must be by a judicial body with "full jurisdiction"; (iv) the judicial body must have the power to quash the decision "in all respects on questions of fact and law"; (v) the judicial body must have the power to substitute its own appraisal for that of the decision maker; (vi) the judicial body must conduct its evaluation of the legality of the decision "on the basis of the evidence adduced" by the appellant; and (vii), the existence of a margin of discretion accorded to a competition authority does not dispense with the requirement for an "in depth review of the law and of the facts" by the supervising judicial body."

123. Green LJ went on to note that the conferral of a merits jurisdiction did not mean that the jurisdiction of the Tribunal is unfettered. The Tribunal should interfere only if it concludes that the decision is wrong in a *material* respect. Whether an error is material will be a matter of judgment for the Tribunal. The Court of Appeal dismissed the CMA's appeal against the Tribunal's finding that the CMA had conducted an insufficient examination of evidence of comparators and its

appeal against the Tribunal's conclusion that the CMA had failed to take proper account of patient benefit in its assessment of "economic value" as that phrase is used in paragraph [250] of *United Brands.* It was open to the Tribunal to reach a different conclusion to the CMA on these matters.

124. The fifth main issue addressed by the Court of Appeal concerned the concept of "economic value" as that phrase is used in paragraph 250 of *United Brands*. Green LJ noted that the concept of economic value is not defined in *United Brands.* In broad terms, the economic value of a good or service is what a consumer is willing to pay for it, but it does not follow from the fact that a consumer pays an abusive and exploitative undertaking the price demanded that the price reflects economic value. There must be a reasonable relationship between price and economic value, A proxy for economic value might be what consumers are prepared to pay in an effectively competitive market. He held as follows:

> "172. … It is evident from the judgment in United Brands that the reference to "economic value" is a part of the overall descriptor of the abuse; it is not the test. The test should therefore, when properly applied, be capable of evaluating economic value. So, for instance, as the CMA argues, when evaluating patient benefit it would be possible to measure its economic value in the plus element of cost-plus, or even in the fairness element. Equally, if there is evidence of the prices being charged in relevant, comparator, markets which were effectively competitive then those prices could be capable of acting as proxy evidence of the economic value of patient benefit. In so far as an issue of fact arises which can be categorised as an aspect of "economic value" it needs to be measured and it can be evaluated in various parts of that test. If it is properly factored into "plus" or "fairness" or into some other part of the test, or is reflected in other evidence which can stand as a proxy for economic value, then there is no incremental obligation to take it into account again, as a discrete advantage or justification for a high price. … In short, economic value needs to be factored in and fairly evaluated, somewhere, but it is properly a matter which falls to the judgment of the competition authority as to where in the analysis this occurs."

125. The CMA argued that the Tribunal had misunderstood the concept of "economic value" as used in *United Brands* and had erred in finding that the CMA had attributed a nil value to patient benefit in its Cost Plus analysis. The Court of Appeal rejected this ground of appeal, holding that the Tribunal had made findings of fact which were not capable of being challenged. They were to the effect that the CMA had failed to accord at least "some" weight to economic value.

(3) "Workable competition"

126. A central theme of the appeals in the present case was the argument that, in rejecting the various comparators relied on by the Appellants to justify Advanz's prices, the CMA had ignored the basic test for unfair pricing, as set out in *United Brands* and *Phenytoin*, which was the need to show that "the dominant undertaking has reaped trading benefits which it could not have obtained in conditions of normal and sufficiently effective competition, i.e. workable competition."

127. The *United Brands* test does not define what was meant by "normal and sufficiently effective competition". It was not suggested by any of the parties to this appeal that these words or the words "workable competition" are terms of art in economics. Read in context, the words "normal and sufficiently effective competition" denote a counterfactual to conditions of insufficiently effective competition in which an undertaking is able to exploit opportunities arising from its dominant position.

128. The comparator of Post Entry prices relied on by the Appellants raised an issue as to whether, four years after new entrants began to compete in the market for Liothyronine Tablets, there was normal, sufficiently effective and workable competition, such that the prices were a valid comparator, or whether, despite the lapse of time, the prices remained contaminated by Advanz's abusive prices during the Infringement Period and hence did not reflect normal, sufficiently effective and workable competition and were not a valid benchmark. This issue is considered later in this judgment in detail in the context of the Post Entry Prices comparator.

129. Normal, sufficiently effective and workable competition, as well as being distinct from abnormal, insufficiently effective competition, is also distinct from perfect, maximally competitive or idealised competition. As the Tribunal noted in *Phenytoin,* normal, effective competition is the "most that should be expected in the real world" as distinct from "idealised or near perfect competition which is a theoretical concept."

130. The Appellants contended that, in rejecting Post Entry prices as a comparator on the basis that they had not yet reached an equilibrium level close to the cost of production, the CMA was applying a benchmark of perfect competition. The CMA rejected this contention. Again, this issue is considered in detail in the context of the Post Entry Prices comparator.

131. It was submitted on behalf of the Cinven Appellants that the correct way to apply the '*workably competitive*' criterion was first to establish what workably competitive price levels look like in the market in question and then to compare that to the challenged prices. The Cinven Appellants alleged that the CMA had failed to follow that logical sequence, pre-determining that Cost Plus is to be favoured over all else in this case for reasons of policy and marginalising any proper consideration of whether Cost Plus bears any relation to how workable competition actually functions in the market at hand.

132. In our view, the submission that the CMA's starting point should have been workably competitive prices was not well founded. As Green LJ held, there is no rule that the competition authority must establish workably competitive prices at any stage:

> "123. Third, I note that in paragraph [249] the Court says only that it is "*advisable*" to ascertain whether the undertaking had exploited its dominance in a way which it could not have "… *if there had been normal and sufficiently effective competition*", these being the words said to create the requirement for a hypothetical benchmark price. There is no specific reference to price in the paragraph and in any event the expression "*advisable*" is inconsistent with the Court intending to provide anything more than guidance as to best practice. It would have used more directive language had it intended to lay down a fixed rule.
>
> In my view by the nature of the abuse in issue there needs to be "*a*" benchmark. But, in the first instance at least, the choice of benchmark is for the competition authority to choose and can be based upon the costs of the undertaking being investigated or it can be based upon comparables such as the prices charged by the same or different undertakings in the same or different geographical markets or indeed any other benchmark or combinations thereof capable of providing a "*sufficient*" indication that the prices charged are excessive and unfair."

133. Whilst there is no rule that the competition authority must start with workably competitive prices as a benchmark, the authorities make clear that an over-rigid or exclusive reliance on a Cost Plus analysis at the expense of a proper consideration of competition is wrong. In *BHB Enterprises v Victor Chandler*

[2005] EWHC 1074 Laddie J held that simply charging in excess of the cost of production was not in principle an abuse, that there is no necessary correlation between the cost of production and the cost of capital and the price which can be achieved in the marketplace and that in considering unfairness it is necessary to consider all of the market conditions. His approach was approved by the Court of Appeal in *Attheraces Limited and another v British Horseracing Board Limited and another* [2007] ECC 7. It held that Etherton J (as he then was) failed to take proper account of the economic value of the data to the purchaser and how much the purchaser could make out of it as a source of income. A competitive market might yield a rate of profit above, as well as below, the reasonable margin represented by cost plus. Mummery LJ stated as follows:

> "173. It is well recognised, in cases such as the pricing for pharmaceutical products, that it is not correct to apply the cost+ approach uniformly to the determination of all issues of excessive pricing. It is necessary to consider all the relevant circumstances and to have regard to the particular circumstances of the product in question."

134. At paragraph 217, Mummery LJ reiterated that the Article 82 prohibition on excessive pricing:

> "…is not a general provision for the regulation of prices. It seeks to prevent the abuse of dominant market positions with the object of protecting and promoting competition."

135. In *Phenytoin*, Green LJ, in rejecting the need for a hypothetical benchmark noted that caselaw supported the conclusion that the counterfactuals of greatest practical value are often those drawn from real life, as opposed to some hypothetical model.

136. The Appellants also submitted that the CMA erred in law in setting its Cost Plus benchmark at a price below the price level needed to incentivise entry by other competitors. This submission was advanced by Cinven on the ground that the CMA had no power to set prices below the level of workable competition. The Appellants contended that the CMA's approach was itself distortive of competition since it replaced the interplay of competition between suppliers to serve consumers with what was a monopoly benchmark that would deter entry.

137. This issue is considered in detail in the context of Entry-Incentivising prices. In short, we agree with the CMA that there is no legal principle that its Cost Plus

benchmark must be no lower than the price level needed to incentivise entry by other competitors. Under the *United Brands* test as clarified in *Phenytoin*, there is no absolute requirement that a fair price must be no lower than an Entry Incentivising price. The reference to '*workably competitive*' conditions is not a mandatory requirement but part of a flexible test in relation to which the competition authority has a margin of manoeuvre. As noted by Green LJ, it is only "advisable", i.e. not required, for the competition authority to ascertain whether the undertaking has exploited its dominance in a way which it could not have done in workably competitive conditions. Moreover, the principle contended for by the Appellants would be inconsistent with the purpose of the law against excessive pricing since, in a market with high barriers to entry, it would enable a dominant supplier to charge inflated prices which could not be achieved in circumstances of normal and sufficiently effective competition.

(4) Multi-firm or single-firm Cost Plus

138. The Appellants' case that the Cost Plus benchmark had to reflect workably competitive prices also underlay their argument that the CMA's Cost Plus model had to be calculated on a 'multi-firm' rather than 'single-firm' basis. The significance of the difference between a single-firm and multi-firm Cost Plus model is that in a market, such as the market for Liothyronine Tablets, in which there are significant fixed entry costs, the price needed to sustain multiple firms is higher than the price needed to sustain a single firm because each firm has to recover its costs over a smaller share of the market. The more firms that enter, the higher the minimum price required to cover the costs.

139. By the end of the hearing, the Appellants accepted that a single-firm Cost Plus calculation was appropriate for the purposes of the Excessive Limb of the *United Brands* test but maintained that a multi-firm adjustment was necessary for the purposes of the Unfairness Limb.

140. In the Decision, the CMA contended that a multi-firm adjustment was inappropriate both as a matter of economic logic and from the perspective of effective competition policy enforcement. The Appellants contended that it was wrong in principle to choose a benchmark for the assessment of excessive prices

that is below the prices that could emerge from competition and made alternative calculations incorporating a multi-firm adjustment.

141. We have concluded that the single-firm rather than multi-firm Cost Plus basis is appropriate as a benchmark for reasons set out in the context of our consideration of the Cost Plus calculation.

F. ISSUES ON THE APPEALS

142. The grounds of appeal of the Appellants, though framed in different ways, give rise to common issues. The main issues are as follows:

(1) Did the CMA err in its assessment of Cost Plus? The Appellants contended that the CMA understated the relevant costs and that when its errors are corrected there is no strong and compelling evidence that Advanz's prices were above the correct Cost Plus. The Advanz Pharma Appellants further contended that the CMA's approach to Cost Plus failed to take sufficient account of either the value to patients of Liothyronine Tablets or the use of portfolio pricing in the pharmaceutical industry (i.e. setting prices of a product by reference to the pricing and costs of an overall portfolio).

(2) Did the CMA err in its assessment of the comparators put forward by the Appellants? Did the CMA wrongly ignore these "real-world" indicators of economic value which, according to the Appellants, showed that its Cost Plus model was wrong?

(3) Did the NHS acquiesce in the price increases and, if so, does that mean that there was no abuse?

(4) Was the CMA wrong to conclude that Advanz had a dominant position in the market for the supply of Liothyronine Tablets, having regard to the NHS's countervailing market power?

(5) Should the penalties imposed by the CMA be quashed in their entirety or reduced in amount?

G. ISSUE (1) DID THE CMA ERR IN ITS ASSESSMENT OF COST PLUS?

(1) The CMA's Cost Plus calculation

143. The Excessive Limb of the *United Brands* test, as clarified in *Phenytoin,* asks whether the difference between the costs actually incurred and the price actually charged is excessive. The competition authority may compare the cost of production with the selling price in order to disclose the profit margin. The authority should determine whether the margin is 'excessive' by comparing the selling price to the cost of production plus a reasonable rate of return. This benchmark is referred to as "Cost Plus", as referenced at paragraph 4 above.

144. The experts agreed that the economic logic underlying Cost Plus is that the benchmark represents the prices at which potential entrants would be indifferent between entering the Liothyronine market or not doing so. The benchmark calculates the point at which entry would break even.

145. As noted above, in the Decision, the CMA split the total costs incurred in the supply of Liothyronine Tablets into direct costs, indirect costs and reasonable rate of return, giving rise to a Cost Plus calculation ranging from £2.08 per pack of Liothyronine Tablets to £9.87 per pack during the Infringement Period, with an average of £4.94.

146. The Appellants alleged that there were the following errors in the CMA's approach to Cost Plus calculation for the purpose of the Excessive Limb:

(1) The CMA understated the cost of Product Rights;

(2) The CMA allocated costs incorrectly; and

(3) The CMA understated the cost of capital.

147. In addition, the Appellants contended that, for the purpose of the Unfairness Limb, the CMA should have made the multi-firm adjustment referred to above. Advanz Pharma also contended that the plus element of Cost Plus should have taken account of patient benefit and portfolio pricing.

148. Cinven's expert Dr Bennett and Hg's expert Ms Jackson contended that a correctly calculated Cost Plus, with reasonable assumptions and on a multi-firm basis, produced a much higher range of prices than those found by the CMA. According to Dr Bennett, the correct range was between around £24 to around £81. According to Ms Jackson, the correct range was between £12 and £48.

149. Consistently with the Tribunal's role as the supervising judicial body as set out in *Phenytoin* on an appeal "on the merits", we received and evaluated detailed evidence about the Cost Plus calculation and formed our own independent view of that evidence.

(2) Cost of Product Rights

150. In the Decision, the CMA referred to the manufacturing know-how and the MA required for the supply of Liothyronine Tablets as "Product Rights", as referenced above at paragraph 86. Product Rights formed an important part of Advanz's capital base. The Decision stated that there were two alternative approaches to determining the economic cost of Product Rights, the first being the actual acquisition cost and the second being a value to the business approach which was the lower of replacement cost and recoverable amount. The CMA rejected the actual acquisition cost because it was unlikely to reflect the economic cost of Product Rights during the Infringement Period. Instead it used, as a proxy for the value of Product Rights the "replacement cost" of Product Rights (which was lower than the recoverable amount) calculated by reference to the entry costs actually incurred by the firms that have successfully entered the UK market for Liothyronine Tablets. At the time of the Decision, two firms had entered the market: Morningside, which incurred costs of £420,000; and Teva, which estimated its costs as being in a range from £[…][✂] to £[…][✂]. The CMA's replacement cost valuation ranged from £420,000 to £[…][✂]. The CMA used the upper end of that range (£[…][✂]). In response to the parties' representations

that this valuation failed to take account of the risk of failure by a new entrant (i.e. the risk that a potential entrant requires more than one attempt), the CMA also included a sensitivity on the Product Rights valuation to factor in a possible risk of failure and to reflect uncertainty around the level of investment required to obtain the Product Rights, leading to an upper end valuation of £2.1 million.

151. The sensitivity involved identifying the probability of entry succeeding and the cost of entry. To estimate the probability of success, the CMA collected evidence from 16 firms. It considered that six firms that had applied for an MA and incurred significant costs would be regarded as having made a realistic attempt to enter the market. Of those six, two had withdrawn their application (Lucis and Uni-Pharma). Two had applications pending (AUK and Sigmapharm). The CMA therefore used the cost information of those six firms and assumed that AUK's and Sigmapharm's applications would fail, so that there was a probability of success of 33%.

152. The Appellants did not challenge the CMA's use of the value to the business approach but contended that the CMA had measured the value of Product Rights incorrectly for the following reasons.

(1) Notwithstanding the sensitivity adjustment in the Decision referred to above, the CMA failed to take proper account of the risk of failure. If an undertaking anticipated that a competitive price would cover the CMA's measure of cost plus a small margin, it would choose not to enter the market. This is because there would be insufficient profits to justify the risk of spending the sums measured by the CMA and then earning no revenues at all if the product development fails. It was therefore necessary to take account of uncertainty. The CMA's sensitivity failed to do so adequately and should have treated more firms as having attempted and failed for these purposes;

(2) The CMA had understated the costs of entry; and

(3) The CMA wrongly ignored reasonable estimates of Product Rights put forward in reports prepared by Ernst & Young LLP ("EY") in 2016 and Globalview in 2012.

153. Instead of basing its estimate of Product Rights on the single information point of Teva's costs, the CMA should have addressed the value of the Product Rights based on a methodology which incorporated a range of plausible alternative approaches, taking into account the EY and Globalview reports, the risk of failure and the cost of delay. Both Dr Bennett and Ms Jackson (Cinven's and Hg's expert economists) assumed a replacement cost for the Product Rights of £3m.

(a) The risk of failure

154. Ms Jackson criticised the CMA's expert Mr Harman's approach for excluding from the benchmark calculation the costs of potential entrants who failed to obtain an MA. He did so on the basis that they were not as efficient as the successful applicants Teva or Morningside and that Advanz and other entrants would not have known about the costs of unsuccessful applicants which, once incurred, would be sunk. Ms Jackson contends that this approach did not make economic sense. Product development is inherently uncertain and risky and a failure to obtain an MA did not necessarily denote inefficiency or incompetence. She went on to state as follows:

> If the probability of success were 100%, then (ignoring any delay in rights creation or other considerations) the value of existing rights would also be £1m. By contrast, no rational firm would spend £1m for only a 50% chance of obtaining Product Rights if it could instead spend £1m to obtain the existing rights with certainty. In that simple example, abstracting from any other considerations, the existing rights would be worth at least £2m (and more, to the extent that investors behave in a risk-averse fashion). This is true regardless of whether potential entrants can observe the costs of others' failed entry (if not, they will need to be estimated), and regardless of whether or not those costs of entry are sunk (as they are still real costs that a prospective entrant needs to consider).

155. Ms Jackson argued that it was wrong to exclude from the sensitivity calculation the costs of a larger group of firms who had expressed interest in Liothyronine. She also argued that it was wrong to assume that investors were risk neutral and that some (unquantified) increase to the costs should be made to reflect risk aversion.

156. Dr Bennett considered that the use of the Marketing Authorisation criterion was arbitrary. If the criterion was applied before June 2019 it would have missed both Sigmapharm and AUK's entry attempts despite the fact that they subsequently

applied for an MA. It would miss all those entrants who would apply in the future. The threshold would miss investments made by potential entrants who failed even though their investments needed to be factored in. There were likely to be other relevant firms that should have been included but about which the CMA collated little information.

157. Mr Harman supported the CMA's approach and argued that the CMA's sensitivity calculation was, if anything, likely to be unduly favourable to Advanz in that it assumed that the costs of a second and subsequent attempts would be the same, whereas it was reasonable to assume that the costs would be lower and the probability of success higher.

158. In our view, there is force in the Appellants' contention that, in calculating the cost of Product Rights for the purposes of the Cost Plus benchmark, it was unduly restrictive of the CMA to disregard the costs of potential entrants who were not successful in obtaining an MA on the basis that they were inefficient. In valuing the cost of Product Rights it is relevant to consider the probability of success and in that context the position of applicants who failed to obtain an MA. The costs which they incurred are potentially relevant irrespective of whether their costs are visible, for the reasons given by Ms Jackson.

159. The CMA's sensitivity did, however, take account of the risk of failure by taking into account, not only Teva's and Morningside's position, but also the probability of success and costs of the six firms that had applied for an MA. In our view, that was a reasonable approach. If a firm has merely expressed an interest in applying, it will not reveal useful information on the likelihood and costs of entry. Moreover, since the Decision was issued, Sigmapharm and AUK have received their respective MAs. It follows that the probability of success across the sample of six firms is 66% rather than the 33% rate used in the sensitivity. If the sensitivity is recalculated, it produces a figure of £1.05 million, half the £2.1 million figure in the sensitivity.

160. We agree with Mr Harman's evidence that no adjustment need be made to reflect the issue of risk neutrality on the basis that the cost of capital included in the Cost Plus already assumes that investors are risk averse.

(b) Underestimate of costs

161. Both Ms Jackson and Dr Bennett contended that the CMA omitted relevant costs. Sigmapharm, AUK and Teva had all developed or are developing their 20mcg strength alongside another strength formulation. Ms Jackson and Dr Bennett argued that the CMA should have considered the standalone cost of the 20mcg strength but had not done so. They also contended that there were relevant groups of costs which may not have been included in the estimates provided by potential and actual entrants. For example, two firms which did not have their MAs at the time of the Decision, AUK and Sigmapharm, may well have further costs which will not have been captured.

162. In the case of Sigmapharm, it developed two strengths of Liothyronine together (5 mcg and 20 mcg). The CMA approached the assessment of costs by asking Sigmapharm, "*to confirm whether in Sigmapharm's view any of the costs would be reduced if the project did not include 5 mcg tablets*". Sigmapharm's initial response in October 2020 was that they had not conducted any analysis to determine the costs for a 20 mcg strength separately, but that they estimated that the cost of a 20 mcg development alone would be around €100,000 less. In response to a further enquiry by the CMA, Sigmapharm explained to the CMA that each strength required its own production, testing, analysis and associated consultancy work and hence there were minimal efficiencies in developing multiple strengths and that the total costs should be allocated 50/50 between the two strengths. Ms Jackson's position was that the lower allocation was not consistent with Sigmapharm's earlier response or with the approach taken by AUK and Teva. In our view, it was reasonable to accept the revised information from Sigmapharm.

163. Ms Jackson and Dr Bennett also alleged that the CMA was wrong not to have included indirect costs, such as internal staff costs, incurred by Lucis. Lucis is a small firm with low overheads which largely outsourced the development work on Liothyronine. Lucis' costs were averaged with those of the other five firms. We agree with the position of the CMA, however, that it is most unlikely that Lucis' indirect costs were material.

164. Mr Harman rejected the argument that the future costs of AUK and Sigmapharm whose applications were pending, should have been taken into account on the basis that inclusion of these costs would be inconsistent with the assumption that their applications would fail. We accept that it was not necessary to take their future costs into account and note that it was recorded in the Decision that AUK and Sigmapharm told the CMA that they did not expect to incur further costs on their development projects.

165. Ms Jackson and Dr Bennett also argued that the CMA had failed to take account of the time delay associated with developing rights from scratch thereby underestimating the true cost of entry. This was said to have a significant impact on the costs due to the potentially significant period between starting to develop Liothyronine tablets and being able to start to recover that investment, a gap which would have to be financed. Ms Jackson argued that this time lag would be at least three years. Dr Bennett suggested a five-year delay.

166. Mr Harman's response was that it was reasonable for the CMA not to take account of those costs, given that the object of the exercise was to develop a calculation of the costs of Advanz, and Advanz has held the Product Rights since 1992 and had incurred no financing costs. Mr Harman nevertheless estimated the financing cost, which assumed that the £[…][✂] investment cost associated with Teva's entry was incurred uniformly over a 34-month period, and applied the 10% WACC considered by the CMA in its Cost Plus. This resulted in a financing cost of around £145,000, equivalent to an increase to the Cost Plus of between £0.09 and £0.11 across the period.

167. In our view, contrary to the CMA's position, it was appropriate to take account of financing costs. The fact that Advanz did not incur financing costs is not a valid reason for excluding them. As Dr Bennett points out, this would be consistent with the Decision's approach to the valuation of Product Rights - which is to estimate the typical development cost based on those of actual and potential entrants. The time taken for an entrant to realise a return on its investment is highly relevant to the cost of entering a market. There is no reason to take account of the costs and probability of delay but not the time delay with which success may be achieved.

168. However, we agree with Mr Harman's calculation of the financing costs and his conclusion that these would not have made a material difference to the Cost Plus calculation.

(c) The EY Report

169. The EY report was produced on behalf of Concordia Healthcare Corporation "to provide recommendations of fair value for certain of Advanz's identifiable assets." In order to value Product Rights, EY chose a method of valuation that involved assessing the future income of products using a discounted cashflow approach. Separately, EY valued know-how based on the replacement cost approach. This was based on discussions with management about the time and cost to develop know-how for "hard to make" products, the number of employees required and the number of products.

170. Ms Jackson and Dr Bennett contended that the EY report generated a value of £5.5 million for Product Rights and that this was a plausible estimate which the CMA should have taken into account. The figure of £5.5 million was calculated in the following way. EY's estimate of the total cost of acquiring the know-how for the top 24 products in Advanz's "hard to make" portfolio (which included Liothyronine) was £53.1 million. The average cost per product was £2.2 million. EY had assumed that the relevant costs were incurred over an average two-year period. Dr Bennett contended that an adjustment should be made to account for the longer time (5 years) which it takes for a firm to enter the market for Liothyronine. Multiplying £2.2 million by a factor of 2.5 produced a figure of £5.5 million.

171. The CMA's response to the EY report in the Decision was that it was not a sound basis for calculating the Product Rights for the following reasons:

(1) It was produced for a specific accounting purpose, namely to explain why the purchase of AMCo by Concordia was above book value. It was based on unaudited data and information from Advanz management. They had no direct experience of the effort required to develop the know-how for Liothyronine Tablets which were not developed in-house.

(2) The valuation derived from the EY report was orders of magnitude higher than the actual costs incurred by successful entrants.

(3) The Parties' application of a multiple of 2.5 to the EY valuation of £2.2 million per product assumed that the cost of Product Rights varied strictly in accordance with time whereas the time profile of costs is likely to be more dependent on the specific measures required to satisfy the MRHA and the strength of the company's desire to achieve entry.

172. Mr Harman supported the CMA's approach. He considered that the valuation of Product Rights based on the EY report was inappropriate for the following reasons. First, the EY valuation was driven by accounting standards governing how the difference between the acquisition price of AMCo and its net book value should be disclosed for financial reporting purposes. Second, the report contained a caveat that it should not be used for any other purposes. Third, it was unclear what costs were included in EY's estimate of know-how which was used by Ms Jackson and Dr Bennett as the basis for their valuation. Fourth, the scaling up of the cost based on the amount of time taken for an average applicant was not necessarily comparing like with like. If the average entrant deployed a team of only one person working part time it would be inappropriate to scale up the EY estimate as they had done.

173. The Cinven Appellant's response to these arguments was, in summary, as follows:

(1) The purpose for which the EY report was prepared did not affect the substance of what EY did, which was to form a replacement cost valuation figure.

(2) The disclaimer was standard and did not indicate that the report had been prepared other than carefully.

(3) The scaling up was reasonable given that Liothyronine was a hard to make drug and actual development times for Liothyronine Tablets are on average more than six years.

174. In our view, the CMA was justified in rejecting the valuation of Product Rights based on the EY report, not because of the disclaimer (which was not of great significance) nor because the EY report was prepared for a specific accounting purpose. Of greater significance was the fact that the EY report did not give an estimate of the time taken for any product to enter the market. It applied a broad estimate of the work involved up to the point of regulatory filing (not entry) of 24 months. It was therefore wrong to compare that period with the 5 years taken by an average undertaking to enter the market, as Dr Bennett and Ms Jackson did. Second, the EY report was based on high-level assumptions across a large number of different molecules rather than any observed data specific to Liothyronine Tablets. EY had relied entirely on information from management and did not conduct any review or audit.

(d) The Globalview Report

175. The Globalview report was produced by Globalview Advisers in 2013 for Cinven for the purposes of valuing the intangible assets of Advanz which had been acquired by Cinven in August 2012. The valuation was on a net present value basis by reference to, inter alia, future cash flows i.e. the revenues and profits that were expected to be derived from Liothyronine Tablets. Globalview conducted a valuation for the Product Rights of the top molecules, using an MPEEM (multi-period excess earnings) approach, which is an income approach to fair value measurement, often used when two or more assets work together to generate a cash-flow stream. Therefore, the estimated value of the Product Rights depends directly on the revenues and hence on the prices charged. In order to meet the "circularity" objection, Dr Bennett and Ms Jackson suggested an alternative approach of replacing the actual prices used in the Globalview valuation with three competitive price benchmarks (£25 per pack, £50 per pack and £66 per pack). They advanced a wide range for the value of Product Rights (£3m to £35.7 million assuming no multi-firm entry).

176. The CMA dismissed the valuation of Product Rights in the Globalview report on the ground that it used prices as the relevant measure to value Product Rights leading to a circularity in reasoning as to the net present value. The alternative prices proposed by Cinven and Hg were those found to be abusive in the Decision

so the problem of circularity remained. The Globalview valuations were significantly out of line with the observed costs of the actual firms which entered the market.

