Neutral Citation: [2017] CAT 1

Case No: 1274/1/12/16 (IR)

IN THE COMPETITION APPEAL TRIBUNAL

Victoria House
Bloomsbury Place
London WC1A 2EB

19 January 2017

Before:

PETER FREEMAN CBE QC (Hon)
(Chairman)

B E T W E E N:

(1) FLYNN PHARMA LIMITED
(2) FLYNN PHARMA (HOLDINGS) LIMITED

Applicants

- v -

COMPETITION AND MARKETS AUTHORITY

Respondent

Heard at Victoria House on 17 January 2017

JUDGMENT ON INTERIM RELIEF

APPEARANCES

Ms. Ronit Kreisberger and Mr. Tom Pascoe (instructed by Macfarlanes LLP) appeared for the Applicants.

Mr. Rob Williams and Ms. Jennifer MacLeod (instructed by CMA Legal) appeared for the Respondent.

Mr. Robert O'Donoghue and Mr. Tim Johnston (instructed by Clifford Chance) appeared for Pfizer Limited and Pfizer Inc.

Mr. Brendan McGurk (instructed by Clifford Chance) appeared for the Department of Health.

Introduction

1. This is an application by Flynn Pharma Limited and Flynn Pharma (Holdings) Limited (together, "Flynn") for interim relief pursuant to rule 24 of the Competition Appeal Tribunal Rules 2015 (S.I. 2015 No. 1648) ("the Tribunal Rules"), by which Flynn seeks a suspension of the directions (the "Directions") given by the Competition and Markets Authority ("CMA") at Annex B of its decision of 7 December 2016 in Case CE/9742-13 *Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK* ("the Decision") made under section 18 of the Competition Act 1998 ("the 1998 Act"). The Decision is addressed to Flynn and Pfizer Limited and Pfizer Inc (together, "Pfizer"). The Directions are due to come into effect from 23 January 2017. The deadline for Flynn and Pfizer to file appeals against the Decision is 7 February 2017.

2. Flynn seeks a suspension of the Directions, insofar as they apply to it. Because the Directions come into effect before the deadline for Flynn to file its appeal, Flynn originally sought a short preliminary suspension, pending a hearing to be scheduled shortly after it had filed its appeal. However, the Tribunal's practice is to hear requests for interim relief as soon as practicable owing to their urgency, save where there are exceptional circumstances or where all concerned parties consent to the request being dealt with on the papers. A hearing was fixed for 17 January 2017 and Flynn therefore no longer pursued its preliminary request. It now instead seeks that the Directions should be suspended, insofar as they apply to it, from the date of they are due to come into force (23 January 2017) until the Tribunal's judgment on the substantive appeal which Flynn intends to make against the Decision. The Tribunal directed Flynn's legal representatives to serve non-confidential copies of its request on potentially interested parties. Further to that direction the Tribunal has received observations on Flynn's request from Pfizer and from the Department of Health ("DoH"). Pfizer and the DoH were also represented at the hearing of this application.

3. Section 18(1) of the 1998 Act provides:

> "18.-(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;
>
> […]
>
> (3) In this section—

"dominant position" means a dominant position within the United Kingdom; and

"the United Kingdom" means the United Kingdom or any part of it.

(4) The prohibition imposed by subsection (1) is referred to in this Act as "the Chapter II prohibition".

4. In the Decision the CMA found that: (i) Pfizer's supply prices to Flynn; and (ii) Flynn's selling prices, for the prescription medicine phenytoin sodium, supplied in capsule form, are unfairly high in breach of the Chapter II prohibition of the 1998 Act and/or Article 102 of the Treaty on the Functioning of the European Union (the "TFEU"). The provisions of Article 102 TFEU are materially the same as the Chapter II prohibition, save that the dominant position must be within the internal market or substantial part of it and there must be an effect on trade between EU Member States. The Directions require each of Pfizer and Flynn to implement price reductions within 30 working days of the Decision (*i.e.* by 23 January 2017). The circumstances are summarised below.

Background

5. I have taken the following outline of the relevant facts from Flynn's application and the CMA's Decision, a version of which, confidential to Flynn, was attached to the application. Flynn is a specialist pharmaceutical company established in 1994. Since its inception, Flynn has grown its business through both acquiring and licensing products from multinational pharmaceutical companies such as Eli Lilly, Neurim, Medice and Pfizer, and organic growth (extending existing product ranges and developing new products).

6. Flynn has particular experience in the acquisition and "rescue" of so called "end of life" products. These are mature drugs for which demand is declining, usually because there are newer, more effective treatments on the market.

7. Phenytoin sodium is a prescription drug primarily used to treat epilepsy. It is available in a variety of forms, including as capsules and tablets. It was originally synthesised in 1908 and it became the first widely available treatment for epilepsy. Patent protection for it expired some time ago and it has since been superseded by newer drugs which have fewer side effects and it is no longer recommended as a first-line or second-line treatment. Consequently very few newly diagnosed epilepsy patients are prescribed phenytoin sodium capsules and demand for the product is declining. In the Decision, the CMA estimates that there are around 48,000

patients taking phenytoin sodium capsules in the UK; this is approximately 10% of epilepsy patients in the UK.

8. Phenytoin sodium has a narrow therapeutic index ("NTI") and non-linear pharmacokinetics. These characteristics mean that even small changes to the dose delivered to the circulation can give rise to a disproportionate change in the level of the drug in the body. These characteristics can give rise to the risk of therapeutic failure and toxic side effects, such as seizures which may have potentially life-changing implications.

9. These potentially significant risks have resulted in clinical guidance, including guidance published by the National Institute for Health and Care Excellence ("NICE"), in October 2004 and January 2012, and by the Medicines and Healthcare Products Regulatory Agency ("MHRA"), in November 2013, recommending that patients who are stabilised on a particular manufacturer's phenytoin sodium capsule should be maintained on that manufacturer's product and should not be switched to another manufacturer's capsule. This principle is referred to as "Continuity of Supply" in the Decision and I adopt it here also.

10. There are two companies which manufacture and supply phenytoin sodium capsules to the UK; these are Pfizer and NRIM Limited ("NRIM").

11. Until 24th September 2012 Pfizer's phenytoin sodium capsules were sold under the brand name Epanutin. Epanutin was first marketed in 1938 and was acquired by Pfizer in 2000 by which time it was no longer subject to patent protection. Pfizer's phenytoin sodium capsules are available in four strengths: 25mg, 50mg, 100mg and 300mg. The 100mg capsule is by far the biggest selling capsule strength, accounting for over 70% of all phenytoin sodium capsule dispensed in the UK.

12. NRIM began supplying its phenytoin sodium capsules in April 2013. Its capsules are only available in the 100mg strength. They are sold under the name Phenytoin Sodium NRIM Capsules. Phenytoin sodium is also available in the UK in tablet form; the main supplier is Teva UK Limited ("Teva").

13. Prior to 24 September 2012, Pfizer manufactured Epanutin in Germany before delivering the capsules to a logistics company, United Drugs Group ("UDG"), which delivered them to pharmacies in the UK. During this time, the prices of Epanutin were regulated as part of Pfizer's portfolio of branded drugs under the National Health Service's ("NHS") Pharmaceutical Price Regulation Scheme (the "PPRS").

14. During the course of 2012, Pfizer and Flynn entered into agreements under which Pfizer transferred its Marketing Authorisations ("MAs") for Epanutin to Flynn for £1. Pfizer continued to manufacture its phenytoin sodium capsules which it exclusively supplied to Flynn for distribution in the UK.

