IN THE COMPETITION COMMISSION

APPEAL TRIBUNAL

Case No. 1001/1/1/01

New Court
Carey Street
London WC2A 2JT

15 January 2002

Before:

SIR CHRISTOPHER BELLAMY
(President)
MR BARRY COLGATE
PROFESSOR PETER GRINYER

BETWEEN:

NAPP PHARMACEUTICAL HOLDINGS LIMITED AND SUBSIDIARIES

Applicant

and

DIRECTOR GENERAL OF FAIR TRADING

Respondent

Mr Nicholas Green QC (instructed by Messrs Herbert Smith) appeared for the Applicant

Mr Peter Roth QC and Mr Jon Turner (instructed by The Director of Legal Services, Office of Fair Trading) appeared for the Respondent

JUDGMENT (Non-confidential version):

Note: Excisions in this judgment relate to commercially confidential information: Section 56 and Schedule 8, paragraph 4(3) of the Competition Act 1998.

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Note: For simplicity, this judgment will refer throughout to Articles 81 and 82 of the EC Treaty, whether in citations from judgments or otherwise, notwithstanding that the original citation referred to Articles 85 and 86 of the EC Treaty which were renumbered as Articles 81 and 82 by the Treaty of Amsterdam with effect from 1 May 1999.

I – INTRODUCTION

1. This is the judgment of the Tribunal on the substantive appeal by Napp Pharmaceutical Holdings Limited and subsidiaries ("Napp") against:

   (i) the decision by the Director General of Fair Trading ("the Director") dated 30 March 2001 ("the Decision") which found that Napp had abused a dominant position in the supply of sustained release morphine tablets and capsules in the United Kingdom, contrary to the Chapter II prohibition of the Competition Act 1998, and imposed a penalty of £3.21 million; and

   (ii) the directions made by the Director dated 4 May 2001 ("the Directions") regulating the prices at which Napp's sustained release morphine products are to be sold.

   Earlier decisions of this Tribunal on 22 May, 10 July and 8 August 2001 have previously dealt with interim relief and various interlocutory matters: see [2001] CompAR 1, 21 and 33.

The statutory framework

2. The Competition Act 1998 ("the Act") came into force on 1 March 2000. This case concerns section 18 of the Act which provides, so far as material:

> "18.–(1) … [A]ny 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;
>
> (b) limiting production, markets or technical development to the prejudice of consumers;
>
> (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
>
> (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of the contracts.
>
> (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"."

3. Following an investigation under the powers contained in Chapter III of the Act, the Director may, pursuant to section 31(1)(b), make a decision that the Chapter II prohibition has been infringed.

4. Section 33(1) of the Act provides that, if the Director has made a decision that conduct infringes the Chapter II prohibition, he may give "such directions as he considers appropriate to bring the infringement to an end." Such directions may be enforced by the Director on an application to the Court: section 34

5. Section 36(2) provides that on making a decision that conduct has infringed the Chapter II prohibition, the Director may require the undertaking concerned to pay him a penalty in respect of the infringement. Under section 36(3), such a penalty may be imposed only if the Director is satisfied that the infringement has been committed intentionally or negligently. By virtue of section 36(8), no penalty fixed by the Director may exceed 10 per cent of the turnover of the undertaking as determined in accordance with the Competition Act 1998 (Determination of Turnover for Penalties) Order 2000 (SI 2000 No. 309). Any penalty so imposed is recoverable as a civil debt following the expiry of the period for appealing to this Tribunal, or the determination of any such appeal: section 37.

6. Section 38(1) of the Act requires the Director to publish guidance as to the appropriate amount of any penalty. Under section 38(8) the Director must have regard to that guidance when setting the amount of the penalty. The Director has published such guidance entitled *Director General of Fair Trading's Guidance as to the Appropriate Amount of Penalty* (OFT 423, March 2000).