177. The Tribunal considers that the CMA was entitled to reject the Globalview valuation, and the alternative basis using other price benchmarks, for the reasons it gave.

(3) Cost allocation

178. Hg and Cinven challenged the CMA's Cost Plus calculation in the Decision on the ground that it understated the allocation of common costs to Liothyronine. Common costs are costs which are common across a number of products and typically include costs such as the costs of employees dealing with administrative matters and overheads.

179. The CMA acknowledged in the Decision that there is no single correct method for cost allocation and that various different methods may be appropriate depending on the circumstances. The CMA concluded that allocation using sales volumes (number of packs sold) as a percentage of Advanz's global pack volumes was appropriate because it was transparent and objective. The CMA accepted that this method might understate the portion of UK specific costs allocated to Liothyronine Tablets and accordingly applied a sensitivity analysis to Advanz's Activity Based Costing ("ABC") methodology which was proposed by Advanz during the administrative phase and adopted by the CMA with some modifications.

180. Ms Jackson and Dr Bennett challenged the use of the volume-based approach as well as the CMA's adjustments to the ABC approach. They contended that both methods remained linked to a volume-based allocation of shared costs which was not consistent with the fact that Liothyronine Tablets are a particularly hard to make drug (as was common ground) and likely to account for a higher share of costs than their share of volumes.

181. Advanz provided information on indirect costs for the period 2014 to 2017. Equivalent information for the prior years was not available. The CMA concluded that it was not possible to determine the indirect costs incurred by Advanz before 2014 on a reliable basis. It therefore assumed that indirect costs pre-2014 were consistent with indirect costs between 2014 and 2017 and applied the average cost over the period 2014 to 2017 to the pre-2014 period.

182. Ms Jackson claimed that costs were understated in the Hg period because Advanz is likely to have benefited from economies of scale in the period 2014 – 2017. As set out at paragraph 55 above, after the sale of the business to Cinven, Cinven acquired Amdipharm and merged the two to form AMCo. She contends that it is highly unlikely that the costs per pack for AMCo were the same as those of the business pre-merger during the Hg period with total group costs increasing from £51m in 2011 to £116m.

183. Moreover, in relation to total volumes, the CMA only had data going back to 2012, and even in 2012 the CMA's data for total volumes across the business are very similar to those recorded in 2013. According to Ms Jackson this would suggest that the CMA's measure of 2012 volumes also includes Amdipharm's volumes in their entirety throughout 2012, despite the transaction only taking place after the end of Hg's ownership period. This means that – even leaving aside the question of economies of scale – the CMA's assumptions on volume-based cost allocations significantly understated the importance of Liothyronine to Goldshield prior to its merger (as Mercury) with Amdipharm.

184. In response to the objection that a value based approach was flawed because it leads to circularity, with inflated prices generating a corresponding increase in allocated costs, Ms Jackson argued that her allocation methods only allocated overhead costs that were actually incurred, so could not be used to justify *any* price level, and that there was no reason to presume that the prices were excessive. Dr Bennett supported the use of a value-based approach because it better reflects the fact that Liothyronine is a difficult drug to produce than does a volume-based approach.

185. Mr Harman stated that the volume-based approach to cost allocation was reasonable on the grounds that it was a widely recognised approach, the sale unit was relatively homogeneous across products, the approach relies on observable metrics and is consistent with the principle of objectivity. Ms Jackson's response was that value-based approaches are also recognised, the products were not homogeneous, there were no observable metrics for volumes in the Hg period and a volume-based approach is not more inherently objective that a value-based approach.

186. Mr Harman's response to these criticisms was, in summary, first, that there was no reason why, from an economic perspective, Liothyronine Tablets should attract a higher proportion of common costs on the basis that they are difficult to make. There is no necessary causal link between common costs and the activity of making the product. To the extent that there are higher costs relating to the manufacture of the product these should be reflected in, for example, direct costs and the valuation of Product Rights. To the extent that Liothyronine Tablets should attract a higher proportion of indirect costs, these were covered in the CMA's Cost Plus with sensitivities which adopted drivers other than volumes for certain cost categories.

187. Second, he contended that Ms. Jackson's claim that costs are understated under the Hg Period because of the economies of scale that would have been achieved in 2014-2017 was unsubstantiated. Hg had provided no evidence to demonstrate that unit common costs were higher during the Hg Period or the extent to which they were materially higher.

188. Third, he considered that the CMA's calculation of the volume-based allocation for the period before, though sub-optimal, was reasonable given the data available and the alternatives available for the allocation. Moreover, he had not seen any evidence that if this assumption were changed, or if further data were available, there would be a material difference in the allocation of common costs for the period between 2009 and 2011. Given that the allocation of indirect costs to Liothyronine Tablets during the Hg Period ranged from £0.53 to £0.57 per pack, it is likely that any adjustment for economies of scale would have an immaterial effect on the CMA's Cost Plus.

189. Mr Harman also analysed in detail the ABC indirect cost allocations adopted by the CMA as a sensitivity. He agreed with the CMA that the approach adopted by Advanz in their ABC analysis was reasonable and that there were significant concerns relating to some of the data used in the model. He considered that the adjustments made by the CMA to resolve these issues were reasonable.

190. In our judgment, the CMA was right to reject the value-based approach to the assessment of common costs on the ground of circularity as the Tribunal has done in previous cases. In *Socrates Training Limited v The Law Society of England and Wales* [2017] CAT 10, the Tribunal addressed the risk of circularity. It considered that the method of cost allocation (whereby an increase in revenue automatically generates a corresponding increase in attributable cost) was an unreliable basis for any fair assessment. In *Genzyme*, the Tribunal held that the allocation of costs according to turnover would allocate an unduly high proportion of overheads to Cerezyme, because of the high cost of the drug. In *Phenytoin* the Tribunal noted that there was no single over-riding preferred method of cost allocation and that different methods may be used for different purposes. The Tribunal concluded that, since Flynn did not itself allocate costs to individual products and that there was no clearly preferable method of allocation, the CMA's allocation of common costs based on volume was reasonable.

191. We were not persuaded that costs were understated in the Hg period. There was no evidence to support the existence of economies of scale other than the observation that larger firms typically enjoy economies of scale. Nor was it unreasonable of the CMA to have calculated the allocation of costs during the Hg period by reference to 2012 volumes, which included the Amdipharm volumes, given the absence of alternative data, albeit that this was, as Mr Harman recognised, sub-optimal. Ms Jackson accepted in cross-examination that her method of applying a value based allocation method to the total group costs in the period 2014 – 2017 would result in an over-allocation for the Hg Period.

(4) Cost of capital

192. In the Decision, the CMA explained that, when establishing the costs actually incurred in supplying a product, it is normally necessary to allocate a reasonable rate of return to cover the cost of capital i.e. the "plus" element of Cost Plus. The reasonable rate of return reflects the opportunity cost to investors of providing capital to Advanz to purchase assets and fund working capital requirements.

193. In order to determine a reasonable rate of return in this case, the CMA followed the return on capital employed ("ROCE") model. It stated that, where capital employed can be reliably measured, ROCE is generally accepted as the most objective way of calculating a reasonable rate of return and is therefore preferable to other methods. In this case, the relevant data was available to measure both the capital employed and the cost of that capital (the WACC), which are the two inputs. The reasonable rate of return is calculated by multiplying capital employed by cost of capital. The capital employed was the amount of capital that Advanz had to deploy to operate in the UK Liothyronine Tablets market during the Infringement Period including both tangible and intangible assets and working capital (deducting any amortisation or depreciation already incurred). The WACC is the average percentage return that debt and equity investors expect in return for providing funds to a company they have invested in.

194. In the Decision, the CMA explained that the internal documents produced by Advanz and its advisers during the Infringement Period were not reliable as a guide to the WACC on the basis that they were created for a specific purpose. The CMA estimated a "low" and a "high" case WACC of 7.4% and 12.7% respectively. The CMA concluded that a reasonable WACC estimate was likely to fall between the "low" and "high" estimates and that a WACC of 10%, the midpoint of the CMA range, was reasonable. The CMA performed a sensitivity analysis using a WACC of 15% which was above the majority of the WACC estimates set out in Advanz's internal documents. According to the Decision, applying this rate of WACC to Advanz's tangible and intangible assets increased Cost Plus by on average £0.56.

195. The WACC was based on three inputs:

(1) The cost of equity using the Capital Asset Pricing Model ("CAPM"). The model involves identifying a 'beta' value which is a measure of investors' exposure to systemic risk;

(2) The cost of debt, assessed by observing the yields of corporate bonds with credit ratings comparable to those of a typical pharmaceutical business active in the generics sector in the UK; and

(3) Gearing, using the average gearing ratio of a set of comparator companies operating in the UK generics sector during the Infringement Period.

196. The CMA assessed these inputs by reference to six listed companies operating in the generics pharmaceutical sector. The higher estimate of 12.7% reflected evidence provided by Hg and the CMA's analysis that the cost of debt was higher in the earlier part of the Infringement Period.

197. Dr Bennett, Cinven's expert, argued for the following adjustments to be included:

(1) A small company premium of 3.89%;

(2) An illiquidity premium of 1.25%;

(3) A cost of debt for Advanz of 6.5%.

These adjustments are shown in the table below:

Table 4: Impact of adjustments to the components of the cost of capital

	CMA's estimates		Adjustment to CMA's estimates	
	CMA Base	CMA High	Base	High
Nominal risk-free rate (%)	3.0%	4.4%	3.0%	4.4%
Equity risk premium (%)	5.2%	6.5%	5.2%	6.5%
Asset beta	0.70	0.90	0.70	0.90
Small company premium	n.a.	n.a.	3.89%	3.89%
Illiquidity premium (DLOM multiplier)	n.a.	n.a.	1.25	1.25

Tax rate (%)	24.0%	28.0%	24.0%	28.0%
Pre-tax, nominal cost of equity (%)	**8.74%**	**14.24 %**	**17.32 %**	**24.55%**
Pre-tax, nominal cost of debt (%)	3.8%	8.6%	6.5%	8.6%
Gearing (%)	28.0%	28.0%	28.0%	28.0%
Pre-tax, nominal WACC (%)	**7.4%**	**12.7%**	**14.3%**	**20.08%**

(a) Inclusion of a small company premium and an illiquid company premium

198. The small company premium is an adjustment to the cost of equity to allow for the hypothesis that investors require additional beta-adjusted returns for investing in smaller companies instead of otherwise equivalent larger companies. The illiquidity premium is an adjustment to the cost of equity to allow for the proposition that investors require additional returns for investing in assets that are illiquid instead of assets that are liquid but otherwise equivalent. All else being equal, applying a small company premium or an illiquidity premium will increase the cost of equity and, by extension, the cost of capital.

199. In support of the inclusion of a small company and illiquidity premium Dr Bennett relied on (i) the acceptance and application of such premia by academics and investors; (ii) the adoption of a small company premium by Globalview Advisors in 2013 and by EY in 2016; (iii) the fact that Advanz was acquired by private equity firms twice was consistent with it being viewed as an illiquid investment.

200. Mr Harman's evidence was that it was not appropriate to add a small company premium. In his experience, practitioners do not use small company premia. He pointed to academic and survey evidence that the small company premium was an outdated concept. He noted that the Globalview and EY valuation analyses were produced for accounting and financial reporting purposes rather than by an investor for investment purposes and that, in his experience, valuations for financial reporting purposes sometimes apply a conservative approach, using a higher WACC than would in principle be appropriate, in order to give comfort to auditors. He considered that the analysis performed by Goldman Sachs was

more relevant as it reported on the value of the business in a transaction context, which did not include either a small company or an illiquidity premium in the assessment of the WACC and calculated a WACC which was lower than the CMA's assessment. He also referred to internal documents suggesting that Advanz did not apply a small company premium when determining the enterprise value of the business and that Advanz considered that any specific risks with respect to Liothyronine Tablets were low so there was no requirement to include a specific risk premium in this case. Mr Harman also suggested that the fact that Advanz had been sold four times over a twelve year period suggested that Advanz might not be an illiquid investment, although Dr Bennett countered this suggestion by citing empirical research suggesting that private equity investments are typically "lumpy and illiquid".

201. In our view, the CMA was correct not to adjust the cost of capital by the addition of an illiquidity premium. Neither Advanz nor Liothyronine Tablets were an illiquid asset. No illiquidity premium was applied by any of the contemporaneous valuations of Advanz. Furthermore, as Mr Harman explained, the use of specific risk premia (illiquidity or small company) is inconsistent with the theory underpinning the CAPM, which is that investors have a well-diversified portfolio and do not need any return for exposure to specific risks.

202. In our view, the CMA was similarly justified in not including a small company premium. The academic research referred to by Mr Harman indicated that small company premia were not supported by historical data and no longer generally applied in the valuation of small companies for investment purposes. The EY and Globalview reports, which did include a small company premium, were prepared for financial reporting purposes. They were not provided in the context of a transaction, unlike the Goldman Sachs report, which did not include the premium. Again, a small company premium is not appropriate for the purpose of calculating the rate of return on capital employed in supplying Liothyronine Tablets.

(b) Application of the sensitivity to working capital

203. As noted above, the CMA included in its analysis a sensitivity of a WACC at 15% but did not apply this to the cost of working capital. The CMA reasoned that (i) the higher WACC in the sensitivity need not be applied to working capital, as the risk profile of working capital is lower than other assets; (ii) the calculation of working capital was already significantly inflated by the higher prices charged by Advanz and that applying the higher 15% WACC in the sensitivity would therefore not be reasonable.

204. Ms Jackson argued that investors will look at the risks of a firm as a whole, not the risks associated with particular assets. In response to the two arguments of the CMA, Dr Bennett contended, as to the first, that whether or not there was a different degree of risk was a factual matter and that the Decision did not contain any factual evidence as to whether there were actually any differing degrees of risk as between different types of capital in the business. As to the second, he contended that the reasoning was circular and that the Decision should, at the very least, have applied the WACC to a proportion of working capital in step with the working capital levels that would be required if the price were not excessive.

205. We consider that these arguments are not well founded. Lenders may invest in specific assets. There is good reason to assume that the risk profile of working capital would be lower than other assets. The working capital was composed largely of receivables, the funding for which came from the NHS, which was paying inflated prices. This approach of applying a lower risk to working capital was supported by the Globalview and EY analyses which indicated that working capital was subject to lower risks and expected returns than Advanz's other assets.

(c) Cost of debt

206. In order to assess the cost of debt, the Decision took into account the likely debt financing costs of six comparator companies and applied a range between 3.4%

as a base rate based on indices of bonds with a BBB rating and 8.6% based on Hg's actual cost of debt. The mid-point of these figures is 6.2%.

207. Dr Bennett argued that the CMA's selection of the six listed generics pharmaceuticals firms was inappropriate for estimating the cost of capital, and led to that cost being understated, because those firms had a higher credit rating (BBB or BB) than Advanz did (B) in 2012.

208. Mr Harman's evidence was that the CMA's use of bonds with a credit rating of BBB rather than B was appropriate on the basis that (i) most of the comparator companies have an investment-grade rating, lending support to the view that an efficiently financed company would be unlikely to take on sub-investment grade debt represented by a B rating and (ii) as the CMA considered the actual efficiency of Teva in its calculation of Product Rights, it was consistent to also have regard to Teva's credit rating, which was BBB. The argument did not affect the CMA's high case WACC calculation. The Globalview report used a figure of 6.5% for the cost of debt which is close to the midpoint of the CMA's range.

209. We are satisfied that the CMA correctly calculated the cost of debt for the reasons given in the Decision and supported by Mr Harman. Even if the calculation had been done by reference to a credit rating of B, this would not have affected the CMA's high case estimate of the cost of debt.

(d) WACC in relation to the Hg Period

210. Ms Jackson contended that the CMA erred in calculating a single WACC for the full Infringement Period when there was evidence that the cost of capital was higher in the earlier part of that period. She estimated the relevant cost of capital for the Hg Period as being in the 16% to 18% range within a broader range of plausible values between 13% and 20%. She therefore considered that the CMA's upper sensitivity of 15% was within a reasonable range of estimates for the Hg Period, albeit towards the lower end. However, she disagreed with the CMA's base rate of 10% on the grounds that the market-wide cost of capital was higher in the Hg Period, coming relatively shortly after the global financial crisis, than in the later years of the Infringement Period.

211. Mr Harman accepted that the costs of capital can change over time but considered that the CMA's use of a single rate was reasonable in the circumstances for two main reasons. First, adjusting the cost of capital for conditions during the Hg Period only increased the cost of capital to 11.5% which was significantly below the CMA's sensitivity of 15%. Second, the Cost Plus calculation was insensitive to the cost of capital due to Advanz's low level of capital employed. For example, changing the cost of capital in the CMA's Cost Plus to 15% increases the Cost Plus by only £0.63 on average over the Hg Period, which would not have changed the CMA's findings.

212. In our view, the CMA's use of a single WACC rate was justified. The range of values used by the CMA to calculate the cost of equity did take account of the cost of debt in the early part of the Infringement Period. The Tribunal accepts that, in any event, applying higher rates would not make a material difference to the overall WACC calculation.

(5) Patient benefit

213. In the Decision the CMA considered patient benefit in the context of the economic value of Liothyronine Tablets. It concluded that there were no demand-side factors which would materially add to their economic value. In reaching this conclusion the CMA reasoned, in summary, as follows:

(1) The price that an unbranded generic medicine can command in the third phase of the drug lifecycle is unrelated to its therapeutic value and is instead primarily driven by the degree of competition faced by suppliers.

(2) In any event, the therapeutic value of Liothyronine Tablets is likely to be no higher than that of levothyroxine tablets. The consequence of this is that even if it were the case that generic drugs with greater therapeutic value could have a higher economic value, there would be no reason to assign an additional 'premium' above Cost Plus to Liothyronine Tablets.

(3) The DHSC was not readily willing to pay a premium for Advanz's Liothyronine Tablets above their Cost Plus: the prices achieved by

Advanz reflected its ability to exercise market power and the lack of any available alternatives to its product.

214. Advanz Pharma argued that, in its Cost Plus calculation, the CMA failed to take sufficient account of the patient value of Liothyronine Tablets on the basis that the medicine was 'old'. It referred to the Court of Appeal judgment in *Phenytoin* which ruled that patient dependency did not necessarily preclude the existence of economic value based on patient value. It contended that there should be some unspecified uplift to the 'plus' in Cost Plus to reflect this value.

215. In response to Advanz Pharma's arguments, the CMA contended that Advanz Pharma had mischaracterised its case on patient value in the Decision and failed to engage with its reasoning as summarised above.

216. In our view, it was not necessary to increase the Cost Plus to reflect patient benefit. The rationale for increasing the Cost Plus price would be to ensure that the price reflected the economic value of Liothyronine Tablets in accordance with the *United Brands* test, that is to say, as explained by Green LJ in *Phenytoin* at [155], the price which consumers would be prepared to pay for the drug in an effectively competitive market. The price of levothyroxine, which is also indicated for hypothyroidism, was significantly below the Cost Plus. The economic value of a product may be higher than its Cost Plus if there are "additional benefits not reflected in the costs of supply" or any "particular enhanced value from the customer's perspective" of that product; *Albion Water II* [2008] CAT 31, paragraph [222]. In the Decision, the CMA considered whether there was any reason to attribute additional economic value above Cost Plus based on the therapeutic value it provides to the cohort of patients for whom levothyroxine is ineffective and concluded that there was not. This was because, first, levothyroxine remains the preferred treatment for the significant majority of patients. Second, the cohort prescribed Liothyronine Tablets is effectively captive and it is their dependency that explains the 'premium' charged rather than any superiority of Liothyronine Tablets over levothyroxine. We agree with this reasoning. The Tribunal's finding in *Phenytoin* that some allowance should be made for patient value in that case was based on different facts. Furthermore, we agree that if any adjustment were to be made to reflect patient value, it would not

affect the CMA's conclusion as to the substantial disparity between Advanz's prices for Liothyronine Tablets during the Infringement Period and their economic value.

(6) Portfolio pricing

217. Advanz Pharma also contended that the CMA's Cost Plus was wrong because it failed to take account of the fact that Advanz, in common with other pharmaceutical companies, charged on a portfolio basis. Mr Williams, an expert witness called by Advanz, argued that restricting the returns on individual products could remove the ability of pharmaceutical companies to cross subsidise other products and lead to price increases on previously subsidised products. He carried out an analysis of Advanz's assessed profit levels on the supply of the entirety of its NHS medicines, using the normal DHSC PPRS profit assessment methodology, and concluded that its profits were well below the maximum allowed profitability under the PPRS. Mr Beighton's evidence in his witness statement was similarly that portfolio pricing was the norm in the pharmaceutical industry and that this was recognised by the PPRS and by the DHSC in its approach to establishing a fair price for generic drugs. His evidence was that Advanz would pursue a portfolio approach to pricing. However, the only document that he relied on in support of this evidence as to Advanz's approach was a slide prepared by Advanz's lawyers for the CMA in 2018 and did not relate to the Infringement Period.

218. The CMA considered this argument in the Decision and rejected it on the basis, first, that it was contrary to a legal principle, based on the Tribunal's judgment in *Napp,* that the question of whether the pricing of a product is abusive is not determined by reference to the pricing of products in other markets:

> "Napp's whole argument based on 'portfolio pricing', impermissibly directs attention away from the specific product market which we are required to consider when deciding whether there is an abuse of a dominant position under section 18 of the Act. In our view, it is not appropriate, when deciding whether an undertaking has abused a dominant position by charging excessive prices in a particular market, to take into account the reasonableness or otherwise of its profits in other, unspecified, markets comprised in some wider but undefined 'portfolio' unrelated to the market in which dominance exists."

219. The second reason for rejecting the portfolio pricing argument was that the evidence from Mr Williams did not, in any event, reflect the reality in that there was no evidence that Advanz's management actually assessed or allocated the costs applicable to its portfolio of medicines in the way that Mr Williams described.

220. It is not necessary for the Tribunal to determine whether the judgment in *Napp* is to be read as establishing a general principle that portfolio pricing can never be relevant to the question of whether a price of a particular product is abusive. We agree with the CMA that the portfolio pricing issue is a red herring in this case given the absence of evidence that Advanz was actually setting the price of Liothyronine on a portfolio basis, rather than increasing the price as a means of profit maximisation without reference to other products.

(7) Multi-firm or single-firm Cost Plus

221. In the Decision, the CMA considered whether to adjust its Cost Plus analysis to take account of the fact that, in a competitive market where there are multiple suppliers, each firm would need to recover its costs over a smaller share of the market so that unit costs would be higher than in a market with a single supplier. The Appellants argued that an adjustment to reflect multiple suppliers should have been included in the CMA's Cost Plus calculation and calculated what they consider to be appropriate costs under such conditions. It is to be noted that, throughout the Infringement Period, Advanz was in a monopoly position in relation to the supply of Liothyronine Tablets. A multi-firm scenario was therefore entirely hypothetical. The Tribunal was not referred to any case in which the multi-firm adjustment was made to a Cost Plus calculation.

222. A multi-firm adjustment can make a significant difference to the end result. This is illustrated by the following table in Dr Bennett's report (which uses the CMA's cost assumptions):

Table 5: CRA analysis of CMA's Cost Plus predictions for Post-Entry prices

Scenario	2009	2010	2011	2012	2013	2014	2015	2016	2017	Simple average

Single-firm Cost Plus with sensitivities (Decision)	4.94	4.88	6.00	5.02	6.34	7.49	7.51	12.08	11.88	7.35
Three firm Cost Plus with sensitivities	12.65	12.41	12.75	11.62	12.65	15.10	12.95	17.21	18.13	13.94
Five firm Cost Plus with sensitivities	20.35	19.94	19.50	18.22	18.96	22.71	18.40	22.34	24.14	20.51

223. Extending these examples further, with ten firms the Cost Plus would be £37.50 and with 70 firms £247.88

224. By the end of the hearing, the Appellants accepted that a single-firm Cost Plus calculation was appropriate for the purposes of the Excessive Limb of the *United Brands* test but maintained that a multi-firm adjustment was necessary for the purposes of the Unfairness Limb.

225. In the Decision, the CMA contended that a multi-firm adjustment was inappropriate both as a matter of economic logic and from the perspective of effective competition policy enforcement, for the following reasons.

(1) The multi-firm adjustment is flawed because it is premised on the incorrect assumption that the CMA's intervention threshold must leave room for entry by other competitors. In a market which is characterised by high entry costs relative to market size, as is the case for Liothyronine Tablets, applying a multi-firm adjustment would defeat the purpose of the law, which is to require companies with significant market power to exercise restraint.

(2) Permitting an incumbent to charge a multi-firm price in such a scenario would be perverse in that it would enable an incumbent to recoup as pure economic profit the modelled costs of operating in a hypothetical multi-player market. This would result in significant harm to consumer welfare. The adjustment is also divorced from economic reality since the significantly higher prices produced by the adjustment bear no relationship to the incumbents' costs or the products' economic value.

226. Hg's expert economist Ms Jackson considered that it was highly problematic from an economic perspective to choose a benchmark for the assessment of excessive prices that is below the prices that could emerge from competition. Cinven's expert economist Dr Bennett similarly argued against the use of single-firm cost plus on the basis that it entailed the rejection of the multi-firm Cost Plus which was a benchmark that allowed a competitive firm to recover its costs whereas the single-firm Cost Plus created an obligation on a dominant firm to price at a level that forecloses equally efficient entrants.

227. Professor Valletti supported the CMA's position arguing that the use of a multi-firm Cost Plus is inappropriate for the following reasons.

(1) Cost Plus is an appropriate policy tool to determine what price a firm should be allowed to charge.

(2) In a market with high fixed costs relative to the size of the market and very little scope for innovation, the presence of multiple firms is inefficient and would not maximise consumer welfare. Competition between multiple firms would be economically inefficient because (i) the total output in the market would not be produced at the lowest possible cost and (ii) in order to recover duplicated fixed costs, prices would need to be set further away from variable costs in order to generate margins that cover the additional fixed costs.

(3) The market for Liothyronine Tablets has such characteristics. There are significant fixed costs, especially fixed entry costs, and variable costs are low. The CMA's estimates indicate that the main component of fixed costs is due to the costs of entry. The evidence received by the CMA shows that the fixed costs of entry into the market range between £420,000 and £[…][✂]. This compares with a yearly sales value for the entire market of approximately £600,000 in 2006, before Advanz started to increase prices. On the other hand, variable costs are low. The CMA estimated that Advanz's cost of purchase was at most £3.23 per pack in the period up to 2017.

(4) The multi-firm adjustment makes no sense as it implies that more firms should lead to higher prices whereas it is usually assumed that more firms lead to a more competitive market with lower, not higher, prices.

(5) The application of a multi-firm adjustment would also imply that the higher the entry costs, and so the higher the barriers to entry, the higher the incumbent is allowed to price through the multi-firm adjustment, above its own costs. Allowing a firm protected by barriers to entry to exercise market power in this fashion goes contrary to what competition policy is supposed to achieve.

(6) The application of a multi-firm adjustment would lead to an over-recovery of the single supplier's costs. It would be unreasonable to allow a monopolist provider to over-recover its costs because they would be higher if multiple providers were present.

(7) Even if a multi-firm adjustment were to be applied (quod non), the prices charged during the Infringement Period were still way above the multi-firm Cost Plus. For example, in the case of three firms, the multi-firm adjustment would generate a price of £12.64 per pack in 2009, which would increase to £17.89 per pack in 2017. These levels are still much lower than the actual prices charged during the period: in 2009, the average price was £20.80, 65% higher than the multi-firm price; in 2017, it reached £247.77, 1,285% higher than the multi-firm price.

228. In our view, the CMA was right not to make a multi-firm adjustment to its Cost Plus model when considering whether the prices charged by Advanz were unfair. This is for the following reasons:

(1) The use of the multi-firm Cost Plus is not an appropriate tool for assessing the fairness of a dominant undertaking's prices. It would enable an incumbent to retain as pure profit the costs of operating in a hypothetical multi-player market even though the higher prices produced by the adjustment are unrelated to the incumbent's actual costs incurred in a single-party market.

(2) The application of a multi-firm adjustment would enable an incumbent in a market with high barriers to entry to profit from those barriers and charge prices unrelated to its own costs or to the product's economic value.

(3) It was common ground between the experts that the multi-firm Cost Plus is not informative of the price that would be obtained under conditions of workable competition. The multi-firm cost plus does not model competitive prices or predict the price that would be obtained under competitive conditions. The calculation depends on the number of competing firms. The competitive price could be higher or lower than the multi-firm Cost Plus. Furthermore, the costs taken into account in the multi-firm Cost Plus include the fixed costs of entry but those costs have no long-term effect on a firm's pricing. Once firms have recovered their fixed costs, competition would drive prices closer to the direct costs of production.