15. Following the transfer of the MAs, in September 2012 Flynn de-branded ("genericised" in the language of the Decision) Epanutin and began distributing the product under the name Phenytoin Sodium Flynn Hard Capsules ("PSFH Capsules"). According to the Decision, there was little discernible change to the supply chain following Flynn's introduction in September 2012. Pfizer continued to manufacture its capsules in Germany and to deliver them directly to UDG within the UK, which processed orders for them on behalf of Flynn. Flynn does not take receipt of the products at any time and, according to the CMA, only undertakes minimal activities, such as placing orders for the products with Pfizer and setting its own prices. Moreover, the CMA states that Flynn has taken on very limited commercial risk as it has contracted out of many of its responsibilities as the MA holder.

16. At the same time as the product was de-branded, the product was withdrawn from the PPRS, such that it was no longer subject to price regulation and both Pfizer's average selling price ("ASP") to Flynn and Flynn's ASPs were increased substantially. The increased cost of PSFH Capsules has resulted in a significant increase in the NHS's overall annual expenditure on phenytoin sodium capsules. Prior to September 2012, the NHS's annual expenditure on phenytoin sodium capsules was approximately £2 million. Despite the volumes purchased by the NHS falling year-on-year, this expenditure stood at approximately £50 million in 2013, approximately £42 million in 2014 and approximately £37 million in 2015.

17. As is well known, the NHS is not a single corporate body, but is made up of numerous executive, advisory bodies or agencies. These include: (a) the Secretary of State for Health; (b) the DoH; (c) NHS England, NHS Scotland, NHS Wales and Health and Social Care in Northern Ireland; and (d) Clinical Commissioning Groups ("CCGs"), of which there are more than 200 in England, with equivalent bodies in Scotland, Wales and Northern Ireland. In the case of England, CCGs are responsible for planning and commissioning healthcare services for their local area. Each year NHS England sets a budget for each CCG. A large portion of each CCG's budget is dedicated to essential services provided by large healthcare providers such as hospitals and community trusts, staff costs and other overheads. CCGs may use their discretion, subject to following NHS constitutional standards, to decide how to spend the remaining portion of their budgets.

18. As is also well known, in recent years the NHS has faced significant budgetary constraints. From 2010 to 2015, the NHS Efficiency Policy (Quality, Innovation, Productivity and Prevention programme, or "QIPP") tasked the NHS to make £20 billon of efficiency savings by 2015 in order to make more funds available to treat patients. The NHS has subsequently been asked to make a further £22 billion in efficiency savings by 2020. CCGs typically use a prioritisation committee to decide their discretionary spending to decide which of the many important services a CCG would like to provide should be funded in a given year. CCGs must balance their budget each year and produce a 1% surplus. Save where NHS England intervenes to assist, a CCG which overspends in one year will face a reduced budget in the following year.

19. In September 2012 the DoH filed a complaint with the CMA about the pricing of PSHF Capsules.

The CMA's investigation

20. The CMA opened an investigation in May 2013. It adopted a Statement of Objections ("the SO") on 6 August 2015 and adopted a revised SO on 17 September 2015.

21. On 7 December 2016, the CMA issued the Decision finding that each of Pfizer and Flynn have, since September 2012, abused a dominant position by imposing unfair prices for phenytoin sodium capsules manufactured by Pfizer in the UK.

22. More specifically, the CMA found that:

    (a) Pfizer-manufactured PSFH Capsules are not substitutable with other anti-epilepsy drugs ("AEDs"), including phenytoin sodium capsules manufactured by NRIM or tablets. The relevant product and geographic markets are accordingly:

        (i) For Pfizer, the manufacture of PSFH Capsules in the UK.

        (ii) For Flynn, the distribution of PSFH Capsules in the UK.

    (b) Each of Pfizer and Flynn has been able to act independently of competitors, customers and consumers in their respective markets and therefore hold a dominant position.

(c) During the relevant period the price of each of the relevant dosages of PSFH Capsules charged by both Flynn and Pfizer was excessive having regard to the costs incurred and a reasonable rate of return. The CMA calculated the direct costs and the common costs of Flynn and Pfizer. The CMA found that the best measure of rate of return is return on sales ("ROS") and for both Pfizer and Flynn a reasonable ROS is 6%. This measure is referred to in the Decision as "Costs Plus".

(d) The CMA found that the economic value of the PSFH Capsules for each of Flynn and Pfizer is Costs Plus, as no demand-side or non-cost factors would increase their value above that level.

(e) The CMA concluded that the prices of each of the relevant dosages of PSFH Capsule charged by Pfizer and Flynn bear no reasonable relation to the economic value of the PSFH Capsules, and are each unfair in themselves.

(f) The CMA also found an adverse effect on the end consumer, *i.e.* the NHS, in particular, the CCGs:

> "5.399 As a consequence of these increased costs, CCGs have needed to commit extra money from their constrained budgets in order to continue to fund the supply of phenytoin sodium capsules to patients. This in turn has compromised the scope of other healthcare services that CCGs have been able to provide because they have needed to transfer funds earmarked for other services to pay for phenytoin sodium capsules."

(g) The CMA found the infringements had been committed intentionally or, at the very least, negligently, and imposed penalties on Flynn and Pfizer of around £5.1 million and £84.2 million respectively.

23. The CMA's Directions require Pfizer and Flynn to bring the infringements to an end and to refrain from any conduct having the same of equivalent effect. The Directions also require:

(a) Pfizer to apply revised prices for the supply of phenytoin sodium capsules manufactured by it to Flynn (and other potential purchasers in the UK) within 30 working days of the Directions, i.e. by 23 January 2017.

(b) Flynn to replace its current NHS list prices on the basis of the supply prices that Pfizer is charging before it complied with the Directions, within 30 working days of the Directions, i.e. by 23 January 2017. (Actions required by this date are referred to

as "Step One"). The direction thus applies to existing stock held by Flynn, and purchased from Pfizer at its current supply prices.

(c) Flynn to replace its NHS list prices a second time, ("Step Two") within either two working days of having sold any stock purchased at Pfizer's revised supply prices or, if no such stock is held, within four months of the Directions, i.e. by 7 April 2017. This direction thus applies to new stock purchased from Flynn at the new prices set by Pfizer pursuant to paragraph (a) above.

24. The Directions also provide at paragraph 1(c) and (d):

> "(c) […] when setting (prices) Pfizer and Flynn, as applicable, shall each have regard to the content of this Decision."
>
> "(d) […] nothing in these directions or the Decision should be taken to mean that the Parties are precluded from earning a profit margin greater than the reasonable rate of return adopted by the CMA for the purposes of establishing Cost Plus in this Decision."

The Tribunal's power to grant interim relief

25. I now turn to the relevant law that is applicable in this case.

26. Rule 24 of the Tribunal Rules provides:

> "**Power to make interim orders and to take interim measures**
>
> (1) The Tribunal may make an order on an interim basis—
>
> (a) suspending in whole or part the effect of any decision which is the subject matter of proceedings before it;
>
> (b) in the case of an appeal under section 46 (appealable decisions)(a) or 47 (third party appeals)(b) of the 1998 Act, varying the conditions or obligations attached to an exemption;
>
> (c) granting any remedy which the Tribunal would have the power to grant in its final decision.
>
> (2) Without prejudice to the generality of paragraph (1), if the Tribunal considers that it is necessary as a matter of urgency for the purpose of—
>
> (a) preventing significant damage to a particular person or category of person, or
>
> (b) protecting the public interest,

the Tribunal may give such directions as it considers appropriate for that purpose.

(3) The Tribunal shall exercise its power under this rule taking into account all the relevant circumstances, including—

(a) the urgency of the matter;

(b) the effect on the party making the request if the relief sought is not granted;

(c) the effect on competition if the relief is granted; and

(d) the existence and adequacy of any offer of an undertaking as to damages.