7. The foregoing provisions of the Act are closely modelled on Article 82 of the Treaty establishing the European Community ("the Treaty") and Council Regulation no. 17 OJ 1959-62, p. 87 as amended. So far as possible and appropriate, the Act is to be interpreted and applied in a manner consistent with the principles of European Community law regarding competition: section 60.

8. A person in respect of whose conduct the Director has made a decision may appeal to this Tribunal against, or with respect to, that decision: sections 46(2) and 48(1).

9. The powers of this Tribunal to determine appeals under section 46 are set out in paragraph 3 of Schedule 8 of the Act, which provides:

> "3.–(1) The tribunal must determine the appeal on the merits by reference to the grounds of appeal set out in the notice of appeal.

(2) The tribunal may confirm or set aside the decision which is the subject of the appeal, or any part of it, and may–

(a) remit the matter to the Director,

(b) impose or revoke, or vary the amount of, a penalty,

(c) grant or cancel an individual exemption or vary any conditions or obligations imposed in relation to the exemption by the Director,

(d) give such directions, or take such other steps, as the Director could himself have given or taken, or

(e) make any other decision which the Director could himself have made.

(3) Any decision of the tribunal on an appeal has the same effect, and may be enforced in the same manner, as a decision of the Director.

(4) If the tribunal confirms the decision which is the subject of the appeal it may nevertheless set aside any finding of fact on which the decision was based."

10. The procedure governing such appeals is set out in the Competition Commission Appeal Tribunal Rules 2000, S.I. 2000 No. 261 ("the Tribunal Rules"). Rules 17, 20 and 21 (directions, witnesses and evidence) and Rule 27 (interest on penalties) are relevant to certain issues arising in these proceedings.

General Background

11. Napp, a pharmaceutical company based in Cambridge, is an associate of the Purdue Pharma group of companies which is owned ultimately by the Sackler family. Napp had a United Kingdom turnover of approximately £51.2 million in 2000, of which some £[...] million was derived from sustained release morphine.

12. Morphine is a strong opioid analgesic used to treat moderate and severe pain, particularly in cancer patients. Napp states that there is evidence of growing use of opioid analgesics to treat non-cancer patients such as, for example, those with chronic arthritis. Sustained release morphine extends the duration of action of a morphine preparation and is used when the pain is constant.

13. In 1980 Napp launched the first sustained release morphine product to appear on the market under the name MST CONTINUS ("MST"). According to Napp, the advantage of MST is that the active ingredient is released gradually over a 12 hour period so as to achieve a continuous and uniform level of analgesia. Napp states that it is a mark of the success of MST that, even some 20 years after its launch, it remains "the gold standard for the treatment of severe chronic pain".

14. Napp held a patent on MST between 1980 and 1992. The patent protected the sustained release formulation rather than the morphine sulphate itself. From 1980 to 1991 MST was the only orally administered sustained release morphine product on the market in the United Kingdom.

15. In 1991 Farmitalia launched a rival brand of oral sustained release morphine tablets under the name SRM-Rhotard and later assigned its rights to Boehringer Ingelheim Limited ("BIL"). BIL re-launched the product under the name Oramorph SR in 1994. BIL withdrew Oramorph SR from the market in September 2000 having taken the decision to do so in February of that year.

16. Napp has around 95 per cent of the total market for oral sustained release morphine tablets and capsules in the United Kingdom. Apart from MST, which is supplied in tablets, there are currently two other brands of oral sustained release morphine on the market, namely Morcap SR, launched in 1996 and supplied by Sanofi-Winthrop; and Zomorph, launched in 1997 and supplied by Link Pharmaceuticals Limited ("Link"). Link's total turnover in all products in the year to March 2001 was £6.7 million. Link's product Zomorph is supplied in capsules which can either be swallowed or broken open and sprinkled on food. There are no generic – i.e. unbranded – sustained release morphine products on the market. Morcap SR has a negligible market share and has hardly figured in the argument in this case.