(4) The *United Brands* test does not compel the use of any particular benchmark. There is no requirement that fairness must be determined by reference to prices in a multi-firm scenario.

229. Furthermore, we accept the CMA's submission, that, even if a multi-firm adjustment were to be made, Advanz's actual prices materially exceeded it. If three hypothetical firms had charged Advanz's actual prices (£20.80 on average in 2009 rising to £247.77 on average in 2017) they would each have made economic profits of £8.16 per pack in 2009, rising to £229.88 per pack in 2017; these equate to a differential above Cost Plus adjusted for multi-firm of around 65% in 2009, rising to around 1,285% in 2017. This adjustment would significantly understate the actual differential which Advanz earned above its costs (900% in 2009, rising to 2,434% in 2017), since it did not incur the modelled costs of operating in a hypothetical multi-player market.

(8) Conclusion

230. For the reasons set out above, the Tribunal concludes that, notwithstanding the Appellants' many challenges, there were no material errors in the CMA's Cost

Plus calculation. The Tribunal therefore dismisses the grounds of appeal based on the contention that the CMA's Cost Plus calculation was wrong. We uphold the CMA's conclusion that Advanz's prices during the Infringement Period were excessive.

H. ISSUE (2): DID THE CMA ERR IN ITS ASSESSMENT OF COMPARATORS?

231. As set out at paragraph 117 above, the Court of Appeal judgment in *Phenytoin* requires a competition authority to conduct a fair evaluation of competing evidence adduced by an undertaking. It may reject comparators so advanced but should give reasons for doing so. In the Decision, the CMA rejected a number of comparators put forward by the Appellants, including Post Entry Prices, Entry Incentivising Prices and Forecast prices. In their appeals, the Appellant argue that the CMA was wrong to reject these comparators.

(1) Post Entry Prices

232. In the Decision, the CMA accepted that Post Entry Prices could in principle provide a valid comparator for the purpose of assessing the fairness of Advanz's prices in the Infringement Period. The entry of Morningside and Teva meant that there were now competitors in the market for Liothyronine Tablets. This had led to significant declines in average selling prices ("ASPs") since their peak level of £247.87 in July 2017, immediately prior to entry. The Decision went on to conclude, however, that the prevailing Post Entry Price in February 2021 of £[…][✂] per pack did not provide a meaningful indication of prices for Liothyronine Tablets in an effectively competitive market. This was because the Post Entry Price was still contaminated by Advanz's abusive exercise of market power. The process of competition which had taken place since 2017 had not been sufficient to eliminate the impact of that abuse in that the prevailing Post Entry Price had not reached the effectively competitive price level that would be expected in a "mature generics market", that is to say a market in which the effect of the market power held by the original incumbent before the entry of competing manufacturers has been sufficiently eliminated through the process of

competition. Prices had continued to fall since September 2017 and there was no evidence that they had stabilised.

233. In support of its conclusions, the CMA relied on a study prepared by Oxera for the BGMA in 2019 which described generic medicines as homogeneous such that competition between suppliers will inevitably be price focused. Low switching costs enable pharmacies and wholesalers rapidly to switch suppliers in order to obtain the best possible deal, limiting the potential for any supplier to sustain prices which are significantly above those of its rivals. The Oxera study found that, four years after generic entry, prices charged by generic suppliers of a sample of products within Scheme M were on average 70% to 90% lower than the branded price at the time of entry. Although prices can continue to oscillate, they tend to remain at a low level, the overall average price remaining at around 20% of the price before loss of exclusivity and, in some cases, falling below a manufacturer's cost of sales, at least in the short-term. This was consistent with the evidence that, even for relatively low volume products such as Liothyronine Tablets, generic drugs rarely cost the NHS more than £10 per pack, and the vast majority cost less than £3 per pack.

234. Given the features of the sector as described above, the Decision found that, in a mature generics market, prices would:

(1) be expected to be substantially below the price charged before the entry of competing generic manufacturers;

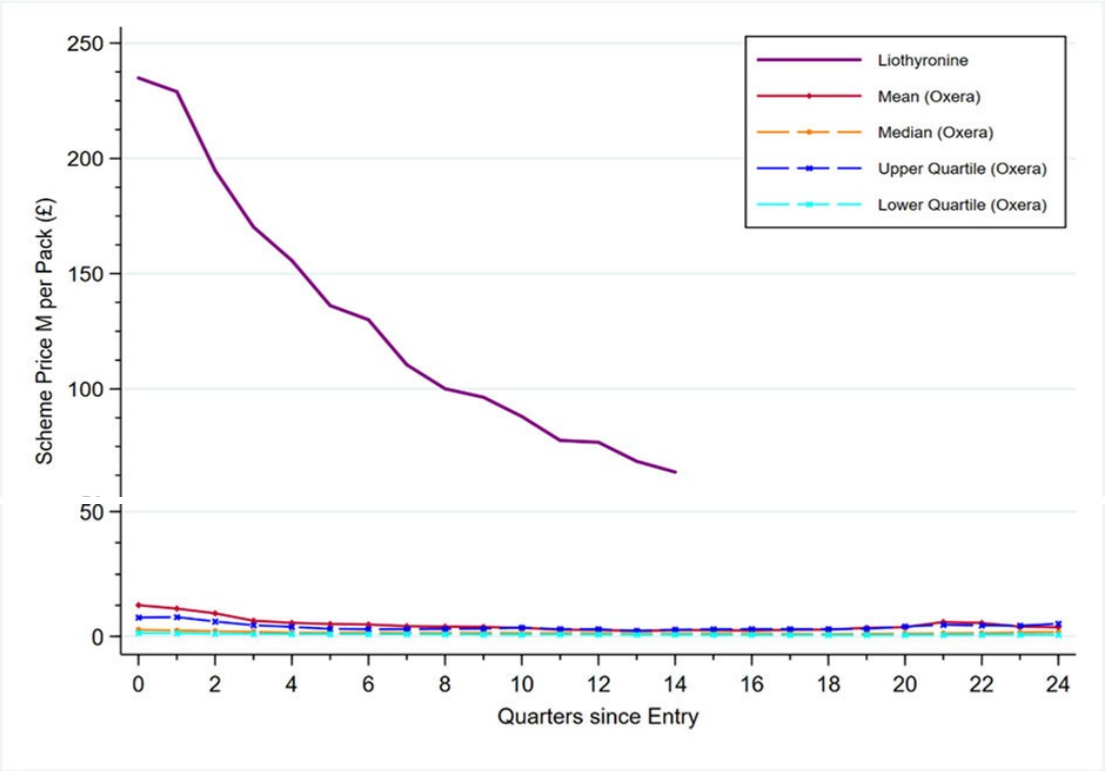
(2) fluctuate around a new equilibrium level; and

(3) be close to (though they will typically exceed) the underlying costs of production.

235. In support of its conclusion that the ASP of Liothyronine Tablets of £[…][✂] per pack had not yet reached the level which would be expected in a mature generics market, the CMA compared the prices of Liothyronine Tablets with a sample of 163 molecules in Category M collected by Oxera. Figure 5.10 reproduced below (as Figure 3) compared the price of Liothyronine Tablets since

September 2017 with the mean, median, upper quartile and lower quartile prices, at each quarter since generic entry of the drugs in Oxera's sample. The mean price across the sample fluctuated between £[…][✂] and £[…][✂] per pack, which was between approximately […][✂]% and […][✂]% of the average price of Liothyronine Tablets in February 2021.

Figure 3: The prices of Liothyronine Tablets and of Scheme M drugs



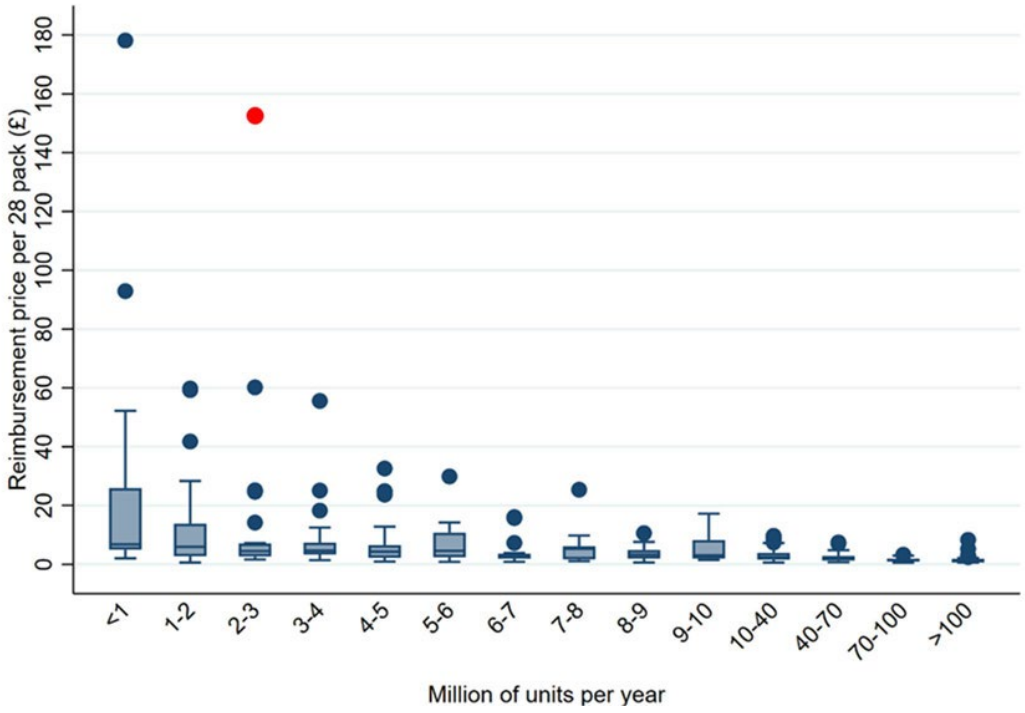
236. The Decision also compared the current price of Liothyronine Tablets with drugs with a similar market size to Liothyronine Tablets. Figure 5.11 reproduced below (as Figure 4) presented the price trajectories of all generic drugs in the Oxera sample with between 20,000 and 30,000 tablet packs dispensed every quarter.

Figure 4: […][✂]

237. The analysis was expanded to the entire set of Category M drugs sold in tablet or capsule by considering NHS Reimbursement Prices rather than ASPs. Figure 5.12 reproduced below (as Figure 5) showed the distribution of average NHS Reimbursement Prices during 2020 of all Category M drugs in tablet or capsule

form (532 in total), disaggregated based on the volume dispensed.[1] NHS Reimbursement Prices were typically well below £10, even for drugs for which volume dispensed was comparable to that of Liothyronine Tablets. In the third quarter of 2021, the NHS Reimbursement Price for Liothyronine Tablets (£101.29 per pack, shown in red in the Figure) was the second highest among all 660 Category M drugs (the highest one being Primidone).

Figure 5: Distribution of NHS Reimbursement Prices over volume intervals under Category M (2020)



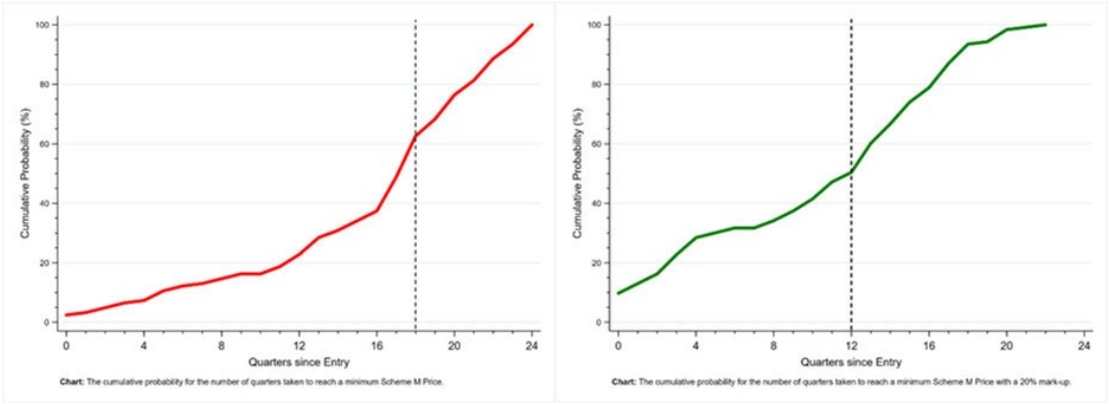
238. The Decision stated that ongoing entry attempts would be expected to have a further downward impact on prices.

239. The Decision found that the price for Liothyronine Tablets was "sticky" on the basis that prices do not adjust immediately to competition and that, for a significant period after entry, the price would continue to be affected by the price

[1] The rectangle of each plot shows the range between the 25th and the 75th percentiles of the distribution; the horizontal line that cuts through the rectangle shows the median price; the 'whiskers' that bound the vertical line show the 'adjacent values' (the extreme points of the distribution bar outliers), and the dots show outliers. The red dot represents Liothyronine Tablets.

charged by Advanz during the Infringement Period. Figure 5.14 reproduced below (as Figure 6) showed the time taken between generic entry and the lowest price observed, based on data collected by Oxera for a sample of generic drugs regulated under Scheme M. 23% of products reach their minimum observed price within three years of generic entry, and 37% of products reach their observed minimum price within four years. The median time taken to reach the minimum price in the sample was 4.5 years (shown by the vertical line in the table on the left) while the longest time observed in the sample was six years. Even when adding a 20% mark-up to the minimum price (as shown in the table on the right), stickiness was still observed, with only 50% of products reaching that threshold within three years.

Figure 6: Distribution of duration between generic entry and lowest price

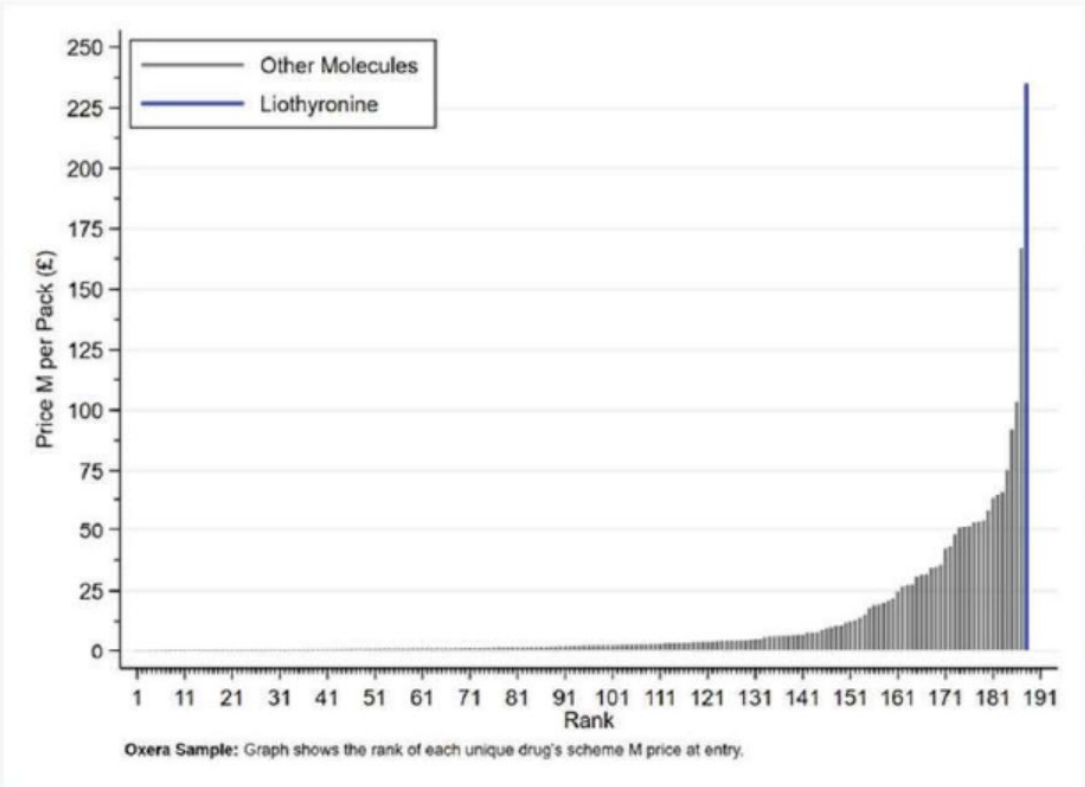


240. The Decision found that the stickiness of generic prices was consistent with the fact that when prices are renegotiated, market participants will often take the Drug Tariff as a reference point. The Drug Tariff is itself constructed using a trailing average of market prices so price stickiness is to some extent built into the way prices are renegotiated.

241. According to the Decision, the particular circumstances in which new entry occurred for Liothyronine Tablets (notably the price increase of more than 6,000% before entry) indicated that the time before which the minimum price was likely to be reached would be expected to be significantly longer than the median or average time observed in the cases of generic drugs. Figure 5.15 reproduced below (as Figure 7) compared the price of Liothyronine Tablets at the

date of entry with the price at the date of entry for any of the generic drugs in Oxera's sample. The price of Liothyronine Tablets at the point of entry was the highest in the sample by a margin of £68 and was 22 times higher than the mean price (and 90 times higher than the median price) of generic drugs at the date of entry.

Figure 7: Price of Liothyronine Tablets compared with other generic drugs at time of entry



242. The Decision also concluded that the much lower pricing of levothyroxine and the pricing of Liothyronine in other European countries supported the conclusion that Post Entry Prices did not constitute a meaningful comparator for the purpose of assessing whether Advanz's pricing of Liothyronine Tablets during the Infringement Period was unfair.

(a) The Appellants' arguments

243. The Appellants contended that the CMA was wrong to dismiss Post Entry Prices as a valid comparator. There was no real dispute that prices immediately after entry or, according to Ms Jackson, Hg's expert, for the first few years after entry, did not represent meaningful benchmarks. In the Joint Expert Statement, Dr

Chowdhury, Cinven's expert, suggested that prices might be viewed as the product of competition after a few days or weeks but that was certainly not the consensus view of the experts. Ms Jackson and Dr Bennett maintained that the February 2021 price of £[…][✂] was a competitive one.

244. The main arguments advanced by the Appellants in support of Post Entry Prices (and in particular the February 2021 price of £[…][✂]) as a valid comparator were as follows.

245. First, the CMA had not found that, post entry, there was a dominant position or evidence of collusion (tacit or otherwise). In the absence of dominance or collusion, with three to five competitors and with the price and market share drops observed to date, it would require wholly exceptional circumstances to suggest that a market was not workably competitive. Cinven referred to decisional practice on generics markets indicating that a three-player market is competitive. For example, in the context of generic pharmaceutical mergers, the European Commission had approved deals in three-player markets, including Case No COMP/M.5865 *Teva/Ratiopharm* which the CMA had cited itself.

246. Second, the Appellants submitted that the post entry market developments bore all the hallmarks of workable competition as illustrated in the Figures below. There were significant market share fluctuations. Within one year of entry, Advanz's market share had dropped 85% and Morningside's had increased to 70%. Morningside's market share oscillated from a high of 70% to a low of c.5%.

Figure 8: […][✂]

Figure 9: […][✂]

247. There were also substantial price reductions. As shown in the Table below, ASPs declined by 34% within one year of entry and 56% within two years compared

to the pre-entry peak of £248. By February 2021, 3.5 years post-entry, prices were […][✂] below the pre-entry price.

Table 3: […][✂]

248. Cinven submitted that the market share and price developments seen post entry in Liothyronine Tablets were well in line with empirical data on developments in generic markets, including the European Commission Pharmaceutical Sector Inquiry Report which analysed 75 of the top selling molecules over a 7-year period across multiple Member States, including the United Kingdom. In the case of products exposed to generic entry, it found prices reduced to around 60% of the entry point peak over a three-year period. The same report found that in the United Kingdom the price charged by the entrants two years after entry is, on average, 55% of the pre-entry price while the incumbent's price decreases to around 80%, which in turn indicated a market average price of around 68% of the pre-entry price after two years.

249. The Appellants referred to evidence gathered by the CMA that showed wholesalers playing the manufacturers off against each other to secure lower prices. At a wholesale level, the two major wholesale customers, AAH and Alliance, had explained in interviews with the CMA the importance they attached to price competition in the post-infringement period as a lever to play suppliers off against each other.

250. Cinven also referred to what it contended were significant and on-going improvements in non-price competition including:

(1) The emergence of UK licensed 5mcg and 10mcg Liothyronine tablet dosages. Under monopoly, there was only a UK licensed 20mcg product and unlicensed smaller doses, which are not advised for patients.

(2) A long shelf-life Liothyronine Tablet (24 months) compared to the 12-month product under monopoly. This would allow customers to purchase

in bulk to secure a better deal since they could store the product longer than before. There is evidence of customers asking specifically about long shelf-life products.

(3) A lactose-free Liothyronine Tablet product marketed by Teva.

(4) A Liothyronine capsule product (as opposed to a tablet), which facilitates ease of swallowing.

(5) The addition of new sources of manufacturing capacity other than Advanz (and its manufacturer), thus enhancing security of supply, which is a critical component of competition in pharmaceutical products.

251. Third, the Appellants submitted that the CMA was wrong to place reliance on the Oxera study for the BGMA to support its findings in the Decision. In the opinion of the primary author of the report, Dr Chowdhury, the CMA had not taken into account the broader context of the study and its main objective which was to gather evidence on the general functioning of the supply of generic medicines in the UK and the adequacy of the current regulatory framework. It was wrong to use the analysis of average price evolution as representative of a specific molecule. This was because the speed of price reductions varies across molecules according to a range of contextual factors including the complexity of production, the availability of the API, profitability and portfolio fit. The pace of reduction in the price of Liothyronine Tablets may therefore be attributable to inherent features of that product.

252. Ms Jackson, Hg's expert, considered that the CMA's comparisons of Liothyronine Tablets with other generic drugs were flawed because it related to products regulated under Category M which she did not view as relevant comparators. Liothyronine Tablets were not listed as a Category M drug during the Infringement Period (see paragraph 26 above). Drugs like Liothyronine Tablets which are more difficult to produce than other Category M drugs require greater investments of cost and time to bring to market and will not be exposed to competition - unless post-entry price is expected to generate a return. Without knowing more about the sample drugs in Category M, including the entry costs,

it was not possible to make a meaningful comparison between the costs of Liothyronine and the respective costs of the sample drugs. Ms Jackson also disputed the CMA's finding in the Decision that stickiness was the result of the regulatory constraint of the Drug Tariff. The evidence of entrants was that prices were set in order to undercut rivals and gain market share rather than as a mechanistic discount to the Drug Tariff.

253. Dr Bennett similarly disputed the CMA's reliance on Category M drugs as a relevant comparator for Liothyronine Tablets. This was on the basis that Liothyronine Tablets are not a typical Category M drug in that it has considerably smaller volumes, is difficult to manufacture, and has a smaller number of competitors. He contended that the characteristics of Liothyronine Tablets are more comparable to drugs in Category A since Category A medicines include generic products which are widely available but which involve smaller markets in terms of volume, value and / or number of suppliers. For this reason, in Dr Bennett's view, it made more sense to consider whether Liothyronine Tablets have significantly higher prices than comparable Category A drugs rather than those in Category M. Compared to other Category A drugs, Liothyronine Tablets were not particularly expensive; they ranked 91 out of 677. Dr Bennett also agreed with Ms Jackson that the price of Liothyronine Tablets was not anchored to the prevailing Drug Tariff price.

254. Fourth, the Appellants disputed the CMA's finding that prices were still contaminated after 3.5 years because of the high starting point of prices post entry and price stickiness. Dr Chowdhury gave examples of the varied price paths followed by different molecules. In her view, there was no significant correlation between the price levels at the point of entry and the speed of decline to the minimum price. She considered that the CMA's conclusion - that the prices for Liothyronine Tablets were significantly higher than other prices and could therefore be expected to decrease - failed to take account of factors that differentiated between individual pharmaceutical products, such as market size, therapeutic indication, costs of production and complexity of the manufacturing process that might drive differences in prices. For the same reason, she considered that the CMA's comparison of absolute prices and its findings as to the price stickiness to be expected from Liothyronine Tablets were erroneous.

255. Ms Jackson's and Dr Bennett's evidence was that, when prices are high, there are greater incentives to cut prices in order to take additional volumes. This was consistent with expectations in the market as evidenced by the forecasts made by AUK, Teva and Advanz showing competition producing steeper declines in prices in forecasts that started at a higher starting point. Cinven submitted that the CMA's description of Post Entry Prices as sticky or contaminated was a pointless distraction. The answer to whether competition in the post-entry period has been workable or not is to be found in looking at the structural features of the market – the numbers of actual/potential competitors, market share changes, price reductions, non-price competition, ease of switching (in this case, open prescriptions make switching seamless) and the detailed interactions between sellers and buyers at multiple market levels. If that analysis shows workable competition, the prices that emerge from it must, by law, be regarded as valid comparators for the purposes of assessing the fairness of prices.

256. Fifth, the Appellants disputed the CMA's finding that competitive prices would reduce to close to the cost of production. The path of competitive prices over time would depend on market characteristics including variable costs (e.g. direct production and distribution costs), fixed costs, entry costs, characteristics of the demand curve (e.g. the sensitivity of demand levels to price changes), the size of the market and the operation of competition. Dr Chowdhury's evidence was that the Oxera study had not analysed costs and margins, so generalised inferences as to price movements relative to costs of production cannot be drawn from it. Moreover, there is a significant variation across molecules and a range of factors influencing supplier behaviour, competitive dynamics and market outcomes after generic entry. The price of Liothyronine Tablets, a difficult to manufacture drug with a relatively small market, would not necessarily have developed in line with an average price evolution. Ms Jackson objected to the CMA's conclusion that it was only when conditions of a "mature generics market" were met that prices would be sufficiently competitive. She considered that, on this basis, there could never in practice be a role for Post Entry Prices as an independent benchmark because in a competitive market firms require a return on capital and a contribution to overheads and not just the costs of production. Dr Bennett considered that there was no basis for assuming that prices would stabilise at a

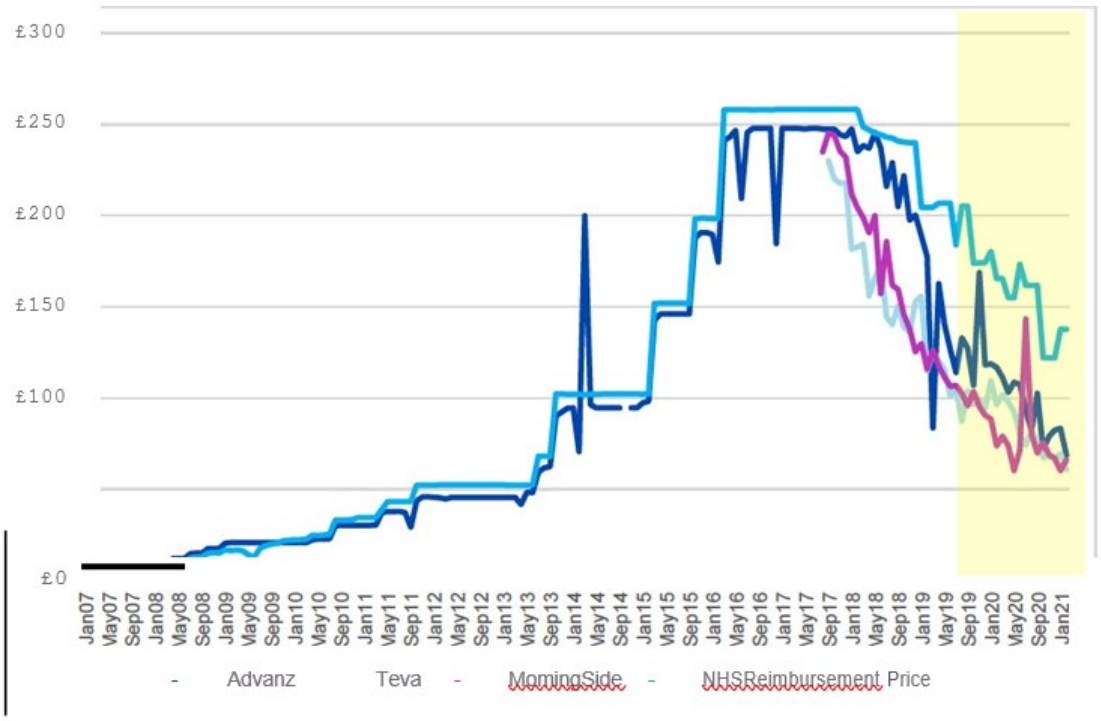
minimum level. Regardless of whether prices continue to fall, they had already reached a competitive level.