(4) Any order or direction under this rule is subject to the Tribunal's further order, direction or final decision.

(5) A party shall apply for an order or a direction under paragraph (1) or (2) by filing a request for interim relief in the form required by paragraph (6).

(6) The request for interim relief shall state—

(a) the subject matter of the proceedings;

(b) in the case of a request for a direction under paragraph (2), the circumstances giving rise to the urgency;

(c) the factual and legal grounds establishing a *prima facie* case for the granting of interim relief by the Tribunal;

(d) the relief sought;

(e) where no appeal or application has been made in accordance with rule 9 in respect of the decision which is the subject of the request for interim relief, an outline of the information required by rule 9(4).

[…]"

27. Rule 24 came into force on 1 October 2015. It replaced Rule 32 of the Competition Appeal Tribunal Rules 2003 (S.I. 2003 No. 1372) ("the 2003 Rules") ("Old Rule 32"). Old Rule 32 was drafted in similar, but not identical, terms to Rule 24. In particular, Old Rule 32(2) provided:

"(2) Without prejudice to the generality of paragraph (1), if the Tribunal considers that it is necessary as a matter of urgency for the purpose of—

(a) preventing **serious and irreparable** damage to a particular person or category of person, or

(b) protecting the public interest,

the Tribunal may give such directions as it considers appropriate for that purpose."

(Emphasis added)

28. As set out in emphasis above, whilst Old Rule 32 referred to "serious and irreparable damage", Rule 24 refers to "significant damage".

Relevant questions to ask concerning grant of interim relief

29. It is well established that a principal purpose of interim relief in Tribunal proceedings is to preserve the integrity of the appeal and that of the decision under appeal. The Tribunal must ensure that the applicant, if successful, does not enjoy a purely Phyrric victory, and similarly that the respondent authority, if it prevails in the appeal, does not lose in the meantime the competitive outcome which, in the public interest, its decision seeks to achieve: *Genzyme Limited v Office of Fair Trading* [2003] CAT 8 ("*Genzyme*"), para. 98.

30. The *American Cyanamid* principles,[1] applicable in the civil courts in the context of the grant of an interim injunction, are not determinative of the issues which arise under rule 24 of the Tribunal Rules because it is not "*party and party litigation*" and the CMA is not obliged to offer any cross-undertaking in damages: *Napp Pharmaceutical Holdings Limited v The Director General of Fair Trading* [2001] CAT 1 ("*Napp*"), para. 39. Instead, the Tribunal has identified the nearest analogous situation as being the approach taken by the European Courts to the grant of interim relief against a decision of the European Commission under Article 101 or 102 TFEU. On this basis, the Tribunal in *Genzyme*, para. 79, identified five questions to be asked. These questions remain relevant and applicable to applications of this kind, but some adjustment to them is needed in the light of developments in the law

31. The third *Genzyme* question refers to whether the applicant is likely to suffer "serious and irreparable damage", reflecting the language of Old Rule 32. Both Flynn and the CMA argued their respective cases on the basis that the relevant harm must be "substantial and irreparable", saying in effect that the change in the wording of rule 24 should make no difference to the approach by the Tribunal. However, it is necessary for me to apply the Tribunal's Rules as they currently stand and to modify the *Genzyme* question accordingly. I also consider it appropriate to modify the fifth question to draw attention to the need to take into account all relevant circumstances as required by rule 24(3), and to take into account the existence and adequacy of any offer of an undertaking as to damages, as required by rule 24(3)(d)

[1] *American Cyanamid v Ethicon* [1975] AC 396.

32. With those modifications, the *Genzyme* questions can be put as follows:

(a) Are the arguments raised by the applicant as to the merits of its substantive appeal, at least *prima facie*, not entirely ungrounded, in the sense that the applicant's arguments cannot be dismissed at the interim stage of the procedure without a more detailed examination?

(b) Is urgency established?

(c) Is the applicant likely to suffer significant damage if interim relief is not granted?

(d) What is the likely effect on competition, or relevant third party interests, of the grant or refusal of interim relief?

(e) What is "the balance of interests" under heads (c) and (d) taking into account all the relevant circumstances including the existence and adequacy of any offer of an undertaking as to damages?

(Emphasis added)

33. The *Genzyme* questions, applied in combination with the Tribunal's Rules, facilitate a two-stage assessment of whether or not interim relief should be adopted. In the first stage the Tribunal must ask questions (a) to (c) to establish whether it has jurisdiction to grant interim relief. These questions reflect the provisions of Rule 24(2), and seek to establish whether the appeal is not entirely ungrounded and is urgent, and whether the implementation of the decision under appeal would give rise to significant damage to the applicant or a relevant third party. The second stage of the assessment involves the exercise of the Tribunal's discretion and reflects the terms of Rule 24(3). The Tribunal must ask questions (c) (for the second time), and (d) and reach a view on the balance of interests under question (e). Only if the balance of interests favours the grant of interim relief will the Tribunal exercise its discretion to make such an order.

Flynn's request

34. On 23 December 2016 Flynn lodged an application with the Tribunal seeking the suspension of the Directions, insofar as they require Flynn to alter its NHS list prices for the products, pending the final determination of Flynn's forthcoming appeal against the Decision. Flynn

has not yet lodged its main appeal for which the deadline is 7 February 2017, pursuant to rule 9(1) of the Tribunal Rules. Flynn's application was accompanied by witness evidence from Mr Cameron Firth, relating mainly to the process before the CMA, and from Dr David Fakes, a Flynn director, describing the anticipated effect on Flynn of complying with the Directions. Dr Fakes provided a second witness statement prior to the Hearing.

Prima facie case on appeal

35. As noted previously, Flynn has not yet filed its appeal of the Decision. However, it has indicated in broad terms its proposed challenges to the CMA's Decision.

36. First, Flynn states that it will challenge the CMA's findings that Flynn held a dominant position because the CMA's market definition excludes: (i) precisely the same medicine, in the same capsule form, supplied by NRIM (at least after November 2013); and (ii) precisely the same medicine, in tablet form, as supplied by Teva and others.

37. Second, Flynn states that it will challenge the CMA's findings that Flynn is abusing its allegedly dominant position by setting unfair prices. In particular, Flynn will contend that the CMA was wrong to:

    (a) disregard phenytoin sodium tablets as a relevant benchmark when assessing the economic value of Flynn's PSFH Capsules and the fairness of Flynn's prices.

    (b) disregard the NHS's avoided costs of switching capsule patients to tablets and/or other more expensive AEDs when assessing the economic value of PSFH Capsules.

    (c) apply a "cost plus" methodology approach based on a benchmark of a ROS of 6% drawn from the PPRS. Flynn contends standard and more appropriate industry measures of profitability show that its pricing is not excessive. Even if a "cost plus" methodology is a legitimate approach, Flynn will contend that the cost allocation methodology adopted by the CMA is arbitrary and produces meaningless results.

38. Flynn submits that its appeal raises important and novel issues concerning the CMA's ability to impose price regulation based on claims of "pure overcharging". Moreover, Flynn contends that the CMA is attempting to price regulate in a field which is already subject to extensive statutory price regulation.

Urgency

39. Flynn claims that its request is urgent owing to the impending deadline for implementation of the Directions.

Flynn's claim of serious and irreparable harm

40. Flynn makes four broad claims regarding the harm it will suffer by implementing the directions:

(a) First, Flynn says that the Directions are not capable of sensible implementation by Flynn because they are vague and unworkable.

(i) The Decision does not specify a rate that Flynn should use or indicate the scale of the price reductions required. Paragraph 1(d) of the Directions leaves open the question of the appropriate rate of return. It is unclear whether prices set at costs plus 6% would be considered excessive.