17. About 86 to 90 per cent of the supply of oral sustained release morphine is to the community segment of the market – i.e. to patients under the care of their GP. Where a GP prescribes by brand name the community pharmacist is obliged to dispense that brand of drug. Napp's market share in the community segment is and has remained for many years around 96 per cent.

18. In the community segment of the market, Napp's NHS list price for MST has remained the same since its launch, subject to periodic reductions negotiated by the pharmaceutical industry as a whole in the context of the Pharmaceutical Price Regulation Scheme ("the PPRS"). The PPRS, of which Napp is a member, is a voluntary price regulation scheme, agreed between the Secretary of State for Health and the Association of the British Pharmaceutical Industry, which operates to control the overall profits of participating pharmaceutical companies and, in some instances, to limit the initial launch price, or subsequent price increases, of branded medicines. The current PPRS, which came into force in 1999 and expires in 2004, is backed by various statutory powers under the Health Act 1999.

19. The remaining 10 to 14 per cent of supply is to the hospital segment of the market. Sustained release morphine is purchased directly from manufacturers by hospitals, where it is prescribed to patients by hospital doctors or specialists. The hospital pharmacist will dispense the branded drug prescribed by the hospital doctor but may have discretion to substitute an equivalent branded drug carried in the hospital formulary. A number of hospital regions purchase by competitive tender through the NHS Purchasing and Supplies Agency (NHS PASA), or its equivalent in Scotland and Northern Ireland, but a separate contract is negotiated for each region. Other regions seek tenders directly without using the NHS PASA. The regional contracts are framework contracts, which mean that an individual hospital may choose to negotiate an individual contract on different terms, possibly with another supplier.

20. In the hospital segment, the purchasing authorities are much more price sensitive than GPs in the community segment of the market. After the launch of SRM Rhotard by Farmitalia in 1991, discounts to hospitals increased, and continued to do so after the re-launch of that product as Oramorph SR by BIL in 1994. Since the mid 1990s Napp has offered discounts off the NHS list price of up to [...] [in excess of 90] per cent on hospital tenders on certain strengths of MST tablets. Napp's market share in the hospital segment is in excess of 90 per cent.

21. As seen below, the hospital segment is not only important in its own right but is a strategic "gateway" for any new supplier who wishes to establish himself in the community segment of the market.

22. In addition to the scheme of voluntary price regulation under the PPRS, the Health Act 1999 makes provision for the establishment of Primary Care Groups and Primary Care Trusts ("PCGs/PCTs") which are being progressively established with effect from 1 April 1999. One of the purposes of this reform is to encourage greater price sensitivity in prescribing by GPs, and to promote a greater awareness of the cost implications, for the community segment of the market, of purchasing decisions made by hospitals.

II – THE DECISION AND DIRECTIONS

The Administrative procedure

23. Following a complaint, the Director's investigation began under the Competition Act 1980 and continued under the Competition Act 1998 after 1 March 2000. A notice dated 6 July 2000, sent to

Napp under section 26 of the Act, required notably the production of minutes of meetings of directors of members of the Napp group and all documents prepared for those meetings relating to the pricing of MST tablets for the period from 1 January 1997, as well as a great deal of other specified documents and information.

24. The Director issued Napp with a notice under Rule 14 of the rules made by the Competition Act 1998 (Director's rules) Order 2000 SI 2000 No. 293 ("the Director's Rules") on 25 August 2000 ("the first Rule 14 Notice"). In that Notice the Director stated his intention to take a decision that the Chapter II prohibition had been infringed, and setting out the facts and matters relied on, as required by Rule 14(3). Napp replied to that notice orally and in writing. A supplementary notice ("the second Rule 14 notice") was served on Napp on 2 February 2001, to which Napp also replied orally and in writing. A third notice under Rule 14 relating to directions the Director proposed to make under section 33 of the Act was served on 15 March 2001. Napp replied in writing on 27 March 2001 and made certain later submissions.