(b) The CMA's response

257. In response to an assertion in Advanz Pharma's pleadings that prices had stabilised since February 2021, the CMA adduced evidence of price movements following the Decision. The CMA did not have access to ASPs after February 2021 but it procured access to data from Wavedata, a commercial data provider, and Drug Tariff data showing the NHS reimbursement prices for Liothyronine Tablets under Category M of the drug tariff updated monthly for the period July 2021 to July 2022 Both metrics indicated that the price of Liothyronine Tablets had fallen significantly since February 2021. The Drug Tariff price was at £138 in February 2021, and fell in stages to £59.31 in July 2022 (the last date for which data was available). Discounting the current Drug Tariff price by an appropriate amount, the ASP as at July 2022 would have been around £36-41. Wavedata prices were at £93 in February 2021 and fell gradually to £61 in March 2022 (the last date for which data was available). Cinven provided a further update based on the Drug Tariff price for October 2022. This shows a further fall to £56.19 (from £59.31 in July 2022), suggesting ASPs of around £34-39.

Figure 11 – […][✂]

Figure 12 – Liothyronine Tablet ASPs by manufacturer and average NHS reimbursement price (January 2007 - February 2021)



Source: CMA analysis of data provided by Advanz, Teva, Morningside and PCA data for England.

258. In the light of the above material, Dr Bennett and Ms Jackson accepted that prices have fallen further since February 2021.

259. The CMA, supported by its expert Professor Valletti, contended that the conclusion in the Decision that Post Entry Prices were not a valid comparator for assessing the fairness of Advanz's prices during the Infringement Period was correct. The Appellants' broad position, according to which observable price competition over a period of some 3.5 years meant that prices were the outcome of workable competition, was oversimplistic. The exceptionally high prices at the time of entry, the stickiness of prices post entry, the continuing price falls, and the exceptional profitability post-entry all indicated that prices were still contaminated by the abuse.

260. Professor Valletti's starting point was that there was no single Post Entry Price between the time of entry of Morningside and Teva and February 2021. Immediately after entry prices are unlikely to have fallen much so that they could immediately be considered competitive. The competitive process then produces a declining price path over time with firms recovering their fixed entry costs at

an early stage when prices and therefore margins are higher. The sensible benchmark for deciding at what point prices have fallen enough to be competitive is cost-related. It is only when prices have reached a competitive equilibrium close to the direct costs of production that the price would be a valid comparator.

261. Professor Valletti disagreed with the view of the other experts that it is not possible to generalise that post entry competition in generic markets leads to prices which are close to the cost of production. This was for three main reasons. First, the typical lifecycle of a pharmaceutical product consists of: a first phase, when substantial investment in research and development takes place; a second phase, being the period of exclusivity during which firms may charge high prices to recoup the costs incurred in the development phase, and a third phase, post-exclusivity, when the expectation is that prices will drop. In his view, the empirical evidence was overwhelmingly in favour of the pattern of drug prices declining over time with generic entry. He referred to a recent meta review of the published studies assessing generic prices after patent expiry which showed a range of price ratios from 6.6% to 66% 1- 5 years after initial entry. He also relied on the conclusion to the Oxera study that, whilst there is variation in the extent and speed of price changes across different products, on average the generic price in the six months after loss of exclusivity is 70% lower, falling to 80-90% lower over a four-year period.

262. Second, there was no reason to believe that the competitive process had stopped as prices did not bear any relation to the costs of production and were significantly above the level to be expected in a mature generics market.

263. Third, the competitive response in a market depends on the behaviour of the market's players, and they mutually reinforce each other. If an incumbent is not aggressive and does not lower prices significantly, then an entrant has no compelling reason to be particularly aggressive either. If instead an incumbent is aggressive and cuts prices significantly to try to win more sales, then the entrant will also have to respond by reducing prices aggressively, else it would lose sales. Advanz had tended to price above Teva and Morningside. In a market with inelastic demand in particular, the incentives to avoid competition are even stronger, as any fall in prices would not result in any

increase in total quantities. In these circumstances, it was not surprising that prices have remained substantially above costs and have declined only slowly. This is an indication of what he termed 'soft' competition. This was in contrast to the typical generic path as shown in the Oxera study and the European Commission's Pharmaceutical Sector Enquiry in which generic entrants significantly undercut the originator from the outset.

264. In cross-examination he accepted that he had not defined the markets for the 13 Scheme M drugs used for comparison in Figure 4 above, that he did not know how difficult these drugs were to make or how many suppliers there were for each one, or what the manufacturing costs or specific market characteristics were. He nevertheless defended the use of these drugs for comparison purposes, pointing out that the large size of the data set such as that used in Figure 5 (referred to at paragraph 237 above) would mean that the information disclosed was meaningful despite the effect on the numbers of unobserved factors.

265. Professor Valletti observed that the median time taken for the Category M drugs in the Oxera sample for prices to decline to what he considered to be a competitive level (i.e. their observed minimum price) was four and a half years. Liothyronine is in many respects an outlier in that the entry price comes as a direct consequence of a long ongoing price abuse. The comparison made by Dr Bennett with Category A products was, in Professor Valletti's view, inapposite given that the comparison was based on data from 2016 when Liothyronine Tablets were classed as a Category C drug, and the comparison was made with a selection of products having significantly lower sales levels than Liothyronine Tablets.

266. Professor Valletti considered that a particular reason why the decline in prices was relatively slow in this case, compared to other generic drugs, was that entry usually coincides with the loss of exclusivity. In this case, the patent expired in the 1970s and exclusivity had been lost for a significant period. A second difference was that in the typical generic market, the drug that loses exclusivity often keeps a brand name. Competing generics are competing against the branded drug, so they have to offer discounts to overcome this initial disadvantage. In this case, there were no branded goods, so there was no need for other generic

manufacturers to jump in with deep discounts. Dr Chowdhury disputed Professor Valletti's evidence on this point, contending that brands were unimportant because doctors prescribe by molecule names not brands. Professor Valletti was of the view that there was inertia in the markets and elderly patients might well ask for a brand with which they were familiar.

267. Professor Valletti accepted that competition brings many benefits and that Morningside and Teva had introduced innovations consisting of a longer shelf life and smaller dosages which may well have been introduced as a result of competition. He did not, however, consider that these improvements were significant since they had not led to an increased demand for the product. Prices had fallen over the period when the possible improvements had been introduced yet there was no sign of any sizeable market expansion. Since 2017, prescription volumes have been declining. Professor Valletti considered that the quality improvements had been marginal, in the sense that they did not come close to outweighing the harm caused by the higher prices and that the benefits around security of supply were limited. If shortages were a significant issue before the entry of competing manufacturers, this would have been reflected in an increase in quantities supplied following the introduction of competition. In those markets where, because of the presence of high entry costs and a small market size, genericisation does not lead to the entry of competing manufacturers, a requirement that firms self-regulate by keeping their prices close to a measure of cost would not materially change their incentive to develop new products which comes from the first and second phase of the drug lifecycle.

(c) The Tribunal's conclusions

268. The central question in relation to Post Entry Prices is whether, by February 2021, some three and a half years after entry of Morningside and Teva into the market for Liothyronine Tablets, the then current ASP of £[…][✂] represented the outcome of a workably competitive process such that it was a valid comparator for the purposes of determining the fairness of prices charged during the Infringement Period.

269. The rival arguments in relation to this question were essentially, for the Appellants, that the price as at February 2021, whilst not representing "perfect" competition, was nevertheless sufficiently competitive for the purposes of the *United Brands* test in that it represented the outcome of a process of dynamic competition in a market free of dominance. For the CMA, it was argued that the standard of "sufficiently competitive", whilst excluding "perfect" competition, also excludes "insufficiently competitive" and that prices which are contaminated by pre-entry abusive pricing are not sufficiently competitive.

270. The difficulty of assessing the use of Post Entry Prices as a comparator arises from the absence of any clear, objective criterion for determining whether, or at what point, those prices are no longer contaminated, that is to say no longer materially affected, by pre-entry abusive pricing. If there was evidence that prices had stabilised, that would have been a good indication that this stage had been reached but there was no cogent evidence that prices had stabilised by February 2021 and the CMA's evidence of price movements since February 2021 showed that prices have continued to fall significantly since then. In the absence of any clear marker to show that the contaminating effect had ceased, the price of £[…][✂] may be seen as an arbitrary price point on a downward trend rather than as a meaningful benchmark of a competitive price.

271. The central element of the Appellants' case was the evidence of the dynamic competition, both in terms of shifting market shares and fluctuating prices, that had taken place between August 2017 and February 2021. At first glance, that evidence would seem to provide powerful support for the proposition that, by February 2021, prices must have reached a workably competitive level. In assessing that evidence, it is, however, necessary to bear in mind a number of factors pointing to a different conclusion.

272. First, the Appellants' experts did not challenge the CMA's case that the price of Liothyronine Tablets at the time of entry was exceptionally high. There had been previous price increases of over 6000%, Advanz had increased prices prior to entry and the price at entry was exceptionally high compared to any other drug in the sample of 187 in Oxera's study.

273. Second, the Appellants relied on the three and a half years which had elapsed after entry as being sufficient to ensure a sufficiently competitive price but it is clear from the Oxera report that, even in an average case of generic price movements after loss of exclusivity, it can take approximately four and a half years for prices to stabilise. Moreover, we accept the evidence of Professor Valletti that the price path in the post entry period in this case was unusual in that the decline in prices was more gradual than is typical. There was no slashing of prices by Advanz or the new entrants. Advanz tended to price above Teva and Morningside. The gradual rate of price reduction may have been attributable to the fact that, in a market with inelastic demand, a fall in prices would not result in any increase in total volume. The relative "softness" of competition may be attributable to a number of factors, such as the absence of a branded originator product, meaning that there was less of a need for new entrants to price below the originator medicine, or the small size of the market.

274. We were referred by the CMA to the 2021 commitments decision of the European Commission in *Aspen* (Case AT.40394). A commitments decision is made when a case is resolved by the undertaking in question offering commitments to meet the concerns expressed by the Commission in its preliminary assessment. It has no binding force, but it is instructive as to the approach taken by another experienced competition authority in a stand-alone excessive pricing case in the pharmaceutical sector. The decision followed an investigation by the Commission into the prices charged by Aspen for certain patent-expired niche medicines used in the treatment of cancer.

275. The Commission's preliminary assessment in relation to the Excessive Limb of the *United Brands* test was that the products may have been earning excessive profits during the relevant period. In relation to the Unfair Limb, the Commission found that there were no legitimate reasons underlying the level of Aspen's prices and that Aspen's high profits originated from the exercise of market power arising from a lack of effective competition. It went on to find that the prices of recent generic entrants did not yet reflect sufficiently effective competition and so did not undermine its preliminary finding that Aspen's prices were unfair. There are factual distinctions between the Aspen case and the present case, including the number of entrants (no more than two in Aspen) and the fact that

the entrants in Aspen had not yet made any significant market share gains. The decision is nevertheless of interest in showing how it may take significant time in small markets before the advent of new entrants brings about sufficiently effective competition.

> "(199) As concerns recent generic entrants in some markets, most generic suppliers have entered Relevant Markets with prices broadly aligned with Aspen's price levels, and their prices have remained broadly aligned with Aspen's prices. Regarding those price levels of generic suppliers, the Commission has serious doubts that they reflect levels of sufficiently effective competition. In fact, empirical data suggests that sufficiently effective generic price competition may require more than one or two entrants, which is not the case on any of the Relevant Markets. The empirical data also suggests that small market sizes may delay the emergence of effective generic competition, and that it may take a significant amount of time in small markets for prices to drop to levels likely reflecting effective competition."

276. In the present case, the exceptionally high starting-point combined with the unusually slow and continuing decline in prices are indications that the post entry price in February 2021 was still contaminated and not sufficiently competitive to be a reliable comparator for the purposes of assessing the fairness of any price during the Infringement Period.

277. Third, we are satisfied that the price of Liothyronine Tablets in February 2021 was a substantial outlier by comparison with the price of other generic drugs. The finding in the Decision in this regard was based on comparisons between the Post Entry price of Liothyronine Tablets and the prices of all other Category M drugs in the Oxera Report; Category M drugs with a similar market volume; NHS Reimbursement Prices across all Category M drugs; overseas Liothyronine tablets; and levothyroxine tablets. In our view, these comparisons were validly made, notwithstanding Dr Chowdhury's view that comparisons between the prices of Liothyronine Tablets and the prices of other generics were inapposite because of the differences between individual molecules. The Tribunal accepts the evidence of Professor Valletti that, given the size of the datasets used in the comparisons, they were meaningful. No adequate explanation was given by the Appellants for Liothyronine Tablets' outlying status in these comparisons. They are an off-patent unbranded product; patients can now switch between manufacturers; there are no research costs or capacity constraints; production can

be outsourced and the costs of production are not high. There was no basis for Dr Bennett's suggestion that non-price factors could explain the differences.

278. Dr Bennett's comparison of Liothyronine ASPs to reimbursement prices of drugs in Category A, on the basis that the latter entailed smaller markets in terms of volume, value and numbers, was not persuasive. Dr Bennett was unaware that Category A could include drugs that were supplied by only one supplier. His comparison was of only the most expensive drugs in Category A (those above £60). As against the full sample of drugs in Category A, Liothyronine Tablets both in 2016 and in 2021 were significant outliers in terms of price. Moreover, as the CMA demonstrated, even as against the most expensive drugs in Category A identified by Dr Bennett from the sample in 2016, Liothyronine Tablets were a significant outlier when both volume and price were considered.

279. Finally, the analysis by Mr Harman, the CMA's forensic accounting expert, of the levels of profitability post-entry showed that Advanz, Teva and Morningside were still likely to be earning profits significantly above the profitability to be expected for a generic drug developed in the mid-1950s. He concluded that, even when prices fell below £70, the EBIT (i.e. earnings before interest and tax) margin remained at 83% or above in each year, and the three suppliers maintained a ROCE of 170%, higher than 95% of the companies considered in his sample. Mr Harman was not challenged on this evidence.

280. These factors are, in our view, sufficient to lead to the conclusion that the CMA was justified in rejecting Post Entry Prices as a valid comparator for the purpose of determining whether Advanz's prices were fair.

281. In reaching this conclusion, it is not necessary for the Tribunal to accept Professor Valletti's evidence that the price of Liothyronine will only become workably competitive once the price has reached an equilibrium close to the direct costs of production. We agree with the Appellants that treating prices as workably competitive only once they fall to an equilibrium around direct costs would effectively equate "workably competitive" prices with "perfectly competitive" prices, a position which the CMA in its closing submissions specifically disavowed. It is likewise not necessary for us to speculate as to what

will happen to the price of Liothyronine Tablets in the future or at what point they will become workably competitive. We have concluded that the February 2021 Post Entry price is not a valid comparator because it is contaminated by the pre-entry abusive pricing, not because prices have yet to converge to an equilibrium around direct costs.

(2) Entry-Incentivising Prices

(a) The Decision

282. The second comparator put forward by Hg and Cinven for the purpose of assessing whether Advanz's prices of Liothyronine Tablets were fair when compared to competing products was the prices which incentivised entry attempts by other suppliers of Liothyronine Tablets ("Entry-Incentivising Prices"). Hg and Cinven argued that Advanz's prices were not unfair because Advanz implemented them in the knowledge that they would lead to new entry, to increased competition and to a subsequent reduction in prices. They contended that the CMA's Cost Plus model would result in dominant undertakings being required to price at a level which would foreclose entry. They relied on the price of £45.52 per pack as the relevant Entry-Incentivising Price on the basis that this was the price prevailing in 2012 when Morningside began its entry efforts.

283. In the Decision, the CMA dismissed Entry-Incentivising Prices as a comparator on a number of grounds. The first was that the use of Entry-Incentivising Prices as a benchmark would significantly reduce the effectiveness of the Chapter II prohibition on excessive pricing. The CMA argued that if it were prevented from intervening when prices were below a supposed Entry-Incentivising level, this would enable an incumbent lawfully to extract high economic profits from consumers indefinitely by pricing at a level that, though excessive within the meaning of Chapter II, was slightly below the Entry-Incentivising level ("limit pricing"). The greater the barriers to entry protecting an incumbent's market position, the higher the economic profits it could lawfully extract. This would defeat the purpose of the law against excessive pricing.

284. Second, the CMA challenged the notion that entry by other competitors would lead to effective competition and a fall in prices. The CMA accepted that, in an effectively competitive market, a temporary period of higher prices which promptly leads to efficient entry and to prices returning to effectively competitive levels within a reasonable period may not give rise to consumer harm. But in a market which is not effectively competitive owing to high barriers to entry, the converse is also true: market forces will not bring about self-correction within a reasonable period. The market for Liothyronine Tablets, which is characterised by high barriers to entry, is such an example. Nine years after the first successful entry attempt was begun, prices remained significantly in excess of the level at which the first successful entrant began developing its own product. Specifically, the price of the tablets was £45.52 per pack in September 2012, when Morningside began its entry attempt. It was £[…][✂] per pack nine years later in February 2021. If entry by other competitors does not lead to effective competition, so the CMA's argument ran, the rationale for treating Entry-Incentivising Prices as a useful benchmark for assessing the fairness of the prices during the Infringement Period is undermined.

285. The CMA also argued that competition by other entrants in the market for Liothyronine Tablets would not be likely to generate the kind of non-price benefits – such as increased output, quality improvements, efficiency enhancement, introduction of new and better products – that competition will normally bring in other markets. There would be no increase in volumes supplied because demand for Liothyronine Tablets is inelastic. As Liothyronine Tablets are an old and established drug with limited scope for improvement, entry has not resulted in substantially increased quality or better products and is unlikely to lead to production efficiencies large enough to compensate for the higher cost to the NHS.

286. Finally, the CMA argued that – when assessing the fairness of the prices of a dominant undertaking - the emergence of competition is not an end in itself. In the vast majority of markets, competition is the most effective market structure to promote consumer welfare. But in the case of Liothyronine Tablets, had Advanz exercised pricing restraint in line with its special responsibility as a dominant supplier, rather than abusing its market power, the principal purchaser

would have benefitted, whether or not entry was ultimately incentivised. Whilst similar cases in other markets are often handled under systems of ex ante regulation (with licensing regimes and price controls), room should be retained to require undertakings to restrain their own prices in cases where they hold significant market power, subject to ex post enforcement.

(b) The Appellants' arguments

287. The Appellants submitted that the CMA was wrong to reject Entry-Incentivising Prices as a comparator for the following main reasons.

288. First, they submitted that there was an inconsistency between, on the one hand, the objective of estimating a price under conditions of workable competition, in accordance with *United Brands*, and on the other, adopting a benchmark which precluded entry by other competitors, which was needed for workable competition to take place. There was a similar inconsistency between the CMA's approach and the objective of the Chapter II prohibition to protect competition. The "special responsibility" imposed on a dominant undertaking cannot be to act in a way that forecloses competition. In addition to its direct price effects, competition also brings quality improvements, security of supply, product variety and dynamic incentives for innovation. That is why, apart from the specific cases in which legislation provides for regulated monopolies, the Competition Act protects and promotes competition.

289. Cinven argued that, in a market where the CMA has not found insurmountable entry barriers, the CMA lacks jurisdiction to intervene to set prices below viable entry levels. In a market where entry was always possible, and ultimately occurred, had the CMA's determination of Cost Plus acted as a cap on prices during the relevant period, it would have deterred that very entry. The CMA did not have jurisdiction to do this; it was contrary to its duty to "promote competition" for the benefit of consumers under Section 25(3) of the Enterprise and Regulatory Reform Act 2013. The CMA would be cutting off the very 'signal' that leads to market entry in the first place. Cinven contended that the CMA's position that entry barriers were "high" did not overcome this

jurisdictional objection and was in any event incorrect. Firms who sought to enter were able to do so within three to five years.

290. Hg submitted that the CMA's case entails a radical redesign of the UK generics market according to which, as soon as a patent expires, the originator would be required to cut its price to single-firm Cost Plus or perhaps seek to guess and then take advantage of what "headroom" the CMA is likely to allow above that, based on its approach in this case. In other words, if Liothyronine had hypothetically come off patent in 2012, with a pre-patent expiry price of £50, Advanz should immediately have cut its prices to £20 or less with the consequence that no entry was likely to occur. According to Hg, characterising prices below an entry incentivising level as abusive amounts to a conclusion that Advanz should price in a way that would have prevented competition. As Ms Jackson put it in her reply report:

> "In effect, the CMA's case was that competition is simply undesirable because it would result in higher prices than could be obtained if Advanz had regulated its own prices based on a monopoly cost benchmark. In my view, this does not make economic sense as a benchmark for workable or sufficiently effective competition."

291. The Appellants rejected as fanciful the suggestion by Mr Harman, the CMA's expert, that, even if Advanz had maintained low prices, close to Cost Plus, entry might nevertheless have occurred if an entrant was more efficient than Advanz and could have driven Advanz out of the market entirely. This was not a contestable market given the high entry costs and low direct costs of production. If an undertaking as large and efficient as Teva could not drive Advanz out, even with competition from Morningside as well, it was not plausible that anyone could.

292. The Appellants took issue with the CMA's argument that Entry-Incentivising Prices should be disregarded because high barriers to entry would enable a dominant undertaking to set extremely high prices. They pointed out that the Liothyronine market is not a market in which entry is impossible or in which there are barriers beyond the time and cost of developing the product. If (as here) the only barrier to entry was the cost of developing the product, where a dominant undertaking sets high prices, entry will naturally occur and establish one or more

benchmarks for competitive pricing. Hg contended that if the dominant undertaking set its price significantly and persistently in excess of those competitive benchmarks (for example, during the period after entry attempts began, but before entry could take place), then that might provide a basis for an excessive pricing claim against the dominant undertaking in respect of the high prices in that interim period.

293. The Appellants also took issue with the CMA's objection based on "limit pricing". If a dominant undertaking engaged in "limit pricing" (strategically pricing just below entry-incentivising levels but potentially still above competitive levels) then, to the extent there was a gap between competitive prices and entry-incentivising prices, it would be open to the CMA to pursue the dominant firm.

294. The Appellants submitted that there is nothing unusual or pernicious about products that are more difficult to develop attracting higher prices than those for which product development is cheap and easy. That is the normal consequence of unconstrained competition. Dr Bennett's evidence was as follows:

> "As I said, I believe that when these barriers to entry are simply the costs of having to have a workable product, we know that competition is feasible. So we are not in a world in which competition is not going to emerge. We know competition can emerge and has emerged in this market, then, yes, an effectively competitive price should increase with the level of barriers to entry. Should entry-incentivising prices be taken into account in determining a competitive price? Yes, but I would also say they should also be taken into account when you are sense checking some of the other benchmarks. For example, if we look at the CMA's cost plus, the fact that it is extremely low but we did not see any entry attempts trying to come in at the levels that the CMA is putting forward in its benchmark should give you an indication that that is not a benchmark which is incentivising competition, which allows competition to come in, and in that sense for me it is clearly below the level at which effective competition could emerge." [Day 5 page 20 line 8 – page 21 line 3]

295. The Appellants rejected the CMA's contention that Entry-Incentivising Prices are necessarily above the level of prices (or trading benefits) that would be obtained under workable competition. The Appellants accepted that Entry Incentivising Prices are not in themselves prices that are produced by a competitive process and may be above or below the prices that later prevail under competition. Hg did not propose that Entry-Incentivising Prices should be treated as the dividing line between infringement and non-infringement or that they

should be used in every unfair pricing case in every market. Hg submitted nevertheless that the Tribunal should use the available documentary record of when attempts to enter the market were commenced and why. Entry may be incentivised because the entrants anticipate that prices will continue to increase while they develop their product. Or they may underestimate the difficulty of entry but decide to continue with their attempt because they observe that prices continue to rise. They contended that Professor Valletti was demonstrably wrong to say that the Entry-Incentivising Price is "for sure the highest price ever observed during a process of competition".

296. Advanz Pharma submitted that the CMA's rejection of Entry-Incentivising Prices as a benchmark was contrary to the Scheme M Agreement between the DHSC and the BGMA as the representative body for the generics industry - the stated objective of which was to promote competition and to stimulate market entry through freedom of pricing. Dr Chowdhury's evidence was that the Department of Health chose to maintain an open market design, with freedom of pricing, rather than a "tender system", in order to encourage entry and therefore promote security of supply. The unchallenged evidence of Dr Smith was to the same effect. It was submitted that the CMA's approach was liable to damage the generic pharmaceutical industry which is recognized by the DHSC/NHS to have brought considerable savings to the DHSC/NHS in contrast to many other countries and to jeopardise an important policy consideration in the health sector: namely, the security of the supply of pharmaceutical drugs essential for patient welfare. Mr Beighton's evidence was that stock shortages of Advanz's medicines were a recurrent problem.

297. More generally, the Appellants argued that the CMA's approach, in requiring price restraint by a dominant supplier even at the expense of competition by other entrants, would sacrifice the material benefits of competition. They argued that it was the advent of competition that led to the introduction of 5 and 10 microgram dosages. The Decision recorded that in 2013 Advanz decided to start developing product variations in 5 and 10 mcg dosages, not only to meet clinical demand but also to counter the competition that Advanz expected to encounter. In June 2015 Advanz invested in the acquisition of Primegen Limited in part because it gave Advanz a development project for 5 and 10 mcg dosages which

would enable it to respond to anticipated competition. Until the introduction of these doses, some patients who were prescribed lower dosages had to crush or dissolve a 20 mcg tablet. There was evidence that giving too high a dose could be clinically damaging. Morningside told the CMA that the MHRA had indicated that there was a clear clinical need for certain patients to be treated with 5 and 10 mcg dosages and that the MHRA had actively encouraged Morningside to enter the market with these dosages. Other innovations relied upon by the Appellants were the introduction of a lactose free product and a doubling of shelf life from 12 to 24 months leading to a reduction in wastage.

298. Advanz Pharma placed particular emphasis on security of supply which would be improved if there were multiple suppliers. It referred to the concerns expressed by a member of the public that only one pharmaceutical company was licensed to produce Liothyronine Tablets. Mr Beighton's evidence was that Advanz was under constant pressure from the DHSC/NHS to ensure continuity of supplies. Dr Chowdury referred to the need to guarantee security of supply as an important policy objective, particularly for those medicines where the incentives for suppliers to enter may be low. If market conditions become adverse, e.g. because too much entry has led to low prices, this can lead to shortages. In her view, Professor Valletti's focus on low prices as the sole measure of consumer welfare meant that he missed a critical aspect of the market context of the supply of generic medicines.

299. As to the level of the Entry-Incentivising Price, Hg contended that there was little scope for dispute. The first credible attempts at entry began in 2012, when the price was more than £45 per pack and just below the £46 highest price during the Hg Period. The CMA did not reject, in the Decision, the submission that these were the minimum prices necessary to incentivise entry. Hg dismissed as trivial the difference between £46 and the figure of £39.28 used in AUK's entry forecast model as the pre-entry price. Moreover, other entrants required significantly higher prices before deciding to enter. The correct approach, according to Hg, was to make an overall judgement taking into account all of the relevant data points. Hg submitted that the evidence therefore establishes that the highest prices charged during the Hg Period were the minimum necessary for competition to take place in this market. Professor Valletti agreed that prices

prevailing when entry decisions were made become informative as to the minimum price level at which entry is attractive.

300. Hg also dismissed Professor Valletti's reliance on the evidence that Uni-Pharma made a "very serious attempt" at entry in 2010, when the prevailing price was lower. Hg submitted that there was no finding in the Decision that Uni-Pharma was a credible entrant and that the position was more complex than Professor Valletti acknowledged. Uni-Pharma was only willing to enter at such a low price because it thought entry would be easy given that it already sold Liothyronine in Greece. When its API supplier withdrew in 2013, it considered whether or not to continue, but decided not to. By then prices had risen yet Uni-Pharma still decided not to incur further costs in the pursuit of entry. Uni-Pharma had explained to the CMA that, when withdrawing the application due to the discontinuation of the supply of the API the dossier was based on, it also realized that significant investment in a bioequivalence study would be required and that physicochemical differences in the API they could source from the market compared to the API used in the local reference product – Tertroxin –would render the investment a high risk.