(ii) Flynn considers that a rate of return based on a 6% ROS may not be economically viable depending on the level of Pfizer's input price reduction.

(iii) Flynn cannot prepare for Step Two of the Directions because it does not know what price Pfizer will set.

(iv) There are serious practical difficulties associated with allocating Flynn's common costs by reference to volumes of sales given peaks in sales lead to significant variations over time.

(v) The CMA's approach is inconsistent since it is based on a return on sales, but is also a "costs up" approach.

(vi) The Directions require a change to Flynn's NHS list price, rather than Flynn's selling prices to wholesalers. Consequently, Flynn must engage in an additional price adjustment to reflect a wholesaler margin.

(b) Second, Flynn states that pricing on the basis of the CMA's cost allocation methodology and a 6% ROS would amount to a gross interference in its business operations and commercial policy.

(c) Third, Flynn faces an immediate and substantial reduction in its revenues by implementing the Directions. A competition authority is not usually required to offer a cross-undertaking as to damages (see *Genzyme* para. 90-91), and the CMA has confirmed in this case that it will not offer any cross-undertaking. The result is that these financial losses Flynn suffers will be irrecoverable.

(d) Fourth, Flynn claims that the reduced prices are likely to be irreversible as: (i) other suppliers, such as NRIM, are likely to follow suit; and (ii) it would not commercially feasible for Flynn to raise its prices to their former levels subsequently, if its appeal is later upheld.

41. At the Hearing, counsel for Flynn also submitted that the implementation of the Directions would adversely affect market dynamics, in particular by deterring new entry.

Flynn's proposed cross-undertaking

42. Flynn says that, were its appeal unsuccessful, the losses to the DoH in the form of higher prices would be purely financial and easily quantifiable once judgment has been issued by the Tribunal. Flynn is prepared to give a cross-undertaking in damages in favour of the DoH. The cross-undertaking offered is in the following terms:

> "In the event that the Appeal is dismissed insofar as it relates to the CMA's finding of infringement, the Appellants shall reimburse the Department of Health, in respect of any phenytoin sodium Flynn hard capsules sold to the NHS by the Appellants between 23 January 2017 and the final dismissal of the Appeal, such part of the purchase price of the phenytoin sodium Flynn hard capsules as is directly attributable to the Appellants' non-implementation of the Directions, and is unfair within the meaning of Article 102 TFEU/the Chapter II prohibition taking into account findings by this Tribunal in its final determination of the Appeal as regards the Appellants' costs and anon-excessive rate of return."

Balance of interests

43. Given its willingness to provide a cross-undertaking, Flynn contends that the appropriate course is to preserve the *status quo ante* by suspending the Directions, which will ensure that the integrity of Flynn's appeal is preserved, while the DoH's losses will be compensated should the CMA prevail. By contrast, Flynn claims that not suspending the Directions would cause it serious, irreversible and uncompensated financial harm.

Pfizer's observations

44. Pfizer submitted observations in support of Flynn's application and was represented by counsel at the hearing. Pfizer stresses the damage to the Flynn's and to its own reputation that would accompany any renewed attempt to increase the price of the product if an appeal succeeded. Pfizer also intends to appeal the CMA's Decision, but for its part, Pfizer does not seek interim relief pending the outcome of its appeal. Pfizer suggests that, if Flynn's interim relief request is granted, Flynn should hold in escrow the difference between the new supply prices charged by Pfizer and the old supply prices so as to avoid Flynn receiving windfall profits as a result of Pfizer complying with the Directions.

CMA's response to Flynn's application

45. The CMA resists Flynn's application for interim relief. Given the low threshold for establishing a *prima facie* case, the CMA did not address the possible merits of on Flynn's proposed appeal in any detail. Instead the CMA' submissions focussed on its role as a competition authority and the likely impact of granting or refusing interim relief.

Proper role of the CMA

46. The CMA agrees with Flynn that the Decision does not purport to tell Flynn what prices to set or how to set those prices. The CMA has made no finding that Flynn's prices should not exceed cost plus 6%. The CMA considers that cost plus 6% is "very generous" to Flynn, given: (i) the high level of return that this has generated in absolute terms; and (ii) the low risks faced by Flynn and the minimal level of its activities. The CMA states that cost plus 6% is an "upper bound" in the sense that a lower rate of return might also have been considered reasonable. Flynn must charge a price that bears a reasonable relation to the economic value of the Capsules. It is not for the CMA to tell Flynn, it is ultimately for Flynn to charge prices which are compatible with EU and UK competition law. Flynn's complaint that the

Directions fail to lay down the scale of the required price reduction is, in effect, a complaint that the CMA failed to act like a price regulator. This is not the CMA's function.

Position if interim relief is wrongly refused

47. With regard to Flynn's contention that the Directions are unworkable, the CMA responds:

(a) Flynn cannot credibly contend that it cannot set the Step One price, in the light of the Decision which analyses its current prices. The effect of the CMA's Decision is that prices set at cost plus 6% would not be considered excessive.

(b) Flynn's suggestion that a rate of return based on a 6% ROS "may" not be economically viable, following Pfizer's price reduction, is unsubstantiated.

(c) To the extent that Flynn requires extra time to set the Step Two price, it will have time. There is nothing to stop Flynn discussing with Pfizer the likely scale of Pfizer's price reductions.

(d) Flynn's assertions regarding the practical difficulties of allocating common costs are vague and conjectural. Flynn does not need to conduct a cost allocation exercise by 23 January 2017, Flynn can have regard to the content of the Decision which analyses Flynn's costs based on Pfizer's current supply prices; this serves as a "benchmark" not a "straitjacket".

(e) There is no inconsistency in the CMA's approach to calculating a ROS based on costs. The uplift in question (6.38%) is identical to a 6% ROS.

(f) The prices that Flynn charges wholesalers are simply a discount from the Drug Tariff prices. Flynn can take into account the normal margin it provides wholesalers when reducing its prices in accordance with the Directions and set a new List Price accordingly.

48. The CMA rejects the suggestion that it is requiring Flynn to change its way of doing business, it is merely requiring Flynn to reduce its prices for this product. Flynn is not required to adopt the CMA's cost methodology or a 6% ROS and it remains open to Flynn to organise the rest of its business as it sees fit.

49. Regarding the immediate financial loss to Flynn, the CMA contends that the losses which might occur pending the appeal hearing, although irrecoverable, are insufficient to show "serious and irreparable" harm. In particular, Flynn will be able to recover all its direct costs, a contribution towards its common costs and a profit margin.

50. Finally, the CMA questions whether a reduced price would become enshrined in the market. The CMA points to Flynn's original launch price in September 2012, which was substantially above Pfizer's former price. The CMA also points to its findings regarding the unusual characteristics of PSFH Capsules which mean Flynn's product is effectively insulated from any competitive pressure.

Position if interim relief is wrongly granted

51. The CMA's response stresses the harm to patients that will arise if interim relief is wrongly granted. CCGs and other purchasing bodies will have more restricted funds available to purchase healthcare and services for patients if the price reductions are not put into effect. In the light of the severe financial pressures to which the NHS is subject, it states that it is "inevitable" that there will be a reduction in the number and scale of such services it interim relief is granted, and it provides evidence from four CCG executives in support of this. The CMA describes this as "direct harm to the public interest".

52. The CMA criticises Flynn's proposed cross-undertaking as insufficient and unworkable. The cross-undertaking cannot compensate for the delay in repayment, during which time patients will miss out on treatments they would have otherwise received. The cross-undertaking also assumes that the Tribunal will give judgment in a certain way and therefore pre-judges the outcome of Flynn's appeal. In addition it is not the DoH that bears the cost of Flynn's overcharging but the more than 200 local CCGs and other purchasing bodies in the UK, meaning that the cross-undertaking is directed at the wrong beneficiaries. It would be complex and costly to give effect to the cross-undertaking.