25. Pursuant to Rule 14(5), Napp was afforded an opportunity to inspect the documents in the Director's file, subject to the protection of confidentiality requested by third parties and of internal documents under Rule 14(6). It appears that the Director kept under review the question of disclosure, and subsequently disclosed to Napp a number of further documents

26. The Decision was notified to Napp on 30 March 2001, and the Directions were notified on 4 May 2001.

The Director's findings on dominance

27. In the Decision the Director finds that the relevant market for the purposes of his analysis is the market for sustained release morphine tablets and capsules in the United Kingdom (paragraphs 45 to 93), and that Napp has a dominant position in that market (paragraphs 94 to 108). Napp contests very few of the primary facts on which the Director relies, without necessarily accepting the conclusions which he draws.

28. On the issue of dominance, in the Decision the Director first relies on Napp's market shares (paragraphs 96 to 100). According to Tables 2 to 4 of the Decision (as revised and updated to 31 March 2001 in the course of these proceedings) the uncontested market shares are as follows:

Table 2: Napp's market share (unit volumes) of sustained release morphine tablets/capsules 1997-2000

Hospital and Community sales (unit volumes)	1997	1998	1999	2000	Q1 2001
MST CONTINUS	89.2	89.6	90.6	91.0	91.6
MXL	5.2	5.9	5.1	4.2	3.9
Napp total	94.4	95.5	95.7	95.2	95.5
ORAMORPH SR	4.9	3.6	3.0	2.0	0.0
MORCAP	0.6	0.7	0.5	0.5	0.6
ZOMORPH	0.1	0.2	0.8	2.3	3.9
TOTAL	100.0	100.0	100.0	100.0	100.0

Table 3: Shares of supply (unit volumes) of sustained release morphine tablets/capsules to the community 1997-2000

Community sales (unit volumes)	1997	1998	1999	2000	Q1 2001
MST CONTINUS	91.7	91.0	91.4	91.5	92.0
MXL	5.0	5.6	5.1	4.2	4.0
Napp total	96.7	96.6	96.5	95.7	96.0
ORAMORPH SR	2.6	2.4	2.3	1.8	0.0
MORCAP	0.7	0.8	0.5	0.5	0.6
ZOMORPH	0.0	0.2	0.7	2.0	3.4
TOTAL	100.0	100.0	100.0	100.0	100.0

Table 4: Shares of supply (unit volumes) of sustained release morphine tablets/capsules to hospitals 1997-2000

Hospital sales (unit volumes)	1997	1998	1999	2000	Q1 2001
MST CONTINUS	71.5	77.2	83.2	87.2	89.0
MXL	6.2	8.0	6.8	4.7	3.7
Napp total	77.7	85.2	90.0	91.9	92.7
ORAMORPH SR	22.0	14.4	8.1	3.6	0.0
MORCAP	0.3	0.4	0.2	0.2	0.0
ZOMORPH	0.0	0.0	1.7	4.3	7.3
TOTAL	100.0	100.0	100.0	100.0	100.0

29. In addition to Napp's market shares, the Director relies in the Decision on three further factors to establish dominance:

(i) regulatory barriers to entry, that is to say the need for any new competitor to obtain the necessary manufacturing, marketing or import authorisations required under the Medicines Act 1968 and other legislation governing medicinal products (paragraphs 102 and 103);

(ii) what the Director describes as Napp's "strong and persistent first mover advantage" (paragraphs 104 to 113); and

(iii) what the Director describes as "the strategic barrier to entry in hospital sales" created by the pricing behaviour of Napp in the hospital segment of the market (paragraphs 114 to 118).