301. Hg submitted that the example of Uni-Pharma was not evidence of a potential entrant being willing to incur the true cost and risk of entry based on prices prevailing in 2010 but was, on the contrary, evidence of a potential entrant being unwilling to incur the true cost and risk of entry based on the (higher) prices prevailing in 2013, which is after the end of the Hg Period. Moreover, several potential entrants – including Teva – were not willing to do so until prices reached substantially higher figures than that. That was significant because Teva had significant cost advantages over Advanz and other smaller manufacturers. If even Teva did not find entry to be an attractive prospect before prices reached £95, the Tribunal should hesitate to conclude that prices substantially below that level were sufficient. Ms Jackson's evidence was that there would have been enough entrants to have an effectively competitive market somewhere between that £45 and £95.

(c) The CMA's response

302. The CMA noted that it was common ground between the experts that Entry-Incentivising Prices did not reflect the outcome of effective competition. It rejected the argument that Entry-Incentivising Prices were nevertheless a useful comparator or indeed that they were informative at all in relation to what was an unfair price, on the following main grounds.

303. The first ground was that Entry-Incentivising Prices are necessarily higher than competitive prices because of the need for entrants to recover their fixed entry costs whereas competition is expected to lead, over time, to prices close to the direct costs of production. Professor Valletti's evidence was that fixed costs, which have already been paid by the incumbent, represent a barrier to entry for competitors and that the initial entry price, reflecting those fixed costs, would be the "highest price" when competition eventually starts.

304. In Professor Valletti's opinion, moreover, it would be perverse to use Entry-Incentivising Prices as a benchmark for a competitive price because, however high the Entry-Incentivising Price, the logic of the Appellants' argument was that such a price could not be excessive because any lower price was insufficient to trigger competition. The argument, if accepted, would rule out the existence of an excessive pricing abuse.

305. The CMA's second main argument was that the use of Entry-Incentivising Prices as a benchmark would allow a dominant company to charge abusive prices. A dominant firm could engage in "limit pricing" (see paragraph [275] above). Alternatively, a dominant undertaking could, during the period needed by competitors to gain entry, raise prices above an effectively competitive rate, not necessarily through deliberate limit-pricing but knowing that it had many years to reap trading benefits that it could not hope to achieve under conditions of normal and sufficiently effective competition. Professor Valletti's evidence was as follows:

> "Those entry costs are precisely what is shielding the incumbent from competition, and if you use entry-incentivising prices you are basically allowing an incumbent to abuse more and more the higher the entry costs, and this is not

> I think what workable and effective competition delivers…" [Day 5 page 17 lines 1 – 6]

306. The CMA's third main argument was that an Entry-Incentivising Price is inherently unreliable and unpredictable as a benchmark. It is not informative because it depends on, amongst other things, the subjective intentions and actions of third parties and the particular market circumstances at the time. In this case, the respective commercial experience, aims and expertise of Uni-Pharma, Morningside and Teva were very different so there was no single price point at which entry might have incentivised all of them. Uni-Pharma has a long tradition in developing, manufacturing and commercialising products designed to treat disorders of the thyroid gland, in certain categories into which Liothyronine Tablets fell. It already manufactured Liothyronine Tablets and evaluated the potential of each market that could be targeted: the UK market appeared to be attractive due to the price level. By comparison, Morningside was a small family-run virtual business that contracts out all development and manufacturing activities. Liothyronine Tablets were one of the first products that Morningside sought to develop itself, rather than sourcing the finished product (through the sourcing of Liothyronine API). Morningside considered that Liothyronine Tablets would be a coherent addition to its intention to develop a portfolio of products on thyroid problems. By contrast, Teva (a large global pharmaceutical company) routinely analysed opportunities to launch new products on a global and / or regional level, considering the size of the market, competitors and other regulatory considerations: it only tended to consider a new product if it could demonstrate gross sales in Europe of at least US$5m. Teva noted that, whilst a product like Liothyronine was rather niche/specialist, a company such as Teva has the technical expertise to develop and market it and will do if the price allows for the recovery of costs.

307. The CMA also submitted that, even if an Entry-Incentivising Price were to be considered of utility, the higher end of the Appellants' proposed benchmark range was unjustifiable even on the Appellants' own case. There was no dispute that entry was incentivised in September 2012 at the price of £45.52, by which time Hg was making margins of 98%. Given the entry costs of £420,000 to £[…][✂], entry was clearly incentivised by this point. There was thus no basis

for the inclusion of Teva's entry incentivising price of £94.63. If one is focusing on the entry attempts of firms which were ultimately successful, the benchmark Entry-Incentivising Price in 2012 was the price which AUK assumed was being charged at that point: a price of £39.28. There was no basis to exclude that (lower) price: AUK were incentivised to enter at that point.

308. The CMA submitted that Uni-Pharma's attempt to enter the UK and Irish markets, which began in 2010, was a credible entry attempt. The CMA accepted that it is not possible to determine whether Uni-Pharma withdrew only because its API manufacturer had withdrawn. It was, however, clear that an experienced manufacturer of hypothyroidism medicines took significant steps towards entry, including through the preparation of a dossier based on an API by a manufacturer in the market and spending €350,000. That was a credible, even if unsuccessful attempt at entry. In the circumstances, the price of £21 at which Uni-Pharma's entry was sparked (March 2010) would be the relevant benchmark for an Entry Incentivising Price.

309. With regard to Advanz's membership of Scheme M, the CMA submitted that this did not, of itself, give Advanz any kind of exemption from the Chapter II prohibition or from s.18(2)(a) of the 1998 Act as regards the prices of individual products. Even if Advanz engaged in 'free pricing' within the meaning of Scheme M during the Infringement Period, that could not in any way absolve Advanz from its responsibility under Chapter II. Moreover, Scheme M provided no written assurance that members would not be penalised for an abuse of dominance if they observed the terms of the scheme. Whilst Advanz's contemporaneous documents referred to the 'free pricing model' that applied to unbranded generic medicines, including Liothyronine Tablets, they do not mention the DHSC's powers to control prices as a material consideration. Further and in any event, Advanz's submissions in respect of Scheme M disregard the practical limitations on the DHSC's ability to exercise its powers under that voluntary scheme.

310. Professor Valletti agreed with the CMA's stance in the Decision that the promotion of competition is not the objective of competition law:

> "While competition among firms is often a very effective tool to maximise consumer welfare, this is not necessarily the case in all market contexts. In particular, in a market with a relatively homogeneous product and high fixed costs relative to the size of the market, the presence of multiple firms is inefficient and would not maximise consumer welfare."
>
> "A general point to remember is that we love competition of course, we all do, but that is not the purpose. It is not to encourage entry. So I have never seen that encouraging entry is what we are trying to achieve …" [Day 5 page 21 lines 10 – 14]

311. He explained that in such a market, participation by multiple firms is economically inefficient because the total output would not be produced at the lowest possible cost and prices would need to be set at a higher level in order to generate margins that would cover the additional fixed costs. The market for Liothyronine Tablets has such characteristics. Professor Valletti considered that a dominant firm should self-regulate, not by reference to the costs incentivising other potential entrants, but by reference to its own cost base plus a normal return on its investment.

312. Setting prices by reference to the single Cost Plus model would allow entrants to recover their fixed costs, depending on the size of the "plus" relevant to the fixed costs although he accepted that entry might be "less likely":

> "If the margin is very small, the plus element is very small, entry will be unlikely. But the plus we said depends on the level of fixed costs, okay. So if the fixed costs are high, this margin will -- may also be higher, and that will be the starting point for entrants. They will make their own conjectures. So once again, they may enter, if they expect competition not to be super-intense, not cut-throat, not to have this kind of price wars, they might considering entering it. So the point is that I do consider it less likely. I do not exclude that possibility a priori." [Day 7 page 159 lines 9 – 19]

313. As to the specific non-price benefits relied on by the Appellants, Professor Valletti's evidence was that the quality improvements were marginal in the sense that they did not come close to outweighing the harm caused by higher prices. As to supply shortages, there was no evidence that the arrival of Teva and Morningside had had an effect on quantities supplied. The shortages experienced in 2013 were linked to the need to find a new supplier for the API. The number of suppliers of API was independent of the number of manufacturers of Liothyronine Tablets.

> "A. So, fine, let me agree with you that competition has brought in benefits, I agree with that. I simply said I have seen benefits from competition in multiple ways, one which is very direct, which is via price cuts which had a massive effect on the market, and I can see that, can observe that, and that is a substantial benefit of competition in my opinion. The other benefits are more -- I would not say -- they are just more difficult to assess, and I have not seen any evidence in favour of that assessment that would make me change vis-à-vis this case overall which I have to look holistically, and I have not seen competition bringing those additional benefits that would have been foregone if Advanz had not abused its excessive market power." [Day 7 page 124 lines 5 -19]

314. The CMA submitted that the arguments of the Appellants sought to add a further limb to the *United Brands* test: that a price may not be unlawful if it is below a price which allows for further entry into the market; it submitted that no such gloss on the clear test laid down by the Court of Appeal as set out at paragraph 116 above is required and that to do so would strip the CMA of the ability to protect consumers, which is the ultimate objective warranting the intervention of competition law. No party has undertaken a thorough comparison of the benefits of competition in this market compared to the harm suffered through the extraordinary prices charged. That is because it does not form part of the legal test: the Tribunal is equally not required to undertake such an analysis.

315. As to the level of Entry-Incentivising Price, if considered to be of utility, the CMA contended that the higher end of the Appellants' proposed benchmark range was unjustifiable even on the Appellants' own case. By 2012, Hg was already making an extraordinary profit as was apparent from the Project Glacier documents The margins in the business at the time were 98% and even on an EBIT basis were 95-97%. There was no basis for the inclusion of Teva's entry incentivising price of £94.63. The benchmark was put forward as an indicator of when the competitive process was sparked: it is of no assistance to say that the competitive process was *also* sparked at numerous (higher) price points

316. The CMA argued that if the Tribunal focused on the entry attempts of firms which were ultimately successful, the relevant benchmark in 2012 was the price which AUK assumed was being charged at that point: a price of £39.28. Uni-Pharma's entry attempt, though ultimately unsuccessful, was a credible one taking a number of years, involving significant steps towards entry, including through the preparation of a dossier based on an API, and costing €350,000. In

the circumstances the price at the time Uni-Pharma's entry was sparked in March 2011would be the relevant benchmark for an Entry-Incentivising Price: £21.

(d) The Tribunal's conclusions

317. In our view, the CMA was justified in rejecting Entry-Incentivising Prices as a valid competitive benchmark. As noted above, it was common ground between the experts that Entry-Incentivising Prices do not reflect the outcome of an effectively competitive process. They represent the beginnings of the competitive process. The question for the Tribunal is whether Entry-Incentivising prices are nevertheless a valid comparator. In the Tribunal's view, they are not, for the following reasons.

318. First, we consider that treating Entry-Incentivising Prices as a valid benchmark would be incorrect as a matter of legal principle. As noted in *London & South Eastern Railway Ltd and others v Gutmann* [2022] EWCA 1077, the law relating to abuse of dominance is concerned with the protection of consumers from the unfairness which arises when a dominant undertaking is freed from competitive shackles. The level of Entry-Incentivising Prices in a market with high barriers to entry, whether in terms of entry costs or regulatory requirements or other obstacles, must be high enough to give firms the incentive to compete. The higher the barriers to entry, the higher the Entry-Incentivising price. In a market such as this, with barriers to entry that, though not insurmountable, are exceptionally high – as Advanz recognised (see for example paragraphs 48 and 49 above) – the price charged by an incumbent dominant supplier could be excessive and unfair even though below the level required to incentivise other entrants to join the market. Treating Entry-Incentivising prices as a benchmark, far from protecting consumers from unfairness, would allow the dominant undertaking to benefit from those barriers to entry.

319. Treating Entry-Incentivising Prices as a benchmark, as the Appellants urged the Tribunal to do, would not be consistent with the *United Brands* test in that it would give primacy to the furtherance of competition, regardless of whether the trading benefits reaped by the dominant undertaking from charging Entry-Incentivising Prices were vastly higher than the prices achievable in normal and

sufficiently effective competition and regardless of whether there was a reasonable relationship between the Entry-Incentivising Price and the economic value of the product in question. The jurisdictional bar contended for by the Cinven Appellants, according to which the CMA may not set prices below viable entry levels, is flawed because in a market with exceptionally high entry barriers, there may well be no viable entry level. The Competition Act does not identify any such jurisdictional bar. Moreover, the economic literature cited by Dr Bennett does not support his argument that regulation of prices is only justified if barriers to entry are insurmountable. Rather the literature refers to markets which take time to correct.

320. Second, we agree the with the CMA with regard to the inherent unreliability of Entry-Incentivising Pries as a useful benchmark of workably competitive price. Given that Entry-Incentivising Prices depend on, amongst other things, the subjective intentions, circumstances and actions of third party entrants, their access to capital and their approach to risk and on the pricing conduct of the dominant undertaking, it would be wrong to treat them as a proxy for a workably competitive price or as the dividing line between a fair and unfair price. The unsuitability of Entry-Incentivising Prices as hard and fast benchmarks is illustrated by the wide range of prices that were needed to incentivise Uni-Pharma, Morningside and Teva in this case.

321. As to the Appellants' contention that applying a benchmark below the Entry-Incentivising price would deprive consumers of the potential benefits of competition, we agree with the CMA's position that, as noted above, it is not part of the *United Brands* test that the price benchmark must be set at a level to facilitate competition. The test does not presuppose that the potential benefits of competition are such as to justify and render non-abusive whatever price is needed to incentivise other entrants to compete. Nor does the test require a comparison to be made between, on the one hand, the benefits of competition with, on the other hand, the harm resulting from excessive prices. If such a comparison were to be made, the CMA concluded in the Decision that the incremental improvements which have been made in the provision of Liothyronine Tablets since Teva and Morningside began to compete (assuming in the Appellants' favour that these improvements would not have occurred had

Advanz remained as sole supplier of Liothyronine Tablets), that is to say the availability of different dosages, a longer shelf life, a lactose free option and increased security of supply - were disproportionately small to justify the increase in prices needed to stimulate entry. We agree with that assessment. Liothyronine Tablets are an old and established drug with limited scope for improvement.

322. As to the further argument that Advanz's price increases were not unfair because Advanz implemented them in the knowledge that they would lead to new entry, increased competition, and a subsequent reduction in prices, this argument would have validity in an effectively competitive market as mentioned by Green LJ in *Phenytoin*:

> "Where there are no material barriers to entry, high prices can act as a magnet to entry which, in due course, drives prices down. Many markets are thus self-correcting."

323. In a case such as the present, where there were high barriers to entry, and effective competition was lacking, self-correction would not necessarily occur within a reasonable time. Prices were still falling at a significant rate some five years after competition started. Moreover, since demand for Liothyronine Tablets is inelastic, the reduced prices that entry may be expected to lead to in the long term would not result in an increase in the volume supplied.

324. Hg's argument that the CMA's case gave rise to an obligation on Advanz to set prices at a level which would deter entry mischaracterises the CMA's position. Charging prices based on Cost Plus would not necessarily have deterred other entrants from competing even though, on the evidence before the Tribunal, that would have been the outcome during the Infringement Period.

325. Had we considered that Entry-Incentivising Prices were a useful benchmark, we would have taken the relevant Entry-Incentivising Price to be the £21 current in 2010 when Uni-Pharma commenced its entry attempt. Although it is not clear to what extent Uni-Pharma's discontinuance was attributable to the discontinuance of the API or to the need to invest in the bioequivalence study, that price appears

to have been considered by Uni-Pharma to be a viable price which merited significant work and costs.

326. Finally, in so far as the Appellants relied on the significant difference between the correct Cost Plus figures and any of the Entry-Incentivising Prices advanced by the Appellants to cast doubt on the reliability of the Cost Plus calculation, our conclusion as to the correctness of that calculation is unchanged. Cost Plus is concerned with costs, fully and properly accounted for, to which is added an appropriate margin. In some cases, where barriers are relatively low, this margin will be enough to encourage entry. In other cases such as the present case, where the barriers (particularly non-financial barriers such as regulatory factors) are high, cost plus may not be enough to generate entry, though higher prices may encourage it. In extreme cases, entry will never occur.

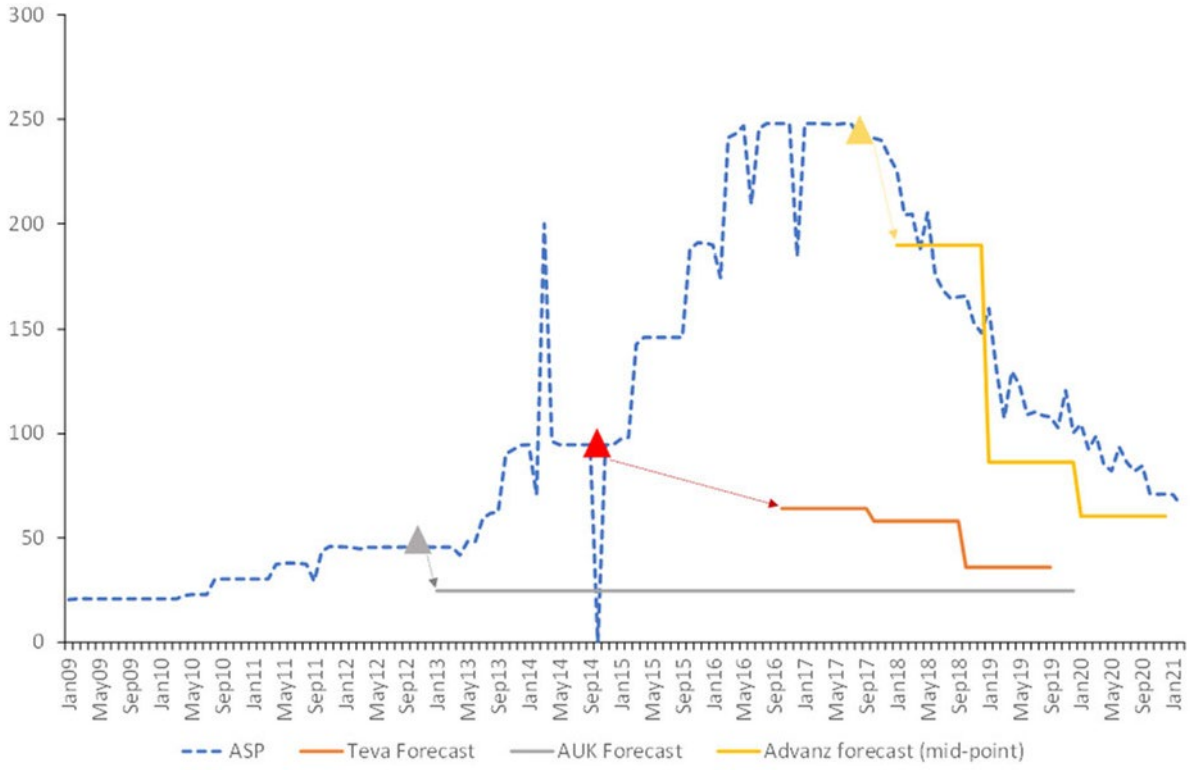
(3) Forecast prices

(a) The Decision

327. A further comparator put forward by Hg and Cinven for the purpose of assessing whether Advanz's prices of Liothyronine Tablets were fair when compared to those obtainable in conditions of workable competition were the pre-entry forecasts of prices made by AUK, Teva and Advanz.

328. AUK's forecasts assumed a pre-entry price of £39.28 in 2012 and predicted a single 40% price drop following entry. This led to a forecast price of £24.68 per pack after entry and no further price drops in subsequent years. Teva's predicted prices were as follows: Year 1 (October 2016 to October 2017) £64.06, Year 2 (October 2017 to September 2018) £58 and Year 3 (October 2018 to September 2019) £35.90. Advanz's forecasts from 2017 assumed a pre-entry price of £247.74 and predicted prices from £247.74 to £131.38 in year 1, £121.40 to £51.15 in year 2 and £79.58 to £28.59 in year 3.

Figure 13 – Price Forecasts made by market participants (CMA Decision)



329. The forecast prices are shown in the Figure 13 above, with the triangles indicating the respective dates at which the forecasts were made and ASP prevailing at that date, and the line showing the forecast.

330. The CMA, having evaluated the Appellants' representations, concluded that the forecast prices did not provide a *prima facie* valid comparator against which to assess whether the pricing of Liothyronine Tablets during the Infringement Period was fair. This was, in summary, for the following reasons:

(1) The forecasts were likely to have been inflated by Advanz's pricing conduct and its exercise of substantial market power during the Infringement Period. The manufacturers' forecasts were based on the price prevailing at the time the forecasts were made and estimated changes in prices within the first three years after entry.

(2) The forecasts were short-term in horizon and did not purport to reflect the effectively competitive price level which would prevail in a mature

generics market. Both Teva and AUK advised the CMA against treating their forecasts as accurate price predictions. Advanz's forecasts appeared to be based on perceptions of the market at the time rather than credible evidence.

(b) The Appellants' arguments

331. Hg and Cinven submitted that the CMA should have attached weight to the price forecasts. This was for the following reasons:

(1) The circumstances in which the forecasts were made indicated that they were undertaken carefully and were intended to be relied upon. AUK and Teva made their forecasts for the purpose of deciding whether to invest large sums of shareholders' money on attempting to enter this market. AUK and Teva were sophisticated firms, experienced in UK generics markets. The Advanz forecasts were developed at the request of Concordia's Board of Directors in Canada. Advanz knew more about this market than anyone else. It stood on the cusp of a major change in a market that was very important to it.

(2) AUK's projection that, if its own entry reduced the price level to £25, there would be no room for further entry because the price would be too low for other manufacturers to incur the costs of entry, had proved to be correct: no other credible entrant was interested in entering before AUK and Morningside and no credible entrant has built a business plan envisaging prices below the level projected by AUK.

(3) Teva's forecast was sophisticated. It did not simply take the prevailing price, or apply a mechanical discount to that price. Rather, it assumed a discount based on the assumed level of generic competition: "low" (meaning one or two generic competitors) in the first year, "medium" in the second year (meaning 3-4 competitors) and "high" (meaning five or more competitors) in the third year.

(4) The forecasts confirmed that market participants perceived stronger incentives for cutting prices when prices are higher. That was significant because it reduced the impact of the prevailing pre-entry price on the price levels that were produced after entry. The forecasts showed that these market participants expected competition to drive down prices. They were remarkably consistent in their end points. The main difference was that Advanz's forecast had a range, whereas each of Teva and AUK only forecast single end points.

(5) The CMA's criticism of reliance on the forecasts on the basis that they were short term was ill-founded. Three years is not short term. It is commonly used in empirical literature on generic prices. The forecasts were broadly consistent with the patterns observed in the empirical literature on generics and therefore contradict the CMA's suggestion that the forecasts were contaminated by prices during the Infringement Period.

(c) The CMA's response

332. The CMA reiterated the arguments made in the Decision for rejecting the Price Forecasts as reliable comparators.

333. First, it contended that the Price Forecasts did not provide indicators of the outcome of normal and sufficiently effective competition as they were contaminated by the abusive prices charged in the Infringement Period.

334. Second, it contended that the Price Forecasts were short term and gave no indication about the long-run price level in a competitive market. They were designed to assist (in Teva and AUK's case) in predicting the recovery of a particular entrant's entry. What they showed, according to Professor Valletti, was the "payback method" of how long it would take for undertakings to recover initial outlays and initial entry costs. They did not provide indicators of the outcome of normal and sufficiently effective competition.

335. Third, the CMA drew attention to the fact that the authors of the forecasts had themselves highlighted limitations in the forecasts. AUK stated that the document in question, a price projection model, contained a simple model calculating a single price which was not intended to be any kind of accurate, long-term forecast. The 40% price drop was not to be read as an estimate by AUK of changes to market-wide prices post launch, but just an assumed approximation of its own net selling prices on entry which would need to be revisited: Teva stated that the CMA should not treat its pro forma Product Evaluation Form as a sophisticated tool to make predictions or model pricing and it was very much a forecast at a particular point in time based on information available to it at that time. Advanz noted that the estimates underlying its forecast were very broad and basic economic assumptions that would apply to any molecule and were not specific to Liothyronine Tablets.

(d) The Tribunal's conclusions

336. Each of the forecasts took as their starting point the then current price charged by Advanz during the Infringement Period, £39.28, £64.06 and £247.74. They show a subsequent three-year trajectory during which these starting prices unwound.

337. The forecasts were thus in part based on, and influenced by, prices which we have concluded were excessive. If we were to treat the forecasts as a guide to a fair, workably competitive price, it would effectively bake in or legitimise those excessive prices.

338. The Appellants did not suggest that the forecasts were other than short term predictions of price movements after entry. They were not intended to be, and were not, estimates of the price that could be charged under conditions of normal competition. As noted by Professor Valletti, in the case of Teva and AUK the purpose of the forecasts was to predict the recovery of entry costs, enabling them to make a rational decision to enter the market.

339. The Appellants' emphasis on the three-year time span of the forecasts as being a sufficiently long period begs the question whether a price point reached three

years after entry is reflective of the price that could be expected to emerge under conditions of normal competition. The pattern of Post-Entry prices in this case shows, on the contrary, that given the price stickiness in this market, even five years post entry, prices are still falling significantly meaning that there is insufficient evidence that a stable, workably competitive price has emerged.

340. The fact that the forecasts are widely divergent further undermines their utility as a benchmark of a workably competitive price. The Tribunal does not accept that at their endpoints the forecasts were "remarkably similar". Teva's endpoint was £35.90. AUK's £24.68 (i.e. a difference of some 50%) and Advanz's a range of £28 to £80.

341. Finally, the disclaimers issued by the Parties in relation to the price forecasts are a further indication that they should be treated cautiously and not as a long-term pricing benchmark.

342. For these reasons, we consider that the CMA was right to reject the price forecasts as comparators for the purposes of assessing the fairness of Advanz's prices.

(4) Levothyroxine Oral Solution

343. The Cinven Appellants argued that levothyroxine oral solution, which is an oral solution form of levothyroxine administered to those who have difficulties taking a tablet form – was a better comparator for the pricing of Liothyronine Tablets than levothyroxine tablets. Dr Bennett's uncontested evidence was that levothyroxine oral solution was priced up to 1.7 times Liothyronine Tablet prices in 2020.

344. The Decision had considered whether levothyroxine oral solution was relevant to the question of the economic value of Liothyronine Tablets and concluded that it was not. This was on the basis that the pricing premium attaching to levothyroxine oral solution was generated by a specific demand-side factor, namely the need for those patients for whom the drug was prescribed to take the drug in oral form. This was very different from Liothyronine which is not sold

in oral solution format and would not be expected to generate a similar premium. The Decision also found that there were materially different supply issues applicable to levothyroxine oral solution in that there are specific difficulties associated with its manufacture which make it more expensive to produce.

345. Dr Bennett considered that oral solution prices were informative as to Liothyronine tablet prices because: (i) both sets of products are hard to make; (ii) oral solutions typically have small volumes like Liothyronine Tablets; and (iii) oral solutions are generally second line drugs like Liothyronine Tablets. Dr Bennett relied in particular in this regard on levothyroxine oral solution since it is also used to treat hypothyroidism patients. In response, the CMA pointed out that Dr Bennett did not undertake any comparative assessment of the costs and difficulties of producing levothyroxine oral solution and Liothyronine Tablets to check whether they were suitable comparators. Ms. Jackson's view was that the exercise of using another specific product as a comparator was inherently very difficult given the need to check that things really are comparable.

346. In the Tribunal's view, levothyroxine oral solution was not a valid comparator for the pricing of Liothyronine Tablets for the reasons given by the CMA. Nor is the Tribunal persuaded that it is a more similar product to Liothyronine Tablets than is levothyroxine tablets. The tablets are very similar in their manufacturing process in contrast to the oral solution, the manufacture of which gives rise to unique difficulties as described in the Decision.

(5) Conclusion

347. For the reasons set out above, we reject the Appellants' grounds of appeal based on the contention that the CMA was wrong to reject as valid comparators Post Entry Prices, Price Forecasts, Entry-Incentivising Prices and levothyroxine oral solution or that the CMA's reliance on its Cost Plus model, in preference to these comparators, was misguided. We have concluded that the comparators were not reliable indicators of the economic value of Liothyronine Tablets and did not reflect the price of Liothyronine Tablets that would be achieved in conditions of sufficiently effective, workable competition.

348. We also reject Advanz's ground of appeal that the CMA's Cost Plus model ignores fundamental policy considerations applicable to, and the nature of, the generics industry. We consider that Cost Plus is an appropriate benchmark for determining a competitive price in generic markets, characterised as they are by low levels of innovation. We agree with the CMA that there are no policy considerations which absolved Advanz from its special responsibility as a dominant supplier of Liothyronine Tablets not to abuse its market power.