53. Finally, the cross-undertaking makes no allowance for inflated wholesaler margins or interest on damages.

The observations of the DoH in support of the CMA

54. The DoH submitted observations in support of the CMA and was represented at the Hearing by counsel. In particular, the DoH provided observations in relation to Flynn's proposed

cross-undertaking. The DoH does not consider the proposed cross-undertaking to be adequate as it would require the DoH to apply and adjudicate on numerous claims for allocation of part of any damages recovered. On the other hand Flynn could not itself directly compensate the affected CCGs because this would be too complex an exercise. Ultimately, the DoH indicated that – if interim relief were granted – it would be willing to act as the beneficiary of the cross-undertaking. The DoH also made a number of further suggestions to deal with the "nuances or complexities" of the situation, including a possible payment into court by Flynn.

The Tribunal's Assessment (1) Does the Tribunal have jurisdiction to grant interim relief?

55. Having set out the background to the case and the arguments of the parties. I now give the tribunal's assessment. I first consider whether in this case the Tribunal has the necessary jurisdiction to grant interim relief. This involves my asking the first three *Genzyme* questions as set out at paragraph 32 above. I deal with the first two questions together before considering the third question.

(a) Are the arguments raised by the applicant as to the merits of its substantive appeal, at least prima facie, not entirely ungrounded?

(b) Is urgency established?

56. As to the likely merits of the appeal Flynn says it will bring, I find that Flynn's case is "not entirely ungrounded" and that the threshold for considering an application for interim relief is met in this respect. I do not find it necessary or appropriate to consider further the merits of any possible appeal by Flynn (or indeed by Pfizer) at this stage. In the course of the hearing my attention has been drawn to some parts of the CMA's Decision, and I refer to aspects of the Decision in this judgment, but these references are for the purpose of considering different aspects of Flynn's application for relief and do not mean that I have had regard to the merits or demerits of the CMA's Decision or any possible appeal against it.

57. I am also willing to consider this application ahead of any actual appeal against the CMA's Decision, on the evidence and assurances provided by Flynn, given that the first relevant date for compliance with the CMA's Directions is well before the expiry of the deadline for filing an appeal. It is essential however that Flynn proceeds to bring its appeal within the due time.

58. For the same reasons I consider that the application fulfils the Tribunal's requirement of urgency. The Directions require action by Flynn (and by Pfizer) well ahead of the earliest possible date for the hearing of any appeal that may be brought. Step One must be complied

with by 23rd January, Step Two at the latest by 7th April. There was discussion at the Hearing as to whether compliance by Flynn with Step One of the Directions was sufficiently straightforward to make the claim of urgency untenable for that stage of compliance. The CMA suggested that it was, Flynn strongly disputed this. In the event I do not think the point matters as both parties approached the application as one to be considered in relation to the Directions as a whole.

(c) Is the applicant likely to suffer significant damage if interim relief is not granted?

59. As to whether interim relief is needed to prevent significant damage to a particular person, Flynn makes a number of claims (see paragraph 40 above) which can be summarised as follows; first that the financial loss it will suffer from immediate compliance with the directions is substantial, both in absolute and relative terms, second that the losses will be irreversible, as it will be impossible to raise its prices again if successful on appeal and irrecoverable because the CMA will not compensate it for its loss; third that it will have to make substantial changes to its way of doing business (in terms of allocation of costs, applying a margin on sales and in relation to its wholesalers) to take account of the requirements of the Directions, which will also be difficult to reverse.

60. I examine the substance of these claims in more detail below in the context of the exercise of my discretion. At this stage I consider merely whether the harm to Flynn would be sufficiently significant to satisfy the jurisdictional requirement in the Tribunal's Rules and under the *Genzyme* test for the grant of relief to be considered.

61. I referred earlier to the need to apply the Tribunal's Rules as they now stand, and to modify the third *Genzyme* question accordingly. Be that as it may, Flynn argued that in any event the harm to it was substantial, irrecoverable and irreversible, as well as being not exclusively financial in nature.

62. Flynn was unable to provide a definite figure for the financial loss that it claimed it would suffer from compliance with the Directions until a final decision on the case. At the Hearing I was referred to table 5.18 of the CMA's Decision, which contains confidential figures of what the CMA estimated Flynn to have earned by way of excess revenue from September 2012 to June 2016.[2] From this it is possible to estimate very roughly a likely annual loss going

[2] Transcript page 17 lines 13-32

forward, although this would not allow for any reduction in Flynn's input price as a result of Pfizer complying with the Directions.

63. For the purposes of jurisdiction I am willing to accept that the possible harm to Flynn from compliance with the Directions is likely to be significant, both in absolute terms –amounting to at least several million pounds per annum – and relative to the Applicant's annual turnover of ca. £51million. At the Hearing, Counsel for the CMA did not seriously contest this aspect of the jurisdictional test [3].

64. Establishing that the Tribunal has jurisdiction to grant the interim relief sought does not mean that the Tribunal must accede to this request for relief.

The Tribunal's Assessment: (2) Should the Tribunal exercise its jurisdiction to grant interim relief?

65. In deciding whether this is a case in which I should exercise my discretion to grant the relief requested, I must now consider the third, fourth and fifth of the *Genzyme* questions identified at paragraph 32 above. This involves the consideration and a careful weighing up of several factors, which may conflict with each other, as well as considering all the relevant circumstances.

(c) Is the applicant likely to suffer significant damage if interim relief is not granted?

66. The first thing to consider is, once again, the question of possible harm to Flynn if the relief is not granted. Flynn argues strongly that the harm it says it will suffer is "irrecoverable, irreversible and substantial" [4] I have already outlined Flynn's claims as to the damage that it would suffer. At the Hearing, Counsel for Flynn put four points on the question of serious harm. First that it was irreparable, in the sense that Flynn would not be compensated for any loss, second that it was substantial, in terms of financial loss and changes to business practices, third that it was irreversible, as Flynn could not raise its prices again even if it won its appeal; and fourth that the Directions were impossible for Flynn to implement, particularly at Step Two.

[3] Transcript page 37 line 27ff .
[4] Transcript page 2 lines 30-32

67. The CMA's response was that Flynn had not established to a sufficient degree of probability that any of the harm claimed was substantial and irreparable. Whilst it did not dispute the order of magnitude estimate of Flynn's possible financial loss from compliance with the Directions, it argued that such loss was not, in the light of the relevant jurisprudence sufficient to justify relief, and that its claims to non-financial loss were put in this context.

68. On the question of unworkability, Flynn claims that the Directions are unclear and contradictory, referring in particular to the juxtaposition of condition C, which requires Flynn to have regard to the content of the Decision and D, which said that a higher rate than that referred to in the Decision may be appropriate. It said that allocating costs by reference to volumes was impossible and made other related claims. Pfizer referred me to a footnote in the Decision which it said was a further contradiction.

69. The CMA replied that the Directions were in the form appropriate for a finding of excessive pricing by a dominant company, that the involvement of Pfizer meant that the Directions had to be combined and sequential, and that there was sufficient material in the Decision to enable Flynn to comply. In relation to Step One, the CMA said that Flynn appeared to accept that it could comply, albeit reluctantly, and that Flynn had over-stated the difficulties in complying with Step Two.

70. There is a danger in considering these conflicting arguments of being drawn into the merits of any future appeal. Counsel for Flynn drew my attention to para. 91 of *Genzyme* where the then President of the Tribunal found that the OFT's directions would result in "a major upheaval in Genzyme's business". The President went on to state "I cannot exclude the risk that Genzyme might find itself in practice unable to re-establish the previous arrangements, even if it were to win the appeal."[5] Counsel for Flynn relied on this to support the submission that no assumptions should be made against Flynn; that the risk of irreversibility of price reductions cannot be excluded and that this points to a finding that Flynn would suffer irreparable harm.