30. In respect of Napp's "first mover" advantage, the Director stresses first, MST's firmly established reputation among GP's, notably as "synonymous with the treatment of chronic severe pain". This reputation is very strong, since Napp has 96 per cent of the community segment of the market. Secondly, GPs are reluctant to experiment with a new strong opioid product of which they have no direct experience, and are extremely wary of possible side-effects and lack of efficacy. Thirdly, there is a lack of price sensitivity among GPs, particularly since the amount of money spent by an individual GP on morphine is relatively low. Fourthly, the costs of promotion to GPs are high, and it is difficult and expensive for later entrants to challenge early entrants to the market. None of these factors is disputed by Napp. According to the Director, the cumulative effect of these factors is to create significant barriers to entry into the community segment of the market, although that does not apply to the hospital segment where purchasers are price sensitive, and hospital specialists are less reluctant to assess the relative efficacy of different brands (see paragraphs 104 to 113 of the Decision).

31. In the Decision the Director also finds that neither the buying power of the NHS (paragraphs 119 and 120), nor the effects of PCGs/PCTs (paragraph 121), nor the system of price regulation under the PPRS (paragraphs 122 to 137), prevented Napp from holding a dominant position.

The Director's findings on abuse

32. As regards abuse, in paragraph 142 of the Decision (and again at paragraph 236) the Director states that Napp has:

> "(a) while charging high prices to customers in the community segment of the market, supplied sustained release morphine tablets and capsules to hospitals at discounts which have the object and effect of hindering competition in the market for the supply of sustained release morphine tablets and capsules in the UK. The pricing behaviour of Napp has to be considered as a whole, but the particular aspects in

which, in the circumstances of the present case, its discounting behaviour is abusive under section 18 of the Act are as follows:

(i) selectively supplying sustained release morphine tablets and capsules to customers in the hospital segment at lower prices than to customers in the community segment;

(ii) more particularly, targeting competitors, both by supplying at higher discounts to hospitals where it faced (or anticipated) competition and by supplying at higher discounts on those strengths of sustained release morphine tablets and capsules where it faced competition; and

(iii) supplying sustained release morphine tablets and capsules to hospitals at excessively low prices.

Moreover Napp has engaged in the above conduct with the intention of eliminating competition.

(b) charged excessive prices to customers in the community segment of the market for the supply of sustained release morphine tablets and capsules in the UK.

In doing so, Napp has abused its dominant position in the market for the supply of sustained release morphine tablets and capsules in the UK."

Discounts to hospitals

33. Napp does not dispute the primary facts regarding its discounts to hospitals. It is thus common ground that Napp supplies hospitals at a discount of up to [...] [in excess of 90] per cent off the NHS list prices for sustained release morphine tablets. Conversely, NHS list prices paid in the community segment are very substantially higher than the discounted hospital prices (paragraph 145 of the Decision).

34. The Director further finds in the Decision that in the period from March to May 2000 Napp's prices to hospitals were: (i) below total delivered costs on all tablets except 15mg and 200mg tablets; and (ii) below direct cost (material and direct labour) on all tablets except 5 mg, 15 mg and 200 mg tablets (paragraphs 146 and 147). The Director considers that direct costs may serve as a proxy for average variable costs ("AVCs"), that is to say costs that vary according to the output produced (see paragraphs 189 and 190 of the Decision).

35. Napp's prices and direct costs during that period are shown in Table 5 of the Decision, but it is not disputed that those figures are representative of the whole period of the infringement to 30 March 2001.

Table 5: Napp's average variable cost on MST tablets and average hospital prices, March to May 2000

Strength	Direct Costs (£)	NHS list price, excl. VAT (£)	Average hospital price (£)
5mg	[redacted]	4.30	[redacted]
10mg	[redacted]	7.17	[redacted]
15mg	[redacted]	12.57	[redacted]
30mg	...	17.22	...
60mg	[redacted]	33.58	[redacted]
100mg	[redacted]	53.16	[redacted]
200mg	[redacted]	106.34	[redacted]

36. The Director also finds in the Decision that Napp's discounts have been selectively targeted at competitors. First, Napp gave their highest discounts, of [...] [in excess of 90] per cent, only on strengths where Napp has faced a rival BIL product at a similar strength (10mg, 30mg, 60mg, and 100mg), whereas where Napp did not face a rival BIL product (5mg, 15 mg and 200 mg) the discounts are only at most [...] [less than 85] per cent (paragraph 182).