349. In our judgment, the CMA's conclusion in the Decision, after taking account of the comparators advanced by the Appellants, that Advanz's prices for Liothyronine during the Infringement Period were both excessive and "unfair in themselves" was the right one having regard, in particular, to the substantial disparity between Advanz's prices and the economic value of the Liothyronine Tablets, the lack of any independent or objective justification for the price increases, the purpose of Advanz's pricing strategy which was to exploit the lack of regulatory or competitive constraints, as evidenced by the facts set out in the factual background above, and the significant adverse impact of the prices on the NHS.

350. We reject Hg's contention that the CMA was wrong to treat Advanz's commercial strategy as relevant to an assessment of its abusive conduct. There is nothing inherently objectionable about increasing prices but Advanz was dominant during the infringement period and, as such, had a special responsibility in relation to how it priced Liothyronine Tablets, given the lack of competition and low demand elasticity. An anti-competitive intent, while not sufficient in itself to constitute abuse, constitutes a fact that may be taken into account in order to determine that a dominant position has been abused; *Generics (UK) Ltd and Others v CMA*, C-307/18, at paragraph 162.

I. ISSUE (3): COUNTERVAILING POWER

351. The comparators relied upon by Hg and Cinven, i.e. Post-Entry Prices, Price Forecasts and Entry-Incentivising Prices, would not justify the much higher prices charged during the Advanz period. Advanz Pharma did not call any economic expert to support its case and the economic experts called by Hg and

Cinven did not attempt to defend those prices. Advanz Pharma relied instead on two alternative grounds of appeal against the Decision. The first of these was that the DHSC/NHS held countervailing buyer power to such an extent that it negated any allegation that Advanz acted independently of the DHSC/NHS in terms of pricing and hence negated Advanz's alleged market dominance.

(1) The Decision

352. In the Decision, the CMA considered and rejected the Appellants' argument that the DHSC/NHS held countervailing market power. The absence of countervailing power was said to be clear from Advanz's pricing behaviour in increasing its prices by over 6,000% without losing sales volumes.

353. In rejecting the Appellants' case on countervailing market power, the CMA relied on the following propositions derived from a number of authorities including the Tribunal's judgments in *Hutchison 3G (UK) v Ofcom (Hutchison 3G (UK) v Ofcom* [2005] CAT 39, *National Grid* [2009] CAT 14 and *Phenytoin* and the judgement of the Court of Justice in Case C-280/08 *Deutsche Telekom v Commission*). These propositions were not disputed by the Appellants.

(1) When considering the issue of the DHSC's countervailing market power, the focus should be on whether there is an effective constraint rather than the theoretical position.

(2) To be an effective constraint on behaviour there has to be a real possibility that this pressure will be exercised in practice and to a sufficient extent.

(3) The question is not just the presence or absence of countervailing buyer power but the degree of such countervailing buyer power and the extent to which it operated as constraint on the undertaking's ability to exert market power.

(4) The DHSC's buyer power consisting of its power to intervene in drug pricing is better described as a form of regulatory power. The relevant

question is whether the DHSC was, as a matter of fact (in the particular case), able to exercise buyer power in the form of regulatory power materially to influence pricing.

(5) The prospect of regulatory intervention by the DHSC/NHS did not negate the possibility of dominance.

(2) Advanz Pharma's case

354. Ground 2 of Advanz Pharma's appeal was that, contrary to the CMA's conclusion in the Decision, the DHSC/NHS did have effective market power to constrain prices.

355. In its Notice of Appeal, Advanz Pharma stated that it is difficult to conceive of an example of greater countervailing buyer power than in the case of the DHSC/NHS, which it described as a sole purchaser possessing the power to control prices charged to it by its suppliers. The DHSC/NHS could have objected to any price increase, had it wanted to, and Advanz believed that it could do so. Advanz was aware of a previous, informal, intervention by the DHSC/NHS in 2007 in relation to the price of another unbranded generic drug, namely Teva's phenytoin tablets. This was clear evidence of the extent of the DHSC/NHS' ability to intervene to control price when it wants to, and therefore of its countervailing power.

356. Advanz Pharma argued that during the Infringement Period the DHSC/NHS possessed effective powers of intervention, both statutory and informal, which enabled it to exercise control over the price level of drugs purchased by the NHS, if it so wished. In practice, the DHSC/NHS could have compelled or persuaded Advanz to reduce its price, and the threat to use such power was sufficient to constrain Advanz's behaviour.

357. The DHS/NHS countervailing power was said to arise, first, from the statutory powers conferred by the following sections of the National Health Act 2006:

"**261 Powers relating to voluntary schemes**

"(1) The powers under this section may be exercised where there is in existence a scheme (referred to in this section and sections 262 and 263 as a "voluntary scheme") made by the Secretary of State and the industry body for the purpose of (a) limiting the prices which may be charged by a manufacturer or supplier to whom the scheme relates for the supply of any health service medicines, or (b) limiting the profits which may accrue to any manufacturer or supplier to whom the scheme relates in connection with the manufacture or supply of any health service medicine.

(2) For the purposes of this section and sections 262 and 263, a voluntary scheme must be treated as applying to a manufacturer or supplier to whom it relates if – (a) he has consented to the scheme being so treated (and has not withdrawn that consent); and (b) no notice is in force in his case under subsection (4).

(4) If any acts or omissions of any manufacturer or supplier to whom a voluntary scheme applies (a "scheme member") have shown that, in the scheme member's case, the scheme is ineffective for either of the purposes mentioned in subsection (1), the Secretary of State may by a written notice given to the scheme member determine that the scheme does not apply to him.

(8) The Secretary of State may (a) prohibit any manufacturer or supplier to whom a voluntary scheme applies from increasing any price charged by him for the supply of any health service medicine covered by the scheme without the approval of the Secretary of State, and (b) provide for any amount representing any increase in contravention of that prohibition in the sums charged by that person for that medicine […] to be paid to the Secretary of State within a reasonable time."

262 Power to control prices

"(1) The Secretary of State may, after consultation with the industry body

(a) limit any price which may be charged by any manufacturer or supplier for the supply of any health service medicine…".

(2) The powers conferred by this section are not exercisable at any time in relation to a manufacturer or supplier to whom at that time a voluntary scheme applies."

358. Advanz Pharma relied, in particular, on:

(1) the power under section 262(1) to limit prices, subject to any voluntary scheme concluded by the DHSC/NHS;

(2) the power under section 261(4) to eject a member from a voluntary scheme if the scheme was considered ineffective to limit prices or the profitability of the scheme member; and

(3) the further reserve power under section 261(8) to limit any further price increase of a medicine even if the prices had permissibly risen under the voluntary scheme.

359. Advanz Pharma relied further on the powers available to the DHSC/NHS under Scheme M. During the Infringement Period, Scheme M, referred to at paragraph 27 above, was a voluntary scheme within the meaning of section 261 of the 2006 Act. Advanz was a Scheme M member and Liothyronine Tablets were a Scheme M medicine. Advanz Pharma characterised Scheme M as resting on four principles: (i) the promotion of a multi-firm, competitive pharmaceutical market for generic drugs; (ii) a continuous and secure chain for generic drugs; (iii) freedom of pricing for generic companies; and (iv) the DHSC/NHS retaining overall power to control an unfair price. They highlighted paragraph 30 of Scheme M, which reflected the DHSC's power to intervene pursuant to section 261(8) of the 2006 Act:

> "Wherever possible, the Department will allow changes in market prices to be influenced by existing market mechanisms. This means that, where there is effective competition in respect of any given generic medicine, then the Department will not interfere in the operation of the market for that medicine. However, should the Department identify any significant events or trends in expenditure that indicate the normal market mechanisms have failed to protect the NHS from significant increases in expenditure, then the Department may intervene to ensure that the NHS pays a reasonable price for the medicine(s) concerned."

360. Under paragraph 31 of the Scheme, Advanz was obliged to provide the DHSC/NHS with details of cost data and profit margins in order to enable the DHSC/NHS to determine whether the DHSC/NHS was paying a reasonable price for Liothyronine. Paragraphs 35 – 41 of the Scheme provided for a dispute resolution process.

361. Advanz Pharma submitted that, notwithstanding the lack of action on the part of DHSC/NHS, Advanz was sufficiently wary that it would exercise its powers under statute and/or Scheme M that it was obliged to constrain its price conduct

and was unable to impose excessive and unfair prices. Advanz Pharma argued that this constraint arose because the DHSC/NHS was aware of Advanz's price increases, and that both Advanz and the DHSC/NHS considered that the latter had formal and informal powers to cap or reduce Advanz's prices and would do so if Advanz's price rises were considered to be unacceptable.

362. Mr Beighton referred to a meeting with the DHSC in or around October 2007 when he was working for Teva. This meeting followed an increase in the price of Phenytoin tablets which prompted intervention. Teva was told at the meeting that the price had to be reduced and that if Teva did not cooperate they had the power to bring the price down themselves. As a result of the meeting, the price was substantially reduced. Mr Beighton said that when he moved to Advanz, he took with him his knowledge and experience of the intervention. His evidence was that Advanz's understanding was that the DHSC could intervene on price and that the higher the price or the greater the price increase, the higher the likelihood of the DHSC intervening.

363. Mr Beighton cited certain internal documents reflecting such understanding, including a presentation prepared for Cinven's acquisition of Mercury in August 2012, which stated that "price increases are possible, although the threat of […] intervention from DHSC means price increases need to be managed carefully" and an internal email dated 27 May 2013 in which the commercial services director of the company had said that he had "not proposed big price increases, wherever I had a fear that this may attract DH notice or other companies may like to launch those products".

364. The evidence of Mr Williams was that the DHSC/NHS had the power to intervene on the issue of the price of Liothyronine in three separate ways, by the power of intervention under Scheme M, by the reserve powers it had or thought it had under the 2006 Act and by its informal bargaining power as Advanz's only customer. The powers of the DHSC/NHS under Scheme M to receive detailed supporting financial and other information and to challenge a price were effective constraints. If a company refused to provide such information it would lose Scheme M membership and thereby severely damage its relationship with the

DHSC/NHS, its only customer. If necessary, the DHSC/NHS could have implemented the dispute resolution process under Scheme M.

365. Advanz Pharma sought to distinguish *Phenytoin*, in which the Tribunal had concluded that the DHSC did not, and was not able to, exercise buyer power in a way that effectively constrained Pfizer or Flynn's conduct on two grounds. First, on the basis that Flynn Pharma was not a member of Scheme M and therefore the DHSC/NHS had to fall back on its reserve powers, the extent of which were at the time subject to some debate.

366. Second, on the basis that relevant documents were not disclosed to the Tribunal in *Phenytoin* which were said to have supported the testimony of Mr Beighton as to the meeting between the DHSC/NHS and Teva in 2007. These documents were said to show that the DHSC would have been in no doubt about the extent of its formal and informal powers to reduce or constrain drug prices. One of these documents was an internal DHSC email exchange in July 2013 in which the author, an official with responsibility for pricing, referred back to the meeting in 2007, noting that consideration had been given to ejecting Teva from Scheme M and enforcing a maximum price by direction of the Secretary of State. The same individual was closely involved in the monitoring of Advanz's prices in 2013 and present at a meeting when the possible ejection of Advanz from the PPRS was mentioned.

367. After the hearing of the appeal had concluded, Advanz Pharma supplied the Tribunal with copies of two sets of correspondence from 2015. The first was between (1) the DHSC (Elizabeth Woodeson) and Professor John Wass, Chair of the Clinical Reference Group for Specialised Endocrinology concerning the prices for endocrinology medicines (which include Liothyronine and Hydrocortisone); and (2) an unnamed person at the DHSC and Philip Cowen, Professor of Psychopharmacology, concerning the pricing by AMCo of another generic medicine, […][✂], an anti-depressant. The correspondence was obtained from the DHSC following a Freedom of Information Request made on behalf of Advanz Pharma. Advanz Pharma submitted that correspondence showed that the DHSC was aware of, and was monitoring, price increases for Scheme M medicines and that the DHSC knew that it could intervene on price

whether under its statutory powers ("…we have the legislative provisions to intervene with regard to prices of medicines") or under Scheme M, if it wanted to, and that the DHSC rejected requests to intervene in respect of these price increases because it thought that despite some recent "large price increases for a small number of medicines, the system, on balance, works well for the majority of products."

368. Advanz Pharma criticised the CMA for failing to disclose the correspondence during either the administrative proceedings or the appeal proceedings and for framing its document requests to the DHSC too narrowly. The CMA's response to this criticism was that it had seen the correspondence for the first time when it was provided by Advanz Pharma, that its disclosure requests had been sufficient and that Advanz Pharma had had ample opportunity to make representations about the CMA's document requests during the administrative proceedings but had failed to do so. Advanz Pharma contended that the CMA's reasons for the failure to disclose the documents were inadequate and that it had raised concerns with the CMA about its failure properly to engage with the DHSC/NHS in order to obtain contemporaneous evidence, its failure to interrogate the sufficiency of the DHSC's disclosure, and its failure to make full and frank disclosure.

(3) Cinven's arguments about the DHSC

369. Cinven did not join Advanz Pharma in contending that the DHSC/NHS's countervailing market power negated Advanz's market dominance or that the DHSC/NHS acquiesced in Advanz's pricing but it did contend that the CMA failed properly to assess the DHSC's powers in respect of direct and indirect measures to control generic prices. Cinven argued that the CMA had had very little, if any, engagement with the DHSC as to how, in practice, it dealt with generic pricing matters. Cinven referred to the fact that the DHSC decided, in 2005, to adopt a market-based approach to generic pricing, stating that its expectation was that where there was competition in the supply of generics, this "*should deliver a competitive and fair NHS price*." It argued that the DHSC could have introduced a statutory scheme for generic medicines and that the CMA did not probe the DHSC as to why it had failed to do so or as to why it had failed to exercise its powers to regulate the price of Liothyronine Tablets in the post-

Infringement period. Cinven also contended that there was also a striking paucity of DHSC-related documentation on the CMA's Case File, and rights of defence concerns arose as to whether the CMA has disclosed all relevant material, particularly exculpatory material.

(4) The CMA's response

370. The CMA rejected the notion that the DHSC/NHS had sufficient countervailing buyer power to exclude the possibility that Advanz was dominant. It contended that it was clear from Advanz's pricing behaviour – essentially an increase in the price of Liothyronine Tablets by over 6,000% without loss of sales volumes – that its conduct was clearly not effectively constrained by countervailing buyer power during the Infringement Period. The CMA observed that the NHS/DHSC did not in fact use Scheme M or any other regulatory power, to impose any constraint on Advanz's prices during the Infringement Period. Mr Williams, Advanz Pharma's expert, made the same observation.

371. The CMA referred to the fragmented composition of the NHS which limited the NHS's ability to exercise buyer power. Decisions on the selection and dispensing of drugs were not made by the entity responsible for paying for the drugs. The CCGs, which were the entities responsible for paying, had no choice over whether to purchase or pay for drugs. The price payable by the CCGs was not determined, negotiated or agreed by the CCGs. Once a prescriber had written a prescription for a particular pharmaceutical product, the relevant CCG had no choice but to fund the medicine dispensed against that prescription. There was no challenge by Advanz Pharma to the findings in the Decision concerning the NHS's fragmented decision making process.

372. With regard to the DHSC's power to intervene in Scheme M arrangements, the CMA submitted (as it had concluded in the Decision) that the DHSC had in practice limited resources and only a small team responsible for procurement. Moreover, the DHSC had competing priorities and focused its efforts on controlling the price of expensive on-patent drugs, as Mr Beighton accepted in cross-examination. Moreover, it would have been difficult for the DHSC to identify significant events or trends in expenditure of Liothyronine since only a

very small proportion of overall expenditure of the primary care spending was devoted to this product. Even if the DHSC had managed to spot the market failure, it could not simply impose a lower price on scheme members. Any intervention could be challenged, triggering the dispute resolution procedure. This involved the appointment of a dispute resolution panel rather than an immediate decision. It was common ground that paragraph 30 of Scheme M was never in fact invoked against Advanz during the Infringement Period.

373. As to the powers under the 2006 Act, the CMA pointed out that s 261(8) was not in force during the Infringement Period and therefore could not have been used without enabling legislation (which was not introduced until after the Infringement Period). The reserve power in s 262(1) was, as noted above, subject to s 262(2), which during the Infringement Period provided that s 262(1) was not exercisable at any time in relation to a manufacturer or supplier to whom at that time a voluntary scheme applied. Therefore it could not be used against Advanz, which was a member of both the PPRS (also a voluntary scheme) and Scheme M. The power in s 262(1) could only have been exercised if the DHSC had ejected Advanz from both such schemes, which would have resulted in all Advanz's branded and unbranded drugs being excluded. It was, moreover, questionable whether the power to eject Advanz from the PPRS could have been exercised on the basis of Advanz's pricing of Liothyronine Tablets. The Tribunal had reached the same conclusion with regard to *Genzyme* and the equivalent power under section 33 of the Health Act 1999.

374. The Government's view was likewise that the reserve power under section 262(2) could not be exercised against a member of Scheme M which was also a member of the PPRS. A factsheet issued by the DHSC in November 2016 commenting on the Health Service Medical Supplies (Costs) Bill, which was intended to close this loophole, stated as follows:

> "… if companies have a mixed portfolio with both branded medicines and unbranded generic medicines and the company has joined the PPRS, no statutory controls can be applied to their unbranded generic products.
>
> The Bill amended the National Health Service 2006 Act to enable the Secretary of State to require companies to reduce the price of an unbranded generic medicine, or impose other controls on that company's unbranded generic medicines, even if the company is in the voluntary scheme for their branded

> medicines. The government intends to use this power to limit the price of unbranded generic medicines where competition in the market fails and companies charge the NHS unreasonably high prices for these products."

375. The CMA further submitted that Advanz was aware of the practical realities facing the DHSC/NHS in the effective use of their respective powers. In the Decision, the CMA pointed to the internal investor document from 2012 quoted at paragraph 39 above pointing out that the prescriber (the doctor), the payor (NHS) and the customer (the pharmacy wholesale channel) were all different and would have difficulty in reducing prices, especially on small products. The CMA also referred to the Project Asclepius document dated December 2014 stating that the UK was a free priced market for generics which allowed for price increases for the right products with no price ceiling for Liothyronine Tablets, being a non PPRS drug. The CMA submitted that Advanz's knowledge of the meeting between the DHSC and Teva (through Mr Beighton) did not in fact constrain its pricing decisions; Mr Beighton fairly accepted that the Teva meeting with the CMA was the only example of which he personally was aware during the Infringement Period, although he said that he had heard of other incidents since.

376. In its Defence, the CMA rejected the arguments advanced by Cinven that the CMA failed adequately to interrogate the DHSC/NHS or to press the DHSC for disclosure.

(5) Conclusion

377. It was common ground that, in order to be relevant to the assessment of an undertaking's market dominance, a buyer's, countervailing power must be effective.

378. Thus it would not be sufficient, in order for Advanz Pharma to negate Advanz's dominance in the supply of Liothyronine Tablets, to show that the DHSC/NHS had some market power. To succeed, Advanz Pharma must show that the effect of such power was to constrain Advanz in its pricing conduct. The need to show effective restraint is particularly acute in his case given that (as was common ground) the DHSC/NHS did not in fact take any steps to constrain Advanz's

pricing other than to place Liothyronine on the DROP-list in 2015 and to refer the matter for investigation by the CMA following an investigation by The Times newspaper in June 2016.

379. The DROP-list was a list of drugs to review for optimised prescribing. It comprised a number of products organised in order of their cost to the NHS that commissioners considered as being "low priority, poor value for money or for which there were safer alternatives." It was maintained by PrescQIPP, an NHS funded not-for-profit organisation in which the CCGs participated, and which supports quality, optimised prescribing for patients. Liothyronine was placed on this list because PrescQIPP was of the view that there was no consistently strong evidence for its superiority over an alternative product, levothyroxine in improving health outcomes.

380. The inclusion of Liothyronine on the DROP list did not however prevent physicians from prescribing the drug and Mr Beighton had not expected that it would have had such an effect. When cross-examined he stated that he "would be very surprised that UK physicians were taking patients off any medicine that […] would cause them harm to do so" and "I do not believe it was harming patients by increasing prices. The drug was still available to be dispensed and reimbursed." It continued to be prescribed and reimbursed, as Advanz's global marketing manager stated in an internal email of 6 June 2016, when he was questioned about the impact of being placed on the DROP-list. He stated that it was "[b]usiness as usual. We have seen a very small volume decline over the last 18 mths but it is very small (1-2%)." In an email dated 29 June 2016 he confirmed that the DROP-list had had no impact on sales volumes.

381. The fact that the inclusion of Liothyronine in the DROP-list appears to have minimal effect on prescriptions by physicians is a further indication of the fragmented composition of the NHS limiting its ability to exercise buyer power, as found by the CMA in the Decision. There was no challenge to this finding.

382. We accept the CMA's argument that it would not have been straightforward for the DHSC to exercise the reserve power under s 262(1) to control the price of Liothyronine Tablets because, on the face of the legislation, the power to do so

was not exercisable in relation to products of a member of a voluntary scheme and Advanz was at all material times a member of the PPRS.

383. In our view, Advanz's membership of Scheme M does not assist Advanz Pharma to demonstrate that the DHSC or the NHS had countervailing power in accordance with the relevant legal principle. As the CMA pointed out, the power to intervene under section 30 was not a unilateral power to set prices since any attempt to control prices could be resisted and trigger a dispute resolution procedure requiring the appointment of three-person panel. There was no evidence that the DHSC threatened to use its power to intervene under paragraph 30 of Scheme M or even alerted Advanz to the possibility that it would be exercised against Advanz.

384. Although Advanz Pharma referred to evidence that officials within the DHSC were aware of the power to control prices, there does not appear to have been any clear view within the DHSC that it had the ability effectively to restrain prices. The internal communication dated 3 June 2013 referred to above, sent in response to a price increase notification relating to Liothyronine and several other Advanz products, records the DHSC official noting that the notifications were of "big increases without them having to provide any justification – they [i.e. Advanz] have us over a barrel." The official went on to ask: "is this sort of thing included in your investigation into phenytoin or others?" It was argued on behalf of Advanz Pharma that, rather than being a reference to the DHSC officials' understanding that they lacked legal powers to restrain the notified price increases, the expression "they have us over a barrel" was more likely to have been a reference to the fact that Liothyronine was supplied by only one manufacturer, so the drug tariff price would automatically follow the price increase. We disagree; on any reasonable interpretation of this document, it shows that the DHSC did not have a clear understanding that it or the NHS had a clear and effective route to limit Advanz's prices or had communicated such a belief to Advanz.

385. The view of the DHSC as to the limited extent of its statutory powers was clearly expressed in its November 2016 guidance on the Health Service Medical Supplies (Costs) Bill. As stated above, the DHSC regarded the amendments to

then current legislation to be required in order to give the Secretary of State sufficient powers to reduce the price of an unbranded generic medicine of a company that is a member of a voluntary scheme for their branded medicines.

386. We accept that is theoretically possible that a countervailing constraint may arise as a result of a dominant undertaking believing that a buyer has greater power to constrain its prices than the buyer believes it has. As the Decision recognised, there was some apprehension within Advanz that the DHSC might intervene in the price of Liothyronine Tablets. For example, in the document entitled Project Glacier - Final Report General Business Plan and Pipeline Validation Report 21 May 2012 it was stated that:

> "… there is a risk that the DoH could decide the tariff price is too high considering the overall cost to the NHS of levothyroxine, and force a discussion to cap price (Note: the likelihood and extent of DoH intervention is unknown: this has been very rare event so far, most notably, the DoH forcing a price reduction of phenytoin to ensure that clinical practice was driven by efficacy and not cost)."

387. Similarly, in Cinven minutes of a meeting of its investment committee in July 2012, referred to from paragraph 39 above, it was stated that the small group responsible for reimbursement of drug manufacturers within the DHSC was focused on high volume drugs (patent and off-patent) while niche products were typically below the radar. However, as the Decision found, this general apprehension did not prevent Advanz from continuing to raise the price of Liothyronine Tablets. Moreover as the authorities above make clear, the potential for economic regulation is not a competitive restraint in itself.

388. We do not consider that the correspondence with the DHSC obtained by Advanz Pharma after the conclusion of the hearing, which we have taken into account, assists Advanz Pharma's case in showing that the DHSC exercised effective restraint on Advanz's pricing of Liothyronine Tablets. In one email, the DHSC stated that it had the legislative power to intervene with regard to the price of medicines but the email went on to say that any investigation would require detailed exploration to be able to make a judgment as to what would be an appropriate price and that the DHSC preferred to give parties freedom of pricing. The correspondence with Ms Woodesen referred in general terms to the freedom

of pricing for generic drugs under Scheme M, a system which was said to work well for the majority of products but it did not make clear how closely the prices of individual drugs were monitored and there was no suggestion that the DHSC would intervene to restrain the prices of drugs in Scheme M.

389. The Tribunal has also considered the criticisms made by Cinven concerning the CMA's failure to interrogate the DHSC or to press it for disclosure. The Tribunal considers that these criticisms were adequately addressed in the CMA's Defence. The Tribunal is not persuaded that its investigation of the DHSC infringed the Cinven Entities' rights of defence.

390. In summary, the Tribunal concludes, as it did in *Phenytoin*, that there was no effective constraint on Advanz's conduct exercisable by the DHSC/NHS, and that the DHSC/NHS did not therefore have countervailing buyer power. The grounds on which Advanz Pharma sought to distinguish *Phenytoin* - Advanz's membership of Scheme M and the documents that were not available to the Tribunal in *Phenytoin* - were not compelling. Scheme M did not confer on the DHSC an effective power to restrain Advanz's prices. The undisclosed documents did not demonstrate that the DHSC had any intention to use formal or informal powers in relation to Liothyronine or somehow communicated such an intention to Advanz.

391. In short, the reasoning of Newey LJ in his order refusing permission to appeal on the issue of countervailing power in *Phenytoin* is also apt in this case:

> "… both the case law and common sense show that the focus should be on whether there is an *effective* constraint rather than the theoretical position, and Case C-280/08 *Deutsche Telekom v Commission* confirms that the failure of the Department to exercise any powers it may have had could not have absolved the appellants from their "special responsibility not to allow their conduct to impair genuine undistorted competition."

J. ISSUE (4): ACQUIESCENCE

(1) The parties' arguments

392. This ground of appeal was based on what was said to be a general principle of acquiescence laid down by the Tribunal in *Genzyme Limited v Office of Fair*

Trading [2004] CAT 4 ("*Genzyme*") and which was said to be applicable to the DHSC/NHS when purchasing medicines.

393. According to Advanz Pharma, there are three main conditions which need to be satisfied for the principle of acquiescence to apply: first that the DHSC/NHS was aware of the several price increases during the infringement period; secondly, that the prices charged to the sole customer were a matter of policy to which the DHSC/NHS might properly address itself; and thirdly, that the DHSC/NHS made no complaint or criticism of those increased prices. Advanz Pharma contended that these conditions were satisfied on the facts of this case.

394. In response, the CMA submitted that Advanz's interpretation of the Tribunal's judgment *Genzyme* was wrong as a matter of law. It contended that the judgment did not lay down any principle of acquiescence. Moreover, it contended that there was in fact no acquiescence on the part of the DHSC/NHS.

(2) Genzyme

395. In *Genzyme*, the Tribunal found that Genzyme was dominant in the supply of a branded pharmaceutical (Cerezyme). The OFT objected to Genzyme bundling the price of this drug with the price of homecare services which included, amongst other services, the delivery of the of the medicine to patient's homes, as the list price contained both the product and the service. The OFT contended that the bundle price constituted an abuse of a dominant position.

396. In order to determine whether the Tribunal established a principle of acquiescence of the kind argued by Advanz Pharma, it is necessary to look at the Tribunal's *Genzyme* judgment in some detail. It is critical to an understanding of that judgment to note that the Tribunal divided the overall alleged infringement period into two shorter periods, and that the nature of the alleged abuse differed as between those two periods.

397. The first period was from March 2000 to May 2001. As the Tribunal confirmed in [527] of its judgment, the only alleged abuse during this period was that Genzyme had offered a bundled price for its drug Cerezyme, indicated for

Gaucher patients, by the inclusion of homecare services for those patients within the NHS list price of the drug.