71. Counsel for the CMA argued that the evidence for the proposition that price changes would be irreversible was "extremely thin" and did not even establish a real prospect of such a consequence.[6] Dr Fakes' first witness statement contains a bald assertion that "NRIM and

[5] Transcript page 9 lines 17 -18.
[6] Transcript page 60 lines 10ff.

Flynn do compete on price […] at least in relation to the 100mg capsule." Dr Fakes' second statement expands on this evidence. He states:

> "7. […] I regard NRIM as a direct competitor to Flynn in the supply of phenytoin capsules. In particular, I do not accept the CMA's case that the principle of continuity of supply means that Flynn's prices are not constrained by those of NRIM given the following facts regarding NRIM's acquisition of customers and its growth since it launched […]:
>
> (a) the products are essentially the same and were recognised by the MHRA as such […];
>
> (b) NRIM has gained customers: as acknowledged by the CMA in § 4.180(c) of the Decision, after launching in April 2013, NRIM convinced the two largest pharmacy chains in the UK by volume, Boots and Lloyds, to dispense NRIM's capsules against open prescriptions instead of Flynn's product in large part. I believe that those pharmacy chains did so on the basis of price-related considerations;
>
> (c) In fact, NRIM has grown significantly since it launched: I estimate that in 2015 Flynn accounted for approximately 13,915 packs of 100mg phenytoin sodium capsules per month in the UK. […]"

72. Counsel for the CMA went on to draw my attention to paragraph 4.180(c)(ii) and(iv) of the Decision, relied on by Dr Fakes.[7] These paragraphs indicate that: (i) the growth NRIM enjoyed occurred primarily (if not entirely) before November 2013, when the MHRA introduced its guidance re-emphasising the Continuity of Supply principle; and (ii) since November 2013 all pharmacies have adhered to the Continuity of Supply principle. In addition, phenytoin sodium is prescribed for very few new patients – this is not in dispute.

73. It is not appropriate for me to decide on the merits, at this stage, whether NRIM exerts price pressure on Flynn. However, it is appropriate for me to consider whether Flynn's argument in respect of a matter in dispute is or is not "entirely ungrounded". In my view, an applicant's argument must provide a plausible explanation as to how that risk will become real. The applicant's argument must allude to facts and matters which if shown to be correct at a hearing on the merits, would explain how the risk would materialise.

74. Taking that approach, the claimed effect on Flynn's business and other products looks highly speculative. The same goes for the claims that any price rise would be irreversible. Flynn has not explained to me why the CMA's directions in relation to phenytoin sodium require it to

[7] Transcript page 60 lines 25ff.

change its pricing methodology of its other products, for which there is no finding that Flynn holds a dominant position or has priced excessively. Flynn's argument in support of its application has not set out a plausible explanation as to why prices would be irreversibly reduced. In particular, Flynn has not suggested that it will adduce evidence that pharmacies do not adhere to the Continuity of Supply principle, nor has it suggested that the number of new patients is sufficiently significant that its pricing of stabilised patients is constrained. Indeed, there is no evidence before me that NRIM's market share has grown since November 2013. Although I do not rule out the possibility that Flynn, by the time of the substantive hearing, will be able to advance a credible explanation supported by relevant evidence, I find that the facts and matters placed before me now are insufficient to reach the view that Flynn's argument regarding the risk of irreversible is not entirely ungrounded.

75. Counsel for Flynn argued that Flynn was under the joint pressure of preparing its appeal and applying for interim relief and did not have much time to prepare evidence in support of its application for interim relief. I make some allowance for that, but there is no suggestion that the CMA's timetable for compliance is unreasonable (it appears to have been relaxed somewhat following representations from Flynn). Moreover, matters such as the formulation of possible Directions and the nature of market conditions and pricing pressures on Flynn must have arisen during the course of the CMA's procedure during which there would have been opportunities for preparing evidence in support of Flynn's claims. As I have already emphasised, the onus rests on the applicant to make its case for interim relief.

76. There is then the claimed unworkability of the Directions. In my view Flynn's argument is significantly weakened by the fact that it admits to having a contingency plan for compliance with Step One on 23rd January, and by the fact that Pfizer has not applied for interim relief and states that it will, albeit reluctantly, comply with the Directions pending trial of its appeal. The principal force of Flynn's claim is therefore in relation to its compliance with Step Two, namely where it has to adjust its margin to a reduced supply price from Pfizer. Flynn says it has no way of knowing what that price will be and is reluctant either to ask or negotiate. At one stage there appeared to be some doubt as to whether Flynn would in any event (eg if it obtained the relief it seeks) pass on the benefit of Pfizer's price reduction. This lies behind Pfizer's proposal of a payment into escrow, which I deal with at paragraph 100 below. It emerged at the Hearing however that Flynn would pass such reductions on, but stressed its difficulties in applying its own margin on the basis of the Decision[8].

[8] Transcript page 44 lines 20ff.

77. Whilst it is clear that reducing its margins and prices as required is deeply undesirable to Flynn, I am not convinced it is either impossible or impracticable. It is for Flynn, relying on the material contained in the Decision to take a view, based on specialist advice if needed, as to what level of margin is likely to be regarded by the CMA as in compliance with the Decision. The fact that the Directions do not set a specific price means that Flynn has some margin for error. It seems in my view unlikely that the CMA, prior to our hearing the full appeals in this case, would pursue Flynn to the last penny, if it was satisfied that a genuine effort had been made to meet its requirements. The CMA has already clarified that a wholesaler margin (where applicable) is permitted and that the mechanics of notifying new NHS List Prices are not difficult. Accordingly, I do not accept that the Directions are impossible to comply with or that Flynn will find it impracticable to do so pending the trial of any appeal brought.

78. This leaves the unspecified but estimated financial loss which Flynn will probably incur if it complies with the Directions. It is not disputed that this is irrecoverable in the sense that the CMA offers no compensation and it would appear to be a significant sum in relation to Flynn's overall business turnover, as I have already noted. The EU jurisprudence to which the CMA referred stresses that such financial loss is not sufficient to satisfy the European Courts' test of substantial and irreparable harm. There must be something more such as a demonstrable threat to the applicant's continuation in business. There is no suggestion of that here and reference was made to Flynn having significant reserves of cash at a date in 2016. Counsel for the CMA also referred to the fact that the Directions expressly allowed Flynn to make a return on its costs, albeit a much lower return than it has enjoyed up to now.[9]

79. I have already referred to the removal of the reference to "irreparable" in the Tribunal's 2015 Rules, but both parties have put their case on the basis that the approach set out in *Genzyme* and which I have described at some length remains basically correct. I am content in this context to take the parties' references to the possible irreparability of the harm as one aspect of its significance.

80. I am, however, reluctant to go as far as the CMA in dismissing the significance of the harm claimed by Flynn altogether. Instead I consider it is in some respects speculative and over-stated but nonetheless has a significant core. It may be observed that Flynn has also obtained very substantial financial benefit from supplying the product in question to the NHS since

[9] Transcript page 59 lines 27ff.

2012, which may serve to put this financial loss into context. Nevertheless, it is there and I so find it.

81. I therefore proceed to consider the possible effect on competition and third party interests if the Directions were suspended and then to weigh the conflicting matters in the balance.

(d) What is the likely effect on competition, or relevant third party interests, of the grant or refusal of interim relief?