37. Secondly, the Director finds that on a number of contracts where Napp has been awarded a sole regional contract, Napp has supplied at a higher level of discount of [...] [in excess of 90] per cent, while offering only a [...] [less than the highest] discount where the contract is to be shared (paragraphs 183 to 186).

38. Thirdly, it is only on those strengths of MST where it faced a rival BIL product at equivalent strength (i.e. 10mg, 30mg, 60mg and 100mg), that Napp's prices to hospitals were below direct costs, where direct costs are defined as materials and direct labour (paragraphs 189 and 190).

39. Fourthly, the Director finds in the Decision that in many cases MST has been supplied to hospitals at prices considerably below the averages shown in Table 5 above. For example, where Napp offers [...] [in excess of 90] per cent discounts off trade price, the hospital prices for 10mg, 30mg, 60mg and 100mg are £[...], £[...], £[...] and £[...] respectively. In these cases, Napp's hospital prices are between [...] [in excess of 30] per cent and [...] [less than 50] per cent lower than direct costs, and significantly below the raw material cost (paragraph 191). None of the foregoing facts are disputed by Napp.

40. In those circumstances the Director considers that Napp has abused its dominant position from 1 March 2000 by seeking to eliminate competition in the hospital sector by pricing below direct costs and selectively targeting competitors: see notably Case C-62/86 *AKZO Chemie BV v Commission* [1991] ECR I-3359 ("*AKZO*") (paragraphs 188 to 196).

41. Furthermore, the Director considers that Napp's pricing has not only eliminated competition in the hospital segment, but has also foreclosed a large part of the total market (paragraphs 160 to 180).

42. The Director considers, first, that Napp has excluded competition in at least 24 to 27 per cent of the total market. That figure is made up of the whole of the hospital segment, which accounts for 10 to 14 per cent of the total, plus 15 per cent of the community segment (which itself accounts for 86 to 90 per cent of the total market), which is foreclosed as a result of what is referred to in the Decision as the "follow-on" effect (paragraph 160). According to footnote 67 to paragraph 111, references in the Decision to the "follow-on" effect "are to those prescriptions for a brand of sustained release morphine in the community, where the choice of brand has been determined by the hospital doctor or specialist. This occurs when patients are prescribed a particular brand in hospital, and the GP subsequently repeats that prescription when the patient re-enters community care."

43. Secondly, the Director considers that the hospital segment is a key strategic point of entry for new competitors in the relevant market. Hospitals serve to establish the reputation of a brand (described in the Decision as "the reputation effect") because (i) the prescribing decisions of hospital specialists can establish the credibility of a product brand in the minds of GPs; and (ii) through the follow-on effect, GPs acquire first hand knowledge of a product and its efficacy. For that reason, the Director considers that over the longer term the influence of hospital prescriptions on community sales is likely to be significantly greater when the reputation effect is allowed for (paragraphs 162 to 167, see also paragraphs 243 and 251).

44. The Director further relies on statements made to him by BIL, to the effect that Napp's pricing policy to hospitals led to BIL's withdrawal from the market (paragraphs 115, 168 and 174 to 178). He also relies on a statement made to him by Link in 1999:

> "[the] lack of sales was primarily due to predatory pricing in the hospital sector of the market and in 1999 we have had to adjust our sales strategy to compete on price. As a result we are now in a position of having to almost give away product to compete with Napp in the hospital market. Of course we are losing money and as a small company I

am not sure that we can continue this policy, reluctant as I am to be 'bullied' out of the market by our much larger competitor." (paragraph 116)

45. According to the Decision, Napp advanced four main arguments against the Director's conclusion that its pricing policy to hospitals is an abuse:

(i) Napp's sales to hospitals at discounted prices, although apparently below direct cost, were incrementally profitable because of the compensating margins to be earned on the "follow-on" sales in the community segment (paragraphs 148, 149 and 192).