398. The Tribunal found that there was no evidence that during this first period the NHS (a) wished to purchase such services from any other provider; or (b) approached Genzyme, either to seek a choice of provider, or to propose any change in the pricing of the drug, for example through the unbundling of the homecare services from the drug price. The NHS had known about Genzyme's practice in this regard for some time and raised no specific objection to it when it was specifically informed of it in 1999. There was evidence that such a practice was not entirely uncommon where homecare services were supplied in conjunction with certain drugs, at least during the 1990s.

399. The Tribunal concluded that, in those circumstances, "[w]hatever the precise scope of the 'special responsibility' of a dominant undertaking, we are reluctant to hold that Genzyme acted in breach of its special responsibility during the period March 2000 to May 2001 when its only customer, the NHS, passively acquiesced in Genzyme's practice, and raised neither complaint nor criticism in that regard." (at [543]).

400. Summarising its findings on this first period, the Tribunal said:

> "547. However, we doubt whether, in respect of that period, it is sufficiently proved that Genzyme's potentially anti-competitive conduct is to be characterised as an abuse for the purposes of the Chapter II prohibition, having regard to the facts that, during that period (a) there is no evidence that the NHS sought an alternative provider to Healthcare at Home, or that any other homecare services provider sought to obtain Cerezyme from Genzyme on discounted terms or otherwise; (b) the NHS knew of, and acquiesced in, Genzyme's practice of including Homecare Services in the NHS list price of Cerezyme; (c) it is not shown that Genzyme acted contrary to any aspect of the NHS system in including Homecare Services in the NHS list price for Cerezyme; and (d) it is not obvious how Genzyme would have been remunerated for the supply of Homecare Services had it "unbundled" the list price of Cerezyme, other than by virtue of a separate contract with the relevant hospital or PCT, but no body on behalf of the NHS ever sought or suggested any such separate contract.
>
> 548. In all these circumstances the effect on competition of Genzyme's "bundling practice" in the period March 2000 to May 2001, although theoretically established, is not proved to have had a sufficient adverse effect on competition, in the particular circumstances of this case, to be characterised as an abuse for the purposes of the application of the Chapter II prohibition."

401. In the first period, therefore, the Tribunal concluded that there was no abuse because no anticompetitive effect arose from the conduct. The NHS was content with a bundled package under which it purchased both the drug and the homecare services, it provided no practical means for an unbundled service to be appropriately remunerated, no hospital or trust had requested an alternative service provider for relevant patients, and no alternative provider had requested a supply of the drugs for such purposes. The NHS's attitude to Genzyme's "bundling practice" was one of the facts relevant to the Tribunal's finding that this practice did not have an adverse effect on competition. Advanz Pharma argued that this is a principle of universal application, at least where the acquiescing party is the NHS and the DHSC, and not one specific to the facts outlined above. We do not accept this. As noted by the CMA, the Tribunal's earlier summary of the legal principles it was applying (at paragraphs 482 – 499) did not mention any principle of acquiescence.

402. In contrast to the first period, the conduct in the second period concerned Genzyme's pricing policy in relation to the sale of its drug to an independent undertaking that had previously been Genzyme's exclusive homecare service provider. Having determined to enter the homecare services market itself, Genzyme agreed to supply the drug to that provider at the same price at which it sold the bundled package to the NHS. The Tribunal found that it was likely to be wholly uneconomic for that undertaking to provide homecare services at no effective margin between its buying and selling price of the drug. The conduct in question was assessed as a margin squeeze, the effect of which was to force the service provider to sustain a loss in the provision of the services.

403. The intention of Genzyme was therefore found to be to eliminate competition from the relevant market, as the NHS would have had to pay additionally for services provided by any undertaking other than Genzyme. It would have required the NHS to pay Genzyme for services it was not receiving from it and then pay again for the services provided by its competitors. The Tribunal found at [558] that it was "abundantly clear […] that Genzyme's pricing policy since May 2001 has been adopted with the intention of reserving to Genzyme Homecare the supply of homecare services to Gaucher patients, in the

expectation of eliminating all competition from Healthcare at Home and other homecare services providers in the supply of such services."

404. The real difference between the two periods is set out in [561] of the Tribunal's judgment:

> "For the reasons we have already given the bundling of "Homecare Services" within the NHS list price of Cerezyme is not itself proved to be an abuse. In our view, from May 2001 onwards Genzyme's practice of bundling the cost of Homecare Services within the NHS list price for Cerezyme facilitated the margin squeeze abuse, which in turn would inevitably eliminate competition in the supply of Homecare Services to Gaucher patients."

405. Genzyme further argued that its conduct in this second period was objectively justified for twelve reasons, two of which were that pricing issues were a matter of policy for the Department of Health, not for the OFT, and that the NHS had been kept informed throughout and had raised no objection. The Tribunal accepted Genzyme's argument that (at [613]):

> "...whether the NHS should seek a price for Homecare Services separate from the price of the drug, whether there should be tendering, block contracting, or other purchasing arrangements, is a matter of policy to which the NHS might properly address itself. We also note that, in the [first period], the NHS was apparently content with the then arrangements. Moreover, for whatever reason, the NHS has never, in fact, sought a separate price for Homecare Services."

406. However, it went on to say that it was the OFT's responsibility under the 1998 Act to enforce the Chapter II prohibition so as to maintain an effective competitive structure in the market. In the circumstances existing in the second period, where the anti-competitive conduct of the dominant undertaking, threatened to eliminate competition in the relevant market, the OFT was "fully entitled to intervene" (at [614]). The Tribunal noted that the margin squeeze abuse existing in the second period related primarily to the terms on which Genzyme was prepared to deal not with the NHS itself, but with other homecare service providers. It added that the "terms on which Genzyme deals with other homecare service providers is not in our view solely 'a policy issue for the NHS', but a matter which the OFT is entitled to investigate under Chapter II of the Act."

407. The Tribunal also pointed to detailed objections to the abusive conduct raised by the two hospital trusts that were responsible for treating most of the patients for

whom the drug was indicated. On this basis, it concluded that it must have been clear to Genzyme by mid-2001 at the latest that its principal customers were opposed to the course it wished to follow. On those grounds, the Tribunal found that Genzyme's conduct in the second period "cannot be dismissed as being solely a matter of policy for the NHS" and that there was "no relevant acquiescence by the NHS in relation to that abuse." (at [616])

408. Contrary to Advanz Pharma's case, these findings do not establish a general principle of acquiescence that would provide a defence to a finding of abusive pricing. The presence or absence of acquiescence was not the principal criterion distinguishing the first and second periods. Those two periods differ because it was only in the second period that the conduct of the dominant undertaking could have an anticompetitive effect.

409. It was quite clear why the DHSC/NHS had not sought to intervene in the first period in *Genzyme* – the arrangements under which the drug tariff price included the cost of homecare services was perfectly acceptable to it as a matter of policy and had no adverse consequences. This cannot be said to be the case in relation to the alleged excessive and unfair prices for Liothyronine, which were neither in the interests of the DHSC/NHS nor incapable of producing an anticompetitive effect for the purposes of Chapter II and Article 102.

(3) Facts relevant to acquiescence

410. Since we find that there is no general principle of acquiescence under which the price of Liothyronine must be regarded as lawful until the DHSC/NHS has objected, it is not necessary to assess whether the conditions relied on by Advanz Pharma to form the basis for such a principle are satisfied on the facts. Nevertheless, for the sake of completeness we address the parties' contentions relating to the alleged knowledge of the price increase on the part of the DHSC/NHS.

411. Advanz Pharma contended, in summary, as follows:

(1) Advanz notified the DHSC/NHS of price increases in two ways: the first by voluntarily sending price increase notifications to senior DHSC/NHS officials including senior members of the DHSC/NHS procurement team and persons in charge at the DHSC/NHS local level (Trusts and Clinical Care Groups) ("price increase notifications"). These price increase notifications were widely disseminated and considered internally. Mr Sully's evidence was that throughout the Infringement Period Advanz fostered an open, transparent and cooperative relationship with the DHSC/NHS.

(2) An example was given of a price increase notification dated 31 May 2013, by which time the price of Liothyronine Tablets had increased to £68.20. A few weeks earlier on 8 May 2013, a meeting had taken place between Advanz and senior DHSC officials including a senior procurement manager, to discuss Advanz's problems of continuity of supply. The pre-notification was sent directly to the procurement manager who forwarded (or reported) it to the Chief Pharmacist noting that the prices notified were big increases. The Chief Pharmacist responded by asking whether this type of conduct was included in the investigation into *Phenytoin*. The ensuring email exchange shows that consideration was being given to what steps could be taken to keep prices down. A few weeks later, in July 2013, DHSC officials were asked to respond to a complaint from a constituent to an MP about shortages in Liothyronine and to its cost. The issue was discussed by officials who had attended the meeting on 8 May 2013. The recommended response noted that there was a range of costs involved in the research, development, production and distribution. It was to be inferred that the officials in question were well aware of the increase in the price of Liothyronine Tablets and its justification and approved it.

(3) The second means of notifying the DHSC/NHS was by submission to the Pricing Division of the NHS Business Services Authority ("the NHS Pricing Division) ("the price submission"). The NHS Pricing Division would respond to the price submission with an automated response referring to two checks:

> "The first is an electronic check to ensure that all the data has been transmitted accurately. The second is by the NHS- BSA-PPD pharmacy team who will check the actual content of your submission"

Advanz would then receive a second automated response stating:

> "We will email you again to let you know whether your submission has been accepted or failed and whether the NHS-BSA has made any changes to your submission",

And subsequently to confirm that:

> "the NHS-BSA-PPD has approved your submission. This submission is now complete. The NHS-BSA- PPD may have made comments or changed your submission and so you should now check for feedback."

(4) The word "approval" gave the impression that the DHSC/NHS had agreed to the increase. No-one from the DHSC/NHS gave evidence as to why the word "approved" was used or exactly what it meant. Mr Sully and Mr Beighton gave evidence that it was their understanding that the proposed price increases had been approved with knowledge and consideration of the price increases.

(5) The price information provided by Advanz to the NHS Pricing Division caused the prices to be on the DHSC/NHS' radar. The assessment by the NHS Pricing Division of the pricing information and the cost data trends, informed the DHSC/NHS's decisions on the Drug Tariff price and to which category of the Drug Tariff it would place a product and when. Mr Sully's (unchallenged) evidence in chief was that

> "In relation to the NHS-BSA process, as far as I was and am aware, it is the only process offered by the DH/NHS to inform them centrally of proposed price increases for generic medicines."

(6) Although approval by the DHSC or NHS was not a component of the principle of acquiescence, Advanz Pharma also argued that the DHSC/NHS had indeed approved the price increases, and did so at least in part on the basis that they were required in order for Advanz to make improvements to security of supply and other compliance issues being experienced by it at the time. The DHSC/NHS was aware of the supply and production issues affecting many of Advanz's products and

consented to at least one price increase on that basis. Mr Sully's evidence was as follows:

> "we had a very good relationship with the Department of Health and the NHS and we were working very closely with them to try to improve our product supply, and I think they understood. I am sure that it was even discussed between our team and their team that […] we were increasing prices in order to pay for some of these things. […].".

412. The CMA's position was, in summary, as follows:

(1) Advanz's portrayal of the NHS and DHSC as though they were a single entity was wrong. As the Tribunal recognised in *Genzyme*, the NHS is made up of numerous executives, advisory bodies or agencies: they are set out in the Decision. The DHSC had certain regulatory powers to monitor and intervene in respect of drug pricing but it was not involved in the prescription of Liothyronine Tablets or in reimbursing pharmacists. CCGs were responsible for funding dispensed prescriptions of medicines supplied on the NHS. In this case, CCGs had no choice but to pay for prescribed Liothyronine Tablets. While they sought to limit prescribing of Liothyronine Tablets, these initiatives had very limited impact on volumes sold during the Infringement Period.

(2) Advanz's argument that the NHS/DHSC was notified, and thus had knowledge, of the pricing practices was at odds with Advanz's own contemporaneous documents, as well as Mr Beighton's evidence in cross-examination, that Advanz understood that the DHSC deployed its limited resources in the regulation of branded on-patent drugs, which in aggregate had a much greater impact on the NHS budget and that the DHSC was not focused on niche off-patent products.

(3) The price increase notifications to the DHSC and NHS were not intended to seek approval, they gave only perfunctory information and were not reviewed to see whether prices were acceptable. The exchanges which ensued from the May 2013 price notification did not entail any assessment of whether the price increase for Liothyronine Tablets was reasonable. It was apparent from internal DHSC emails that officials did

not share Mr Beighton's view that the DHSC was content with the price of Liothyronine Tablets. The response from the DHSC Principal Pharmacist to the increases notified in May 2013 (including Liothyronine) was that "these are big increases without them having to provide any justification – they have us over a barrel.". The email of 3 July 2013 drafted as a response to the MP's request for information, was concerned with the availability of Liothyronine Tablets; it did not address price increases.

(4) The NHS-BSA is an arms-length Department of Health body which gathers pricing information in order to compile the Drug Tariff. Its processes cannot be characterised as a means by which the relevant parts of the NHS or the DHSC acquired 'knowledge' of the price of Liothyronine Tablets. As set out in the Decision, the NHS-BSA had a very specific mandate and a limited administrative role: to collect information in order to produce the Drug Tariff and to verify the accuracy of that information. Its remit did not extend to price approvals in the sense claimed by Advanz, or to cost control. The enquiries made by the NHS-BSA on occasion in respect of price increases were entirely consistent with this process: the reason for those enquiries was not any form of challenge or resistance but was to confirm the accuracy of the information submitted.

(5) Even if the NHS had willingly purchased Liothyronine Tablets at the prices imposed by Advanz, that would not be an indication that the prices reflected a reasonable relationship with economic value. As the Court of Appeal held in *Phenytoin*, a customer's willingness to pay "cannot serve as an adequate definition in an abuse case since otherwise true value would be defined as anything that an exploitative and abusive dominant undertaking could get away with".

(4) The Tribunal's findings

413. The price increase notifications sent by Advanz to the DHSC and NHS were, as the CMA contended, perfunctory in nature and were not intended to, and did not,

enable the NHS to make an informed assessment of whether the price increases were justified.

414. The price increase submissions sent by Advanz to the NHS Pricing Division were received and routinely checked by the NHS-BSA for completeness and not for substantive justification. There was no information in the submissions about the reasons for price changes or any other information that the NHS Pricing Information would need to assess whether the price increases were acceptable. Where large price increases were indicated, the agency engaged in correspondence to ensure that the figure entered was not a mistake but there was no indication on that approval of the price increase was intended as anything more than confirmation that the notification process was complete.

415. The DHSC/NHS did not approve the price increases as a matter of substance or give the impression that it had done so. Mr Beighton accepted during cross-examination that his understanding that the notification process entailed substantive approval may have been wrong. When shown evidence that the notification process was simply confirming that the prices were complete and correct he said that it was "not actually what I understood. I can see what this person is saying in his or her reply, but I understood, particularly as we were on a couple of occasions asked questions about these prices, that they were indeed approving them, it is what I thought." A little later in cross-examination, Mr Beighton accepted, on the basis of an email correspondence following a price rise application, that there was no indication from the NHS that they had scrutinised the prices,

416. There was no agreement or understanding between the DHSC and Advanz, within or outside the price notification process, that the price increases were approved on the basis that they were necessary to improve security of supply or other compliance issues, or any acknowledgement that this was necessary under a so-called portfolio approach to pricing. In any event, those issues had, by December 2014 improved to such an extent that, according to Mr Beighton, the MHRA put the company back on an industry-standard 30-month audit cycle. Further, Mr Beighton stated during cross-examination that the revenue from, inter alia, Liothyronine Tablets was used to invest in the development of other

products and markets and not just in improving supply security and other compliance issues.

417. The ability of the CMA to investigate the prices of generic drugs and to find them to be abusive and unfair is not dispelled by the policy of the DHSC or the NHS in keeping drug prices under review or by the then current regulatory and industry pricing regimes under which prices or profits can be controlled. This is clear from the judgment of the Tribunal in *Albion Water II*, cited above at paragraph 216.

418. In summary, the Tribunal concludes that Advanz did not intend to, and did not, provide the DHSC/NHS with sufficient information to make an informed assessment of the price increases and Advanz could not reasonably have inferred that the DHSC/NHS approved of the price increases.

(5) Conclusion

419. For these reasons, the Tribunal rejects Advanz Pharma's ground of appeal based on the acquiescence of the DHSC/NHS in the price increases up to 2017.

K. ISSUE (5): PENALTIES

420. Cinven and Advanz Pharma appeal against the penalties imposed by the CMA, arguing that there should be no penalty or, if there is one, that it should be significantly reduced. They take issue with the CMA's conclusion that the infringement was intentional or negligent and dispute the correctness of the CMA's penalty calculation.

(1) Was the infringement intentional or negligent?

(a) The Decision

421. In the Decision, the CMA set out the legal framework for the imposition of a penalty on an undertaking which has committed an infringement intentionally or negligently. This was largely undisputed by the Appellants. In summary:

(1) Under section 36(3) of the Act, the CMA may only impose a penalty for an infringement if it is satisfied that the infringement has been committed intentionally or negligently. The terms 'intentionally' and 'negligently' were defined as follows in *Napp*:

> "… an infringement is committed intentionally for the purpose of section 36(3) of the Act if the undertaking must have been aware, or could not have been unaware, that its conduct had the object or would have the effect of restricting competition. An infringement is committed negligently for the purposes of s 36(3) if the undertaking ought to have known that its conduct would result in a restriction or distortion of competition."

(2) Intent or negligence relates to the facts, not the law. As the Tribunal held in *Royal Mail plc v Ofcom* [2010] CAT 27, the CMA is not required to show that the undertaking knew that its conduct infringed the Act – what matters is not whether the undertaking was aware of "any specific legal characterisation" of its conduct, "but whether it was aware of its anticompetitive nature." In cases of exploitative abuse, by analogy, this means that the undertaking must have been aware of the exploitative nature of the conduct.

(3) This is consistent with the approach taken by the Court of Justice, which confirmed in *Deutsche Telekom* C-280/08P, EU:C:2010:603 that "the question whether the infringements were committed intentionally or negligently … is satisfied where the undertaking concerned cannot be unaware of the anti-competitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty."

(4) In cases of unfair pricing, an undertaking will have the necessary intent or at the very least negligence if it knew or should have known the essential facts justifying the findings that (i) the undertaking was in a dominant position, and (ii) the undertaking's price was excessive and unfair.

422. Applying these principles to the facts, the CMA found that Advanz's internal documents clearly indicated that Advanz knew or at the very least should have known that other treatments were not appropriate substitutes for, and did not constrain its pricing of, Liothyronine Tablets, that it was the exclusive UK supplier of Liothyronine Tablets with the ability to raise prices without losing

volumes and that it was exploiting its dominant position in order to charge excessive and unfair prices.

(b) The Appellants' arguments

423. Cinven and Advanz Pharma challenged the CMA's conclusion that Advanz's infringing conduct was intentional or negligent, essentially on the basis that the CMA had failed to show that Advanz knew or ought to have known about the essential facts giving rise to the infringement i.e. the fact that Advanz was dominant in the market for Liothyronine Tablets and that the prices of Liothyronine were unfair.

424. Cinven contended, in summary, that, in reaching this conclusion the CMA had failed to take into account the following matters:

(1) The fact that an undertaking recognises that market conditions may allow it some leeway to raise prices does not permit the conclusion it knew or ought to have known it was dominant and its prices potentially abusive.

(2) The majority of the pricing documents relied upon by the CMA do not relate specifically to Liothyronine.

(3) Advanz understood that its conduct did not foreclose the likelihood of competition but could encourage it. It therefore cannot reasonably be said that it was aware or ought to be aware that its conduct was anti-competitive or that its prices were unfair.

(4) The extent to which a price is unfair as a matter of law or fact is unclear. The CMA's conclusion as to the unfairness of Advanz's prices is based on a number of novel points. Exclusive reliance on the Cost Plus benchmark is unprecedented. The CMA's case on measuring Cost Plus has chopped and changed and would have required omniscience on the part of any firm considering the position *ex ante*.

425. Advanz Pharma contended, in summary, as follows:

(1) Advanz was not dominant in respect of Liothyronine Tablets or, if it was, it did not know and the evidence does not show that it ought to have known. The internal Advanz documents relied on by the CMA as showing that Advanz appreciated that it could increase its price for Liothyronine Tablets without losing sales volumes are irrelevant given that the absence of material interaction between prices and volumes is not indicative of dominance in circumstances where, as here, prescribers make substitution decisions by reference to factors other than price.

(2) Advanz's pricing of Liothyronine Tablets always complied with the applicable regulatory framework on prices for medicinal products. Advanz consistently and voluntarily pre-notified the DHSC/NHS of every proposed increase in the price of Liothyronine Tablets. The DHSC/NHS set the Drug Tariff price for Liothyronine Tablets on the basis of Advanz's price approval notifications and did not raise a query or concern as regards Advanz's prices.

(3) Advanz obtained independent, specialist, legal advice to ensure that its pricing in respect of de-branded generics complied with competition law.

(c) The Tribunal's conclusions

426. We are satisfied, on the basis of the facts set out at paragraphs 5 - 79 above, that Advanz knew or ought to have known of the essential facts giving rise to liability for infringement of the Chapter II prohibition.

427. As to Advanz's knowledge of its dominant position, we are satisfied that Advanz knew that Liothyronine Tablets were not part of a wider relevant product market. It was the sole MA holder and supplier of Liothyronine Tablets in the UK throughout the Infringement Period. It was aware that it was not subject to any effective competitive restraint, that the NHS did not exercise effective countervailing buyer power and that it was in a position to impose significant price increases without any material effect on sales volumes. The Cinven Appellants' characterisation of Advanz as merely recognising that market conditions allowed "some leeway" to raise prices fails to reflect the scale and

persistence of Advanz's price increases during the Infringement Period, of which Advanz was fully aware.

428. As to Advanz's knowledge that its prices were unfair, the essential facts constituting the unfairness of which it was, or should have been, aware were that, in circumstances where there was no effective competition, it made a series of very substantial price increases which were not accompanied by any material increase in production costs or by any improvement to the product or which were explicable on any other basis. The fact that Advanz considered that its pricing was eventually likely to attract new entrants and potential loss of market share does not negate Advanz's knowledge of these essential facts since it was aware that there were significant barriers to entry, including complex manufacturing processes, a costly and long regulatory process and the small market size which enabled it to raise prices in the way that it did.

429. As to the argument that the CMA's approach in this case was based on a number of novel legal points or that it has fundamentally changed its position in the course of the investigation, what matters is not whether Advanz was aware of any specific legal characterisation of its conduct but whether it was aware of its anti-competitive nature: see *Royal Mail* at [782]. We do not, in any event. accept that there was anything fundamentally novel about the CMA's approach or that its case has fundamentally changed in the course of the investigation. It is not suggested that the essential facts relied on by the CMA in support of its conclusion that Advanz was or ought to have been aware of its anti-competitive behaviour have changed.

430. The argument advanced by Advanz Pharma Appellants that Advanz's pricing complied with the "applicable regulatory framework" on prices for medicinal products is based on the fact that Advanz pre-notified the DHSC/NHS of its price increases, the DHSC/NHS set the Drug Tariff price for Liothyronine Tablets on the basis of Advanz's price approval notifications and did not raise any query or concern as regards Advanz's prices. As we have found, however, the DHSC did not approve of Advanz's prices in any meaningful sense. The fact that the DHSC/NHS failed to object to the prices increases does not mean that the prices

complied with the applicable regulatory framework in any meaningful sense or that the price increases were not abusive.

431. The Decision addressed Advanz's argument that the fact that it had obtained independent specialist legal advice and this negated any intent or negligence. The CMA's position was that an undertaking cannot escape the imposition of a fine on the basis that it took legal advice in relation to its unlawful conduct. We agree with this position. In *Bundeswettbewerbsbehörde v Schenker & Co AG* ("*Schenker*"), C-871/11, EU:C:2013:404, the Grand Chamber of the CJEU held as follows:

> "38. …the fact that the undertaking concerned has characterised wrongly in law its conduct upon which the finding of the infringement is based cannot have the effect of exempting it from imposition of a fine insofar as it could not be unaware of the anti-competitive nature of that conduct.
>
> …
>
> 43. Consequently, the answer to the first question is that art. 101 TFEU must be interpreted as meaning that an undertaking which has infringed that provision may not escape imposition of a fine where the infringement has resulted from that undertaking erring as to the lawfulness of its conduct on account of the terms of legal advice given by a lawyer or of the terms of a decision of a national competition authority."

432. It follows that, even if Advanz had reasonably concluded on the basis of independent legal advice, that its pricing was lawful, that would not have exempted it from a penalty insofar as it could not have been unaware of the anti-competitive nature of its pricing. In fact, the legal advice provided to Advanz did not provide it with a reasonable basis for believing that its pricing strategy with regard to Liothyronine Tablets was legitimate. The legal advice on which Advanz seeks to rely was provided in the course of 2014, some five years after the beginning of the abuse (so it could not assist the Appellants in relation to the period January 2009 to January 2014). The legal advice referred to the de-branding of Valoid and Apresoline tablets; its conclusion was that the competition law risk in relation to the pricing and de-branding of those drugs was low.

433. Advanz does not appear to have provided its legal advisers with a full and accurate description of the facts relating to its conduct in relation to Liothyronine

Tablets, in particular the scale of the price increases which were much more substantial than the price increase of Valoid which had doubled since de-branding and Apresoline, which had approximately tripled.

434. For these reasons, the Tribunal rejects the Appellants' arguments that Advanz's infringement of the Chapter II prohibition was not committed intentionally or negligently.

(2) The Penalty Calculation

435. Section 36(7A) of the Act provides that, in fixing a penalty, the CMA must have regard to the seriousness of the infringement concerned and the desirability of deterring both the undertaking on whom the penalty is imposed and others from engaging in anti-competitive activity. When setting the amount of a penalty in respect of an infringement of the Chapter II prohibition, the CMA must have regard to the guidance on penalties in force at the time of setting the penalty (section 38(8) of the Act).

436. In the Decision, the CMA concluded that it was appropriate to exercise its discretion under section 36(2) of the Act to impose a substantial penalty. It considered that the infringement was a very serious abuse, which led to the NHS being overcharged by a significant amount, causing direct harm to patients, whose access to the drug was restricted or withdrawn as a result, and diverting limited NHS resources. There was no objective justification for Advanz's sustained price increases, which were based on a systematic and carefully designed and monitored price optimisation strategy, aimed solely at exploiting the absence of competition in the supply of Liothyronine Tablets in the UK to Advanz's own financial advantage.

437. The CMA also considered that a substantial penalty was appropriate from a general deterrence point of view. As the number of recent unfair pricing investigations conducted by the CMA and other competition authorities showed, unfair pricing appears to be widespread, including in the pharmaceuticals sector. The CMA considered that there was a need to send a strong message to deter similar conduct both by the Parties and other undertakings in the future.

(a) Step 1: starting point

(i) The relevant turnover

438. The Penalty Guidance sets out a six-step approach for calculating the penalty.

439. Step 1 of the Penalty Guidance provides for a starting point of up to 30% to be applied to an undertaking's relevant turnover. The Penalty Guidance states that the "relevant turnover" is the turnover of an undertaking in the relevant product market and relevant geographic market affected by the infringement in the undertaking's last business year, which for these purposes is the financial year preceding the date when the infringement ended. In the Decision, the CMA concluded that the relevant product and geographic market affected by the infringement was the UK market for the supply of Liothyronine Tablets. Advanz's turnover in this market in 2016, the last business year before the date when the infringement ended, was £35,419,521.

440. In the Decision, the CMA addressed the argument raised by the Appellants that it should have calculated the relevant turnover in this case, not by reference to the last business year in the Infringement Period, but by reference to the average annual turnover in the UK market for the supply of Liothyronine Tablets during the Infringement Period, or individually for each ownership period by reference to the turnover generated in the last business year of each of the different ownership periods. Both would have resulted in a lower relevant turnover than the standard approach, as Advanz's turnover from the supply of Liothyronine Tablets increased over the Infringement Period, in line with its sustained price increases. The CMA concluded that in this case, it was appropriate to apply the standard approach to calculating the relevant turnover whilst accepting that, in exceptional circumstances, assuming there are adequate reasons, it was free to depart from the standard approach.

441. The approach was endorsed by the Tribunal in its *Pre-cast drainage products* judgment:

> "The Penalty Guidance does not require the CMA to calculate the average of the turnovers over the period of an infringement which lasted more than one

> year. Accordingly, the normal position is that one does not take an average figure. […] it is clear that the CMA is entitled to depart from this aspect of the Penalty Guidance when it is appropriate to do so. It is not helpful to try to define the cases in which it would be appropriate to depart from the usual approach. […] All one can usefully say is that the Penalty Guidance is to be applied in the normal case so that there must be something out of the norm to justify departing from it and using an average of the turnovers for the whole period of the infringement (or some other approach)."