82. In the present case, I concentrate on the possible effect on competition and third party interests if the interim relief *were* granted. If the relief *were not* granted, apart from one argument advanced by Flynn to which I refer below, it is not seriously suggested by Flynn at this stage that the CMA's Directions will adversely affect competition, although in any subsequent appeal that possibility can by no means be excluded.

83. The adverse effect on competition identified in the Decision consists of the charging of excessive prices by Pfizer and Flynn for a product manufactured by Pfizer that the NHS, by virtue of its own clinical guidance, is required to procure for a particular category of patients. The overcharge is paid out of finite resources, which are diverted away from other needs, to the general detriment of patient care. It is not apparent that Flynn disputes the substance of this harm. It argues that NHS resources are always stretched and that allocating expenditure to one particular product or treatment is bound to affect others. It says that any harm to patients from its price continuing unabated is regrettable but unavoidable and in any case can be compensated in large measure by its cross-undertaking in damages.

84. I deal with the cross undertaking below but note here a further argument advanced by Flynn at the Hearing to the effect that lowering the price of Flynn's product as required by the CMA could deter the entry of companies offering generic forms of the product in dispute and itself harm competition. Counsel for Flynn put this as a "secondary point"[10]. I think she was wise to do so, and I do not think that such speculative matters need be further considered at this juncture. As I have said, the effect on competition of the excessive pricing found in the CMA's Decision may be fully debated in any appeal.

85. Flynn further claims that it ill behoves the CMA to stress the harm to patients from Flynn's pricing during the period up to trial of its appeal, when it itself took some three and a half

[10] Transcript page 8 line 28.

years to reach its Decision. I do not think there is anything in this point. A competition investigation is a complex and time consuming process, not only because of the subject matter but also because of the procedural steps that an authority is obliged to take to respect the parties' rights of defence. Flynn points to its offers to the CMA to speed up the process possibly by committing to change its conduct, but it is for the CMA to decide how and how quickly it conducts a case of this kind, subject of course to the requirements of due process and fairness. Counsel for the CMA said that the harm in question was to the public, not to the authority, and the time taken to reach a decision does not entitle Flynn to further relief. I agree. The question to assess is how serious is the harm to competition and to the public that will be prolonged if the interim relief is granted, not whether the time taken by the CMA to find an infringement means that its effect must be allowed to continue.

86. The CMA described this effect as "*a direct harm to the public interest*". The CMA submitted evidence from representatives of three CCGs and the Greater Manchester Medicines Management Group ("GMMMG"), which represents 12 CCGs in the Greater Manchester area, on the impact of the price rises which occurred following September 2012. This information is summarised in tabular form below:

CCG	Pre-2012 expenses	Post-2012 expenses
Gloucestershire CCG	£24,000	£400,000
Sussex CCG	£20,000	£320,000
Somerset CCG	£20,000	£440,000
GMMMG	£48,000	£2 million

87. This evidence is of course not complete or comprehensive; it is in some respects anecdotal and gives only a partial picture. As such it is open to the same criticism as the CMA levelled at Flynn's evidence of harm, and is indeed so criticised by Flynn, but it is in my view rather more convincing. First it is put as providing examples of the problems faced by individual commissioning groups applying the discretionary element of expenditure within their control. Further it gives actual numbers of expenditure attributable to the overcharge found by the CMA.

88. The DoH's observations were mainly in relation to the efficacy of Flynn's proposed cross-undertaking, but Counsel for the DoH also stressed the serious and irreparable nature of the harm that was being caused by strain on limited NHS resources by an overcharge such as the CMA had found in this case. In particular the DoH agreed with the suggestion that harm to patients in a case such as this, where the high prices had now operated for more than four years, could not be compensated by subsequent payments in later financial years.[11]

89. There was discussion at the Hearing as to what was meant by "harm to competition" and the "effect on third party interests", as set out in the *Genzyme* test. Flynn seemed to accept that in an excessive pricing case such as this the relevant harm to competition would be the direct harm to consumers or relevant third parties arising from the overcharge, rather than the effect on competitors as in an exclusion case such as *Genzyme*. Counsel for the CMA said that the identification of harm to consumers in competition law terms was complicated by the different roles played in the purchasing decision by the prescribing doctor, the dispensing pharmacist, and the funding CCG, all acting in the interests of patient care. In this case patients who received the product in dispute would benefit in any event. It was those who did not receive particular treatment because money was diverted elsewhere who would be harmed. He suggested that consumer harm in this case could be categorised in several different ways for the purposes of applying the *Genzyme* test but the over-riding factor was that the harm was not purely financial. It was harm to public health and hence the public interest.

90. The precise categorisation of consumer harm in this case will no doubt be debated further at the trial, but for present purposes the question of harm to the NHS and its patients, which by any reckoning is substantial and not merely financial in nature, can either be considered as falling within the specific *Genzyme* formulation or be considered as part of the overall surrounding circumstances.

91. Before moving to the stage of balancing these competing considerations of harm, there are further matters to consider. These include the argument advanced by the CMA that there is a strong presumption in public law cases against the grant of interim relief, the question of the existence and adequacy of the cross undertaking in damages offered by Flynn, and the escrow suggestion made by Pfizer.

[11] Transcript page 77 lines 28-31

92. Counsel for the CMA said that the CMA made a decision in the public interest, that the scheme of the Competition Act 1998 is that appeals suspend the payment of penalties but not the compliance with directions and that in this case the Directions should be given effect unless and until the Flynn can demonstrate otherwise. Flynn disputed this approach and argued that a public authority received no special benefit in the consideration of applications for interim relief by virtue of acting in the public interest.

93. I agree with the CMA that it does indeed take decisions in the public interest, to which competition law and policy contribute. However, I do not think this requires the Tribunal to adopt an approach that is different from the *Genzyme* test to which I have already referred. This involves having regard to the need to protect the integrity of any appeal brought against a CMA decision whilst at the same time preserving the integrity of the decision itself. This is precisely what is involved in the balancing exercise associated with the exercise of the Tribunal's discretion whether or not to grant relief that needs to be conducted in this case.

94. I next consider the adequacy of the cross-undertaking in damages offered by Flynn to compensate the NHS for any loss suffered by the suspension of the Directions. This is set out at paragraph 42 above but refers in particular to "such part of the purchase price of the…capsules as is directly attributable to (Flynn's) non-implementation of the Directions and is unfair within the meaning of Art 102 etc.."

95. Whilst it is notable that Flynn offers such an undertaking (it was at one time not thought that the Tribunal could accept an undertaking in favour of a third party in an appeal case) the Tribunal's 2015 Rules now specifically refer this possibility and it is incorporated into the *Genzyme* test to which I have referred. The terms and effect of this undertaking have been strongly criticised by the CMA and by the DoH as inadequate and unworkable. Flynn by contrast argues that it will compensate the NHS for the great majority of the harm suffered as a result of any grant of relief.

96. The CMA's substantive criticisms centre on the implicit assumption that this Tribunal will decide any appeal in a way that allows the amount to be repaid to be easily calculated, that its scope does not extend to wholesaler margins (which may have been inflated by Flynn's excessive price), and it offers no interest on the amount to be repaid. In addition, it cannot compensate for harm to patients. The CMA's implementation criticisms centre on the NHS being the inappropriate recipient, as purchasing decisions are made by individual CCGs in England and equivalent bodies elsewhere in the UK and by hospitals and the undertaking places on the DoH the burden of assessing an allocating the amounts paid in compensation.

The Department supports the CMA in this making a number of detailed further points as to implementation. Counsel for the DoH said that because of both aspects of criticism the harm caused by Flynn's conduct could not adequately be compensated by an undertaking of this kind and was in that sense irreparable.