(ii) What was true for Napp was true for its competitors, who could equally earn compensating margins in the community sector (paragraph 148).

(iii) The market was not foreclosed (paragraphs 167 to 169).

(iv) Napp's discounts to hospitals were the inevitable result of the necessity to meet competition (paragraph 197).

46. In support of its conclusion that hospital sales were incrementally profitable, Napp relied on the results of its internet survey of GPs, (the Internet Survey) which, according to Napp, showed that 15 per cent of patients receiving sustained release morphine in the community have their brand determined by a hospital doctor. Taking the ratio of hospital sales to community sales as 1:9, Napp calculated that one unit sold to hospitals would result in 1.35 "follow-on" units of the same brand sold in the community. According to Napp this follow-on effect is "mechanistic" (paragraph 149 of the Decision).

47. The Director, for his part, accepted in the Decision (at paragraph 150) that there is a "follow-on" effect between hospital and community sales and that Napp's figure of 15 per cent "may serve as a crude estimate of this effect at a national level over time". However, he did not accept Napp's other arguments.

48. First, according to the Director, the magnitude and timing of the follow-on effect is unpredictable, varying as between individual patients and as between different contracting regions. Accordingly, the Director did not accept that the follow-on effect was "mechanistic", or that a new entrant could rely on recovering losses made on a hospital contract by generating higher sales in the community segment (paragraphs 152 to 155).

49. Secondly, according to the Director there is "asymmetry" in Napp's favour, that is to say that Napp has significant advantages which its rivals do not have: see paragraphs 157 to 159 of the Decision.

50. Thirdly, the Director considered that Napp's price cuts to hospitals did not grow the overall market for sustained release morphine. There was therefore no justification for a policy of loss-leading, other than to deny a competitor the opportunity to establish itself in the community segment (paragraph 194).

51. Fourthly, according to the Director, Napp's justification for pricing below AVC is circular. That Napp can earn high compensating margins in the community segment is precisely because its discount policy in the hospital segment has hindered competition in the community segment. Napp's ability to charge high prices in the community segment cannot, therefore, be a justification for charging a price below AVC in the hospital segment. Likewise, the expectation of earning excessive margins on future sales cannot be a justification for current loss-making sales (paragraphs 151 and 195).

52. Fifthly, as regards foreclosure of the market, the Director considers that it is unusual for pioneer brands such as MST to have sustained such a high market share over time. He considers that low prices in the hospital segment were a strong factor in BIL's decision to withdraw from the market, and that Zomorph has not been earning an overall profit for Link due to the high promotional expenditure required. The Director does not consider that the evidence as to potential new entrants undermines his view that Napp's conduct has deterred competition in the relevant market (paragraphs 170 to 180).

53. Finally, as regards Napp's arguments based on "meeting competition", the Director considers that, while pharmaceutical products are sometimes sold at substantial discounts to hospitals, it is not normal that list prices are discounted by up to [...] [in excess of 90] per cent in tendering for hospital contracts. He also notes that the discount of up to [...] [in excess of 90] per cent on MST is only available on those dosages where Napp faced a BIL rival product at an equivalent strength. Furthermore, the level of price discrimination as between the hospital and community segments is exceptional. In the Director's view, Napp's discount policy on MST is different from behaviour which conditions normal competition (paragraphs 198 to 200).

54. The Director finds that Napp knew of the prices being offered to certain customers and sought to respond with lower prices aimed directly at those customers. He finds that Napp's response to competition in the hospital segment has been both unreasonable and disproportionate (paragraphs 201 to 202).