442. The CMA considered that, in this case, there was no need for a departure from the Penalty Guidance in order to ensure that the ultimate level of the penalty was proportionate, specific to the offence and the offender and reflected Advanz's real economic situation at the time the Infringement was committed, including specifically the different levels of direct financial benefit generated in each of the four ownership periods. The CMA concluded that it was better able to take account of these factors by applying the standard approach at Step 1 and making any necessary adjustments in Step 4 of its assessment.

443. The Advanz Pharma Appellants contend that the turnover used by the CMA was "out of the norm" as it was circa 160% higher than Advanz's average turnover during the Infringement Period.

444. In the Tribunal's view, this difference was not sufficient to take the case out of the norm. Accordingly, it considers that the CMA was entitled to use the turnover in the final year of the Infringement as the basis for the calculation at Step 1.

(ii) The seriousness percentage

445. Step 1 of the Penalty Guidance provides that a starting point of up to 30% is to be applied to an undertaking's relevant turnover in order to reflect adequately the seriousness of the particular infringement and ultimately the extent and likelihood of actual or potential harm to competition and consumers. In applying the starting point, the CMA will also reflect the need to deter the infringing undertaking and other undertakings from engaging in that type of infringement in the future. This is a case-specific assessment, taking into account overall how likely it is for the type of infringement at issue, by its nature, to harm competition; the extent and likelihood of harm to competition in the specific relevant

circumstances of the individual case; and whether the starting point is sufficient for the purpose of general deterrence.

446. In the Decision, the CMA concluded that a 30% starting point was appropriate taking into account the following factors:

(1) the likelihood of excessive and unfair pricing by its nature to have a particularly serious exploitative effect;

(2) the nature of the product (including the nature and extent of demand);

(3) the market share, structure of the market and entry conditions;

(4) the actual effect of the infringement on end customers and patients; and

(5) the need to deter other undertakings from engaging in the same or similar conduct.

447. Cinven and Advanz Pharma contended that the 30% maximum starting point was unjustified for the following reasons:

(1) The starting point of 30% is unprecedented.

(2) The 30% starting point was inappropriate for a novel complex and controversial area of unilateral conduct concerning alleged excessive and unfair pricing.

(3) Excessive pricing is less serious than secret cartels and other hardcore agreements. The latter are regarded as the most serious infringements: they are much harder to detect and their effects are inherently more likely to be long-lasting than excessive pricing, as they can alter the structure of markets and undermine the competitiveness of a whole industry.

(4) The CMA's contention that conduct such as excessive pricing and predatory pricing is likely to have a particularly serious exploitative or exclusionary effect is not correct in this case in which the relevant

conduct comprised published price rises without any associated exclusionary conduct and absent any insurmountable barriers to entry, and which stimulated competition in the market.

(5) There was no misleading conduct vis-à-vis the DHSC/NHS or threats to discontinue the supply of the relevant product. The DHSC/NHS acquiesced in the prices. There was a cheaper, "safe alternative" for all hypothyroid patients, that is, levothyroxine. Throughout the Infringement Period, the DHSC/NHS had a choice and exercised it.

(6) The CMA ought to at least recognise "the mitigating effect of the general uncertainty and ambivalence as to the legitimacy of the practice" in question. In *Kier Group and others v Office of Fair Trading* [2011] CAT 3 ("*Kier*"), for example, the Tribunal reduced the starting point to 3.5% on this basis.

448. In our view, the CMA's application of the 30% seriousness percentage was appropriate.

449. The argument that the penalty is unprecedented carries little weight. As the Tribunal noted in *Eden Brown*, each case is dependent on its facts and previous penalty cases have limited precedent value. The question whether the percentage is appropriate depends on the relevant circumstances of this case. The percentages applied in other cases do not make the starting point in this case unreasonable. The CMA has, in any event, applied a 30% starting point in two other excessive pricing cases in the pharmaceutical field, *Phenytoin* and *Hydrocortisone*.

450. As to the seriousness of the infringement, §2.6 of the Penalty Guidance explicitly refers to excessive pricing as conduct that is inherently likely to have a particularly serious effect, justifying a starting point between 21–30% for such as excessive pricing.

451. As the CMA noted in the Decision, protection of customers against exploitation is a core aim of competition law. Unfair pricing is one of key harms that

competition law is designed to prevent. The prices - and consequently the direct financial benefit - resulting from excessive pricing may well be higher, more immediate and more certain to be achieved than those which may be achieved from other forms of anti-competitive behaviour such as cartelisation. We do not consider that excessive and unfair pricing is inherently less serious than exclusionary abuses or secret cartels. Advanz's conduct in this case was exploitative. It had a seriously detrimental impact on the NHS, whose spend on Liothyronine Tablets increased from approximately £604,000 in 2006 to £30 million in 2016 despite sales having stayed largely the same, thereby reducing the money available for other healthcare services. The infringement had a serious impact on those patients requiring Liothyronine Tablets for whom doctors had stopped prescribing them because of the price, as detailed in the Decision. The Appellants have not disputed the finding in the Decision that there were some patients who benefited from Liothyronine Tablets but who were unable to obtain them from the NHS as a result of the abusive pricing.

452. We do not accept that there could have been any genuine uncertainty as to the unlawfulness of excessive and unfair pricing or that the starting point was inappropriate because the law relating to excessive pricing is complex and controversial. The facts in *Kier*, in which there was found to be a widely held view that cover-pricing was not unlawful, are clearly distinguishable from this case. Whilst we accept that whether a price is sufficiently high as to be excessive and unfair is a matter of degree calling for an exercise of judgment, the scale of the increases charged during the Infringement Period ought not to have left Advanz in any uncertainty as to their unfairness.

(b) Step 2: The adjustment for duration

453. The Penalty Guidance provides that the CMA may adjust the starting point reached at the end of Step 1 to take into account the duration of the infringement.

454. Advanz Pharma contend that they have wrongly been held liable for conduct that predates Advanz Pharma Corp's ownership of the Mercury Pharma Companies, 21 October 2015. This contention appears to be mistaken on the basis that Advanz Pharma Appellants are not being held liable for period prior to 21

October 2015. At Step 4, the CMA apportioned the Step 3 penalty between the three undertakings liable to pay it.

(c) Step 3: Aggravating/mitigating factors

(i) Aggravating Factors

455. Step 3 of the Penalty Guidance provides that amount of the financial penalty may be increased at Step 3 where there are aggravating factors or decreased where there are mitigating factors. The CMA must consider whether any adjustments are appropriate in all cases for each undertaking based on the specific circumstances of the infringement.

456. The CMA's position set out in the Decision was that it considered the involvement of directors and senior management to be an aggravating factor that justified a penalty increase of 10%.

457. Advanz and Cinven argue that the 10% uplift is inappropriate given that the pricing was transparent, that the multiple senior members of staff who signed off the price changes were not aware that the prices were unlawful and that the facts of this case are very different from a secret cartel which was treated in *Ping* as an example of the type of case where director-level involvement is likely to be treated as an aggravating factor.

458. In our view, the CMA was justified in treating the involvement of directors and senior management as an aggravating factor justifying a 10% uplift. As noted above at Step 1, unfair pricing abuse is a particularly serious infringement. The intention to charge the NHS prices for which there was no objective justification, based on a strategy which was aimed solely at exploiting the absence of competition in the supply of Liothyronine Tablets in the UK to Advanz's own financial advantage extended to the highest ranks of the undertaking. This aggravated the offence in this case. As the Tribunal observed in *Ping*: "society has a greater expectation that senior management will lead by example and abide by the law."

459. Cinven emphasises the transparency of its pricing and competition law compliance training. In fact, Advanz's repeated price increases were designed to avoid scrutiny by the DHSC/NHS as set out at paragraphs 59 and 363 above. Attendance at compliance training, however laudable, is not something that excuses the involvement of directors and senior managers in Advanz's exploitative pricing strategy.

460. In all the circumstances, it was reasonable for the CMA to conclude that the uplift of 10% should be imposed for director involvement in this case.

(i) Mitigating factors

461. Advanz and Cinven contend that the CMA has failed to give due credit for four factors which they allege mitigate the seriousness of the infringement:

(1) Advanz had every reason to believe its conduct complied with competition law. Advanz Pharma refer to the decision of the General Court in *Compagnie Générale Maritime* Case T-86/95, in support of the proposition that there can be no fine where the conduct in question was in the public domain for a long period of time. The General Court held that a fine should not be imposed in respect of horizontal price fixing, which it described as a "a very serious and classic type of infringement", on the basis that: "[…] numerous factors led the applicants to believe that the contested agreement was lawful [including inter alia] the long-standing and public nature of the contested agreement". *Mutatis mutandis*, if Advanz engaged in the Infringement, which was denied, it should not be issued a fine that is more than nominal.

(2) There was genuine uncertainty as to whether excessive pricing "without more" was unlawful. The Court of Appeal held that the CMA misapplied the law on unfair pricing in *Phenytoin.* There have been only very few cases on excessive and unfair prices. Excessive pricing cases represent the least legally certain and the most difficult and complex area of competition law. The CMA has recast its case on numerous occasions in the course of the administrative proceedings.

(3) There was a genuine belief held by Advanz and the industry generally that the DHSC/NHS possessed the necessary powers to regulate prices for generic drugs.

(4) The fact that Cinven has taken steps to ensure competition law compliance.

462. We do not accept that Advanz had every reason to believe that its conduct was lawful or that there was any relevant uncertainty as to the law. There is no suggestion in Advanz's internal documents that it specifically addressed the lawfulness of its pricing of Liothyronine Tablets or that it concluded that its pricing might be lawful. The facts of *Compagnie Générale Maritime* are clearly distinguishable. In that case the Commission and the various authorities in the Member States were fully aware of the contested agreement and had referred approvingly to the type of agreement in question.

463. As noted above, we accept that excessive pricing cases can be difficult to assess but it does not follow that every case of excessive pricing entails a mitigating circumstance. Advanz's margins during the Infringement Period generating a minimum direct financial benefit of at least £92.3 million per year from 1 January 2008 to 31 July 2017. It should not have been difficult to assess that its prices were excessive and unfair.

464. In the Tribunal's view, the fact that Advanz apprehended that the DHSC/NHS might intervene is not a mitigating factor. Advanz's strategy generally was generally to exploit its freedom to increase prices in the absence of any effective countervailing power.

465. The CMA set out in the Decision and in its Defence the detailed reasons why it was not satisfied with Cinven's compliance programme. To encourage undertakings to adopt compliance measures that are appropriate to their size and activities, the CMA may treat such measures as a mitigating factor:

> "where an undertaking demonstrates that adequate steps, appropriate to the size of the business concerned, have been taken to achieve a clear and unambiguous commitment to competition law compliance throughout the undertaking (from the top down)."

It explained that there is a need to keep such discounts modest, lest the deterrent effect of the penalties regime be weakened inappropriately. In particular, undertakings should not be allowed to form the impression that penalties can be significantly reduced on appeal by formulating compliance policies and measures, however elaborate, after the Decision.

466. The Tribunal is satisfied that no discount should be awarded to Cinven for compliance measures on the basis that its activities did not establish a clear and unambiguous commitment to competition law compliance with the meaning of paragraph 2.19 of the Penalty Guidance.

(d) Step 4: Adjustment for specific deterrence

(i) The Decision

467. Step 4 of the Penalty Guidance provides that the penalty figure reached after Steps 1 to 3 may be increased to ensure that the penalty to be imposed on the undertaking is sufficient to deter the infringing undertaking from breaching competition law in the future, taking into account the specific size and financial position of the undertaking and any other relevant circumstances.

468. In the Decision, before making any adjustment under Step 4, the CMA apportioned the Step 3 penalty between the different periods of ownership of the Advanz undertaking. The stated purpose was to apportion the penalty between the corporate legal entities liable to pay it and to make sure that the penalty would reflect the scale of the infringement during each period of ownership of the Advanz undertaking.

469. In the Decision, the CMA stated that it took into account the following factors in deciding whether to adjust the Step 3 penalty in order to achieve specific deterrence:

(1) Whether the undertaking had made or was likely to make a financial benefit from the infringement that exceeds the Step 3 penalty.

(2) Whether the Step 3 penalty would achieve specific deterrence in light of the size and financial position of the undertaking when the penalty was imposed.

(3) Whether the undertaking generated a significant proportion of its turnover outside the relevant market, such that the Step 3 penalty would be very small by comparison with its size and not act as an adequate specific deterrent.

(4) The serious harm caused by the infringement to the NHS and to patients.

(5) An assessment of whether the Step 4 penalty for each undertaking would be disproportionate or excessive.

470. It concluded, in summary, that in relation to Advanz Pharma Corp the Step 3 penalty of £54.36m was only 3.6% above the minimum direct financial benefit of £52.46m during the Advanz Pharma period of ownership. In light of this, the CMA decided to increase this penalty to £65.2m. It also evaluated Advanz's financial hardship claims, which it considered to be unfounded given its acquisitions worth £130m in the financial year ending 31 December 2020 and its access to the resources of the Nordic Capital group.

471. In relation to Cinven, the CMA concluded that, as the Step 3 penalty of £37.1m exceeded the financial benefit of £34.1m during the Cinven period of ownership by only 8.6% and represented only a tiny proportion of Cinven's worldwide turnover of £14.4 billion in the financial year ending 31 December 2017 and of its average worldwide turnover of £11.8 billion over the last three years, Cinven's Step 3 penalty should be increased to £51.9m.

472. In relation to Hg, the CMA found that the Step 3 penalty of £6.2m exceeded the minimum direct financial benefit of £5.7m during the Hg period of ownership by £490,000. The CMA noted that the true economic or financial benefit from the Infringement was probably above the level of the unadjusted penalty at Step 3 since the CMA chose not to find Advanz's prices to be abusive until they rose to

£20.48 per pack even though the highest Cost Plus figure (with sensitivities) during Hg's ownership period was £6.00 per pack.

473. The CMA assessed whether to adjust the Step 3 penalty having regard to Hg's individual circumstances. It found that a significant uplift at Step 4 was required in order to achieve a sufficient deterrent effect given 'the relatively small size' of Hg's Step 3 penalty compared to its considerable size and financial position.

474. Having assessed all of the circumstances in the round, including the serious harm caused to the NHS and ultimately patients, the CMA increased Hg's Step 3 penalty to £8.6m. This was £2.9m above the minimum financial benefit during its ownership period. The CMA concluded that the Step 4 penalty of £8.6m was neither disproportionate nor excessive, noting that this represented 0.24% of Hg's worldwide turnover of £3.6 billion for 2020 (and 0.31% of the annual average of £2.8 billion for the three financial years before the Decision), 2.71% of Hg's operational profit of £320.4m for the year ending 31 March 2020 and 3.29% for the annual average of £263.9m in the three years to that date).

475. In its Amended Defence, the CMA submitted that the financial penalty imposed on Hg should be upheld in light of Hg's individual circumstances. It referred to the Tribunal's observation in *Sepia Logistics Limited v OFT* [2007] CAT 13 that 'penalties are not supposed to be painless and are intended to have a deterrent effect'. The CMA submitted that a final penalty of just £0.5m over and above the minimum direct financial benefit to Hg would be "painless" and would have a very limited deterrent effect.

(ii) <u>The Appellants' arguments</u>

476. Advanz Pharma and/or Cinven raised the following objections to the CMA's application of Step 4:

(1) The CMA was wrong to base the deterrence uplift on the need to significantly exceed the financial benefit which accrued to Advanz. There is no statutory basis for this approach. It gives rise to complexities and

difficulties. It ignores the possibility of damages claims against Advanz and gives rise to unfairness in the context of such damages claims.

(2) The CMA has in any event miscalculated the gain from the infringement in that it took the difference between the lowest price of Liothyronine Tablets that it found to be excessive and the ASPs during each period of ownership which it then multiplied by the volume sold. This calculation presupposed incorrectly that, had Advanz priced below the lowest price found to be excessive, it would have sold the same volume of Liothyronine Tablets as it actually sold throughout the Infringement Period. In reality, Advanz would, by charging lower prices, have sold additional volumes which would need to be offset against the gain.

(3) The CMA also erred in assessing Advanz's financial position. It did not have proper regard to the applicable methodology set out in its guidance in that it failed to consider appropriate indicators of the undertaking's size and financial position at the time the penalty was being imposed including Advanz's profits after tax, net assets and the level of dividends. Had it done so, the CMA would have found that Advanz's financial position was far less robust than the CMA claimed and the resultant fine disproportionate to it.

(4) The CMA was wrong to take into account the turnover generated by the Cinven Entities outside the relevant market and by its portfolio companies. A private equity investor cannot be compared to undertakings directly active in the supply of goods and services. The turnover of the Cinven portfolio companies is not turnover to which the Cinven Entities (the addressees of the Decision) can have recourse and is, therefore, meaningless for the purposes of assessing the Cinven Entities' own size and economic strength.

(5) Given that the Penalty calculation at Step 3 was already a significant penalty which materially exceeded the minimum financial benefit, a further uplift was unnecessary. A finding of a breach of competition law is a serious matter for an organisation entailing serious adverse

reputational consequences or "stigma," substantial defence costs and exposure to follow-on claims in respect of civil liability for any losses caused. These deterrent factors are all highly relevant to the question of specific deterrence but were not acknowledged adequately by the CMA in the Decision.

(6) The alleged gap in the sector's regulatory coverage that the CMA identified in the Decision as responsible for the present case has now been closed by the new price control powers available under the Health Service Medical Supplies (Costs) Act 2017 ("the Costs Act") which that the DHSC has obtained precisely for these purposes. These regulatory and legislative developments substantially reduce or eliminate the risk of a similar infringement occurring in the future. The Tribunal acknowledged this in *Phenytoin* saying it:

> "would likely have regarded the very substantial uplift for deterrence applied to Pfizer as, on its face, difficult to justify…If we had needed to come to a decision on the level of penalties to be applied to Pfizer in this case, we would have given the appropriate uplift for deterrence close scrutiny, particularly having regard to the new price control powers of the DH that have recently been passed into law."

477. Hg did not challenge its penalty in its original Notice of Appeal. However, after the conclusion of the hearing and following the Tribunal's circulation of its judgment in draft, Hg filed an Amended Notice of Appeal with the permission of the Tribunal Chair adding a ground of appeal (Ground 3) which addressed the deterrence uplift. Hg contended (at paragraph 6A) that its penalty should be reduced from £8.6 million to £6.2 million because the CMA was wrong to conclude that a deterrence uplift was necessary to deter it from breaching competition law in the future. Hg went on to contend (at paragraph 6B) that in the event of any other ground applicable to any Appellant being upheld at a later stage of these proceedings (i.e. on appeal or remittal) and being equally applicable to the position of Hg, Hg's penalty should be reduced in accordance with that ground as well.

478. In its Amended Defence, the CMA objected to Hg's amendment, as a matter of pleading, on the basis that it failed to comply with Rule 9(4)(e) of the Tribunal's

Rules. This Rule requires an appellant to provide a succinct presentation of the arguments supporting each of the grounds of appeal. The CMA contended that Hg's Ground of Appeal 3 provided no such arguments and invited the Tribunal to dismiss Ground of Appeal 3 for want of adequate particulars. The CMA further objected to Hg's attempt (at paragraph 6B of its Amended Notice of Appeal) to rely on arguments raised by other Appellants ("the general adoption ground") on the basis that this would infringe the *ultra petita* rule: it was incumbent on each Appellant to plead and prove its case. According to the CMA, it was particularly inappropriate to seek to rely on arguments raised by other Appellants in the context of penalties, given that the appropriate penalty is determined by reference to factors affecting that specific undertaking. Reasoning applicable to one undertaking may therefore have no relevance to the position of another undertaking, in particular when considering the deterrence uplift at Step 4 of the CMA's penalty assessment.

479. In the Tribunal's view, Hg's Ground of Appeal 3 against the penalty imposed by the CMA does comply with Rule 9(4)(e) in that it presents an argument, namely that the deterrence uplift was unnecessary. The Tribunal has not relied on the general adoption ground in reaching its conclusions on the reduction in Hg's penalty so it is not necessary for the Tribunal to determine whether the general adoption ground infringes the *ultra petita* rule.

(iii) The Tribunal's conclusions

480. Taking these arguments in turn, the CMA's approach in calculating a deterrence uplift by reference to the financial benefit which accrued to Advanz as a result of its infringing conduct was unimpeachable. The Penalty Guidance states that an increase in the Step 3 penalty will be appropriate "where the CMA has evidence that the infringing undertaking has made or is likely to make an economic or financial benefit from the infringement that is above the level of penalty reached at the end of step 3." In the present case, the financial benefit made by the infringing undertakings was below the penalty reached at the end of Step 3 but it was legitimate for the CMA to conclude that a further uplift was appropriate.

481. In support of their argument that the CMA was wrong, Cinven and Advanz Pharma relied upon the following observation of the Tribunal in *Genzyme*:

> "In our view, as the Tribunal stated in *Napp* at [507] to [509], the penalty is not to be fixed in terms of the 'gain' to the infringing party, but in terms of the sanction appropriate for the conduct, having regard to the need for deterrence."

482. This observation does not assist the Appellants. First, the Tribunal's judgment in *Genzyme* predated the Penalty Guidance which the Tribunal is now required to apply. Second, the Tribunal's observation was not purporting to lay down a hard-and-fast rule and needs to be read in context. As the CMA explained in the Decision, the reason why the Tribunal in *Napp* and in *Genzyme* was disinclined to calculate the penalty by reference to the gain generated by the infringing party was the difficulty in those cases of assessing the gain and hence of fixing a penalty which would be an effective deterrent. In *Genzyme* the Tribunal prefaced the observation relied on by the Appellants by the following statement:

> "In this case, as a result of the OFT's intervention, it is difficult to show that Genzyme has made a significant gain from the infringement."

483. There is no such difficulty in the present case. Nor is there any basis for the contention that determining the gain would lead to complication and unfairness in subsequent damages claims.

484. With regard to the CMA's calculation of the gain to Advanz, the Tribunal agrees with the CMA that it was not necessary to set off, against the benefits from the infringement, profits from an increased volume of sales at a lower price. As the CMA pointed out, this argument assumes that Advanz would have sold more Liothyronine Tablets at a lower price whereas in fact demand for Liothyronine was almost inelastic and sales levels remained broadly constant despite the price increases.

485. The Tribunal disagrees with Advanz Pharma's contention that the CMA failed to give sufficient weight to relevant indicators of its financial position including its profits after tax, net assets, the level of dividends or industry margins. It was reasonable of the CMA to use Advanz's adjusted EBITDA, on a three-year average basis as contemplated in the Penalty Guidance, for the reasons set out in the Decision, and not to treat its net assets as a reliable indicator of Advanz's

financial position. As the CMA points out, the price of $846 million paid by Nordic Capital to acquire Advanz Pharma Corp in 2021 confirms that the negative value of its assets is not a reliable indicator of its financial health and shows that the acquirer considered that the business would continue to generate revenues and profits. The fact that the CMA did not take into account that Advanz paid no dividends since 2016 does not invalidate its proportionality assessment, given that it did take account of other indicators including turnover, adjusted EBITDA, and cash flow.

486. The Tribunal does not accept Cinven's argument that the CMA's consideration of turnover of the Cinven Entities outside the relevant market discriminates against private equity investors, in that it treats private equity investors as comparable to undertakings participating directly in the supply of goods and services. The Decision set out in detail the facts relied upon by CMA in support of its conclusion that, as a result of their economic, organisational and legal links, the Cinven Entities exercised decisive control over the Mercury Pharma Companies and formed a single undertaking with them for the purposes of the infringement. Moreover, the Decision refers to limited partnership agreements of the Cinven Entities which indicate that they could have recourse to the turnover and assets of the portfolio companies to indemnify them in respect of losses or claims and to return distributions. If the penalty was calculated solely on the basis of turnover within the relevant market this would have a disproportionately favourable effect.

487. Cinven referred to two EU cases, *Fentanyl* and *Power Cables*, which involved different entities that had committed different infringements affecting different products, and which were fined under the EU fining guidelines. However, as the Tribunal noted in *Roland*, the European Commission has different practices and fining policies and does not apply the Penalty Guidance. The CMA is not required by s.60A of the 1998 Act to calculate the penalties it imposes in the same manner as those imposed by the Commission. Rather the CMA is entitled to take a UK specific view in the light of its own particular experience, which is what it did here.

488. The fundamental issue raised in relation to the deterrence uplift is whether an uplift is necessary in order to deter them from anti-competitive conduct in the future. This is an argument raised by each of the Appellants, including Hg. The CMA stated in the Decision that a substantial deterrence uplift was called for in a case of unfair selling prices in order to deter the Appellants from engaging in the same or similar breaches of competition again in the future, in the pharmaceutical sector or in any sector of the economy. It said that "this is particularly the case given the possibility that future unlawful conduct may not be detected or subject to enforcement."

489. As noted above, the Step 3 penalty imposed of £54.36m was 3.6% above the financial benefit from the infringement of £52.46m to Advanz and the penalty of £37.1m was 8.6% above the financial benefit to Cinven of £34.1m. The Step 3 Penalty of £6,206,035 was also 8.6% higher than the financial benefit to Hg of £5,716,012. The Step 3 penalty was therefore sufficient not only to deprive the Appellants of any commercial gain from the infringement but also to cause them to pay further amounts which, though relatively small in percentage terms, the Tribunal does not consider to be immaterial.

490. It is also reasonable to assume that the management of the Appellants will be mindful of the reputational damage to the undertakings resulting from the Decision and that this would act as a further deterrent against future infringements of competition law.

491. The CMA does not point to any specific reason for believing that, absent a deterrence uplift, there is a risk of further breaches of competition law by the Appellants, whether in the pharmaceutical sector or in any other sector, or that the Appellants may engage in future unlawful conduct that may not be detected or subject to enforcement.

492. In these circumstances the Tribunal is not persuaded that any uplift to the Step 3 penalty is necessary in order to deter the Appellants from breaching competition law in future.

493. Furthermore, the Tribunal considers that the powers available to the DHSC to control prices under the Costs Act are a further reason to conclude that a deterrence uplift is unnecessary. Those powers include the power to make drugs outside a voluntary scheme subject to the potential for intervention under the Reserve Power, even if the licence holder is a member of a voluntary scheme and a power allowing for regulations requiring licence holders to provide cost and other financial information to the DHSC upon request.

494. The CMA correctly points out, in support of the need for a deterrence uplift, that the Costs Act does not in terms affect undertakings' duty to comply with the 1998 Act, that the DHSC has not stated how it will use its powers, that there is no suggestion that the DHSC will impose industry-wide price controls or that the powers do not affect undertakings' duty to comply with the Competition Act 1998, that it would take time for the DHSC, which has limited resources, to introduce a price limit, which might create a "profit window" and that the Cost Act does not apply to other sectors. The Tribunal considers, nevertheless, that some weight should be given to the DHSC's new powers in assessing the need for a deterrence uplift in this case.

495. The CMA has not identified any specific reason for finding that absent a deterrence uplift there is any greater risk of further breaches by Hg than by the other Appellants. The likely concern about reputational damage and the availability of the DHSC's powers under the Cost Act to intervene apply equally to Hg.

496. The removal of the deterrence uplift has the effect of reducing the penalty payable by Cinven from £51.9 to £37.1 million and that payable by Hg from £8.6 million to £6.2 million. But for the statutory cap under Section 36(8), Competition Act 1998, which limits any penalty to 10% of the worldwide turnover of an undertaking in its last business year, the penalty payable by Advanz Pharma would have been reduced from £65.2 million to £54.36 million. The effect of the statutory cap is that the penalty payable by Advanz Pharma is unchanged at £40,942,899.

L. OVERALL CONCLUSION

497. For the reasons set out above, the Tribunal:

(1) dismisses the Appellants' appeals against the CMA's decision that Advanz abused its dominant position by charging excessive and unfair prices for Liothyronine Tablets during the Infringement Period;

(2) reduces the penalty payable by the Cinven Appellants from £51.9 million to £37.1 million; and

(3) reduces the penalty payable by Hg from £8.6 million to £6.2 million.

498. This judgment is unanimous.

Andrew Lenon K.C.
Chair

Tim Frazer

Professor Michael Waterson

Charles Dhanowa O.B.E., K.C. (*Hon*)
Registrar

Date: 8 August 2023