97. Flynn's response to these criticisms is robust. It points out that it is not obliged to offer any undertaking and that the Department can always pursue a civil remedy in damages as it has done in a number of other cases. Moreover the form of undertaking and the beneficiary identified as the NHS are entirely standard and done in other cases, such as in patent proceedings where an interim injunction is granted to a patent relevant to a medicine. Thirdly the difficulty in determining the lawful price is exactly what Flynn is experiencing in relation to complying with the Directions, and would arise in any civil action anyway; finally Flynn's obligation is correctly limited to the unlawful element of the amount it charges its customers, not the overall cost to the NHS.

98. I do not regard Flynn's response in this respect sufficiently convincing. Whilst a cross undertaking in the terms offered, bearing in mind that it is voluntary, would provide some compensation to the NHS, it would not give the full and sufficient compensation that Flynn claims. Apart from the limitations of scope, which Flynn does not deny, the complexities of administration place an unnecessary burden on the Department, on the NHS and on its various constituent parts. The fact that similar burdens may also arise in any subsequent civil claim for damages is not a reason for adding to them. I also consider the parallel Flynn seeks to draw with interim injunctions in patent proceedings inapposite. In that situation, the courts recognise the risk that not granting an interim injunction may undermine incentives for companies to develop new medicines. Reduced innovation itself poses a risk to the public health in the long run. There is no equivalent concern in this case since intellectual property rights are not involved.

99. Most important, the harm to the public is not purely financial and the cross-undertaking clearly cannot compensate for harm suffered by patients denied funds diverted to purchasing Flynn's product. I do not think the suggestion made by Flynn that compensatory payments in later years, even if these could be correctly applied, can be regarded as sufficient recompense for actual patient harm suffered at any given time is adequate.

100. The remaining point is the suggestion made by Pfizer that the difference between its own (reduced) supply price and the price charged by Flynn to its customers should be paid into escrow, to prevent Flynn receiving a windfall gain from Pfizer's compliance with the

Directions if Flynn obtained the relief it seeks. Flynn makes a number of objections to this, but in any event the point fell away during the Hearing as Flynn made it clear that if (at Step Two) Pfizer did reduce its supply price to Flynn, Flynn would in any event pass that reduction on to customers[12]. That concession disposes of the matter. An escrow arrangement would not be without complications, and it is clearly better that the benefit of Pfizer's compliance should accrue to the NHS and not to Flynn.

101. Having considered the question of possible harm to Flynn, the possible effect on competition and the public and other relevant circumstances I now weigh up the various competing factors and decide whether to grant the relief sought.

(e) What is "the balance of interests" under heads (c) and (d) taking all the relevant circumstances into account?

102. The question arises whether taking all these matters into account Flynn's request should be granted. On the one hand I have found that if the Directions are not suspended Flynn will suffer significant, although largely financial, loss, which it will not recover even if, as may be, its prices could subsequently be raised after a successful appeal; on the other hand I have also found that if the Directions are suspended the adverse effect of the higher prices that will continue to be charged by Flynn to the NHS is likely to be substantial, not purely financial, and in part at least irreparable. It is true that, provided Pfizer complies with the Directions, part of the claimed overcharge will be avoided for the duration of the Tribunal's process, but Flynn's part, as was established in considering the amount of Flynn's possible loss, is also substantial.

103. Having weighed all these factors carefully, I have come to the view that as things currently stand I should not grant Flynn the requested relief from compliance with the CMA's Directions. Flynn will have, however, liberty to apply in the event of a material change of circumstance.

104. My reasons for this decision are as follows:-

105. The over-riding consideration is that, taking all the circumstances into account, the harm to the public from allowing the continuation of higher prices for this product outweighs the harm to Flynn that this may cause. A relevant factor in this finding is that it is not only the

[12] See also Flynn's Reply para 36 and Dr Fakes' second witness statement paras 22-23.

pecuniary effect of high prices on the resources of the NHS that is in issue, although that is serious enough, but the consequent effect on the health and well-being of affected patients and hence to public health overall and the public interest.

106. My attention was drawn to several cases suggesting that public health was a more important consideration than the monetary or business interests of individual undertakings. The CMA referred to the case of *Cambridge Healthcare*[13], where the President of the European Court of Justice dismissed an application for interim measures connected to the suspension of a marketing authorisation of certain human medicines. Counsel for the DoH also referred to this case. The President stated that the applicant's "interest in obtaining suspension of the operation of the contested decision could not prevail in the present case over the interest of the Community in the immediate withdrawal of the marketing authorisation held by (the applicant), with a view to protecting public health." (120) and "It must be remembered that, in principle, the protection of public health must unquestionably be given precedence over economic considerations." (121)

107. The facts of that case were very different to those of the present case, and the interim relief in that case would have allowed the continued marketing of products found to be a danger to public health. I do not take the passages quoted as establishing that harm to public health will always over-ride economic interests of undertakings, but they do serve to emphasise that public health may merit special consideration in the hierarchy of interests that I have to consider in weighing up different kinds of harm in this case. Apart from its relevance to the question of the loss being irrecoverable, I find that the question of any harm to patients through the diversion of scarce NHS funds to pay for Flynn's products in the period up to a final decision on appeal must be given particular weight in deciding whether to suspend the Directions. In the light of this and the evidence of direct impact on CCG and other discretionary expenditure adduced by the CMA I find that the adverse effect on competition, public health and the public interest if I grant the relief requested is likely to be substantial, to be medical and health related as well as financial and in that sense irreparable.

108. Against that, the damage to Flynn from leaving the Directions in place, although significant, is not enough to outweigh this damage to the public interest. I am not convinced that all of Flynn's claims as to the harm it may suffer are justified and I do not accept that the CMA's Directions are so unclear and contradictory as to be impossible to comply with.

[13] Case C-471/00 P(R) Order of 11th April 2001

109. The position is complicated by the fact that Pfizer, the manufacturer of the product, has not applied for relief and proposes to comply with the Directions pending an appeal and trial. The confirmation given by Flynn at the Hearing that it will pass on any Pfizer price reductions may bring some relief to the NHS, but in my view, not a sufficient one. That Pfizer proposes to comply with the Directions also suggests that Flynn's claims as to their unworkability may be over-stated. It is in any event for the CMA to decide whether its Directions are being complied with and to take any appropriate action if not. Although one could argue the opposite, in my view Pfizer's proposal to comply with the Directions makes it less rather than more appropriate to grant interim relief to Flynn, even with its assurance of passing on price reductions.

110. The cross-undertaking offered by Flynn, although offered voluntarily, would not adequately compensate the NHS or its various purchasing authorities for the harm they would likely suffer, for the reasons advanced by the CMA and the DoH. The possibility that any subsequent damages action brought by the DoH or NHS may face difficulties or complexities in allocating loss is not a good reason to inflict these difficulties also in relation to the sums being spent by CCGs and others now.

111. Finally, the time taken by the CMA to reach its Decision, which Flynn claims meant that the CMA could not now require its Decision to be immediately complied with, is not a reason for granting interim relief. The CMA was obliged to consider all the evidence and to allow the parties full opportunity to reply to the accusations against them. Such things necessarily take time and in terms of harm to the public the length of time so far taken tends if anything to confirm the need to maintain the Directions in place pending trial.

112. What matters now is that all parties should proceed with the utmost expedition to file their appeals, if they so wish, and bring the disputed matters to trial. The Tribunal will assist in this process to the fullest extent possible. The Tribunal will also accept a renewed application from Flynn for interim relief as the appeal process (once started) continues, if it can show a material change of circumstances.

Conclusion

113. For the reasons set out in this judgment, Flynn's request for interim relief is refused.

Peter Freeman CBE QC *(Hon)*

Charles Dhanowa OBE, QC *(Hon)*
Registrar

19 January 2017