55. For those reasons, the Director concludes in the Decision that Napp has abused a dominant position in pursuing its policy on discounts to hospitals.

Excessive prices

56. The Director finds in the Decision (paragraphs 203 to 234) that the prices charged by Napp for MST in the community segment are excessive. At paragraph 203 of the Decision, the Director considers that a price is excessive and an abuse

> "if it is above that which would exist in a competitive market and where it is clear that high profits will not stimulate successful new entry within a reasonable period. Therefore, to show that prices are excessive, it must be demonstrated that (i) prices are higher than would be expected in a competitive market, and (ii) there is no effective competitive pressure to bring them down to competitive levels, nor is there likely to be."

57. According to the Director, Napp's prices can be shown to be above the competitive level, first, by assessing "whether the difference between costs actually incurred and the price actually charged is excessive": Case 27/76 *United Brands v Commission* [1978] ECR 207 ("*United Brands*"). In the Decision, the Director has sought to do this by showing the profit margins Napp earns on community sales and comparing these with the margins Napp earns on sales of other products, and on sales of MST to other markets (paragraph 204).

58. The second approach, according to the Director, is to establish what the competitive price of MST is likely to be and then compare this with the actual price. In the Decision the Director has sought to find a proxy for the competitive price of MST by looking at the prices of competitors, and the prices Napp charges elsewhere, and seeing whether those prices would enable Napp to earn a reasonable profit (paragraph 205).

59. The Director has not sought to rely on a single comparison, but has made six comparisons, all of which, according to him, support the conclusion that Napp's community prices of MST are

excessive (paragraph 206). Napp does not dispute the Director's figures, but does not accept his conclusion.

— *Comparisons of the prices for MST tablets with those of Napp's competitors (paragraphs 207 to 212)*

60. First, the Director finds that Napp's prices to the community are between 33 per cent and 67 per cent higher than those of its competitors, and typically around 40 per cent higher: see Table 6 in the Decision.

61. As regards Napp's argument that it is entitled to charge higher prices to reflect the research, development and promotional expenditures incurred in bringing MST to market, in the Decision the Director considers that a manufacturer with an innovative product cannot expect prices to remain at excessively high levels indefinitely. Moreover, it is not a feature of normal competition for the premium-priced pioneer product to retain such a large share of sales volume (96 per cent) for such a long time. The Director does not accept that any brand premium for MST would be as high as 40 per cent (paragraphs 208 to 212).

— *Comparison of prices for MST tablets over time (paragraphs 213 to 216)*

62. In the Decision, the Director considers that it is reasonable to infer that the price of MST was set above competitive levels prior to the expiry of its patent in 1992. However, Napp's prices of MST tablets to the community have not responded to the entry of rival products whereas Napp's hospital prices have done so. Napp's exceptionally high market share indicates that Napp's community prices have not been subject to competitive pressure.

— *Comparison of the prices of MST charged to hospitals and the community respectively (paragraphs 217 to 220)*

63. In the Decision, the Director finds that, on average, the wholesale community price for MST was over [...] [in excess of 1000] per cent higher than the average hospital prices on 10mg, 30mg, 60mg, and 100mg tablets, whereas, for example, Napp's price to the community of 5mg tablets is [...] [in excess of 70] per cent higher than its prices to hospitals: see Table 7 in the Decision.

— *Comparison with Napp's export prices (paragraphs 218, 219, 221 and 222)*

64. A similar pattern emerges, according to the Director, when comparing the prices to the community with Napp's export prices. The differential on 5mg tablets is [...] [below 5] per cent, but for higher strength tablets the differential is between [...] [in excess of 100] per cent and [...] [less than 700] per cent. The size of the differentials is, according to the Director, sufficiently large to suggest that Napp's profits on sales to the United Kingdom community segment are supra-normal. The Director does not accept that the differentials can be accounted for fully by the lower risk entailed in contract manufacturing, nor lower marketing and promotion costs.

— *Comparisons of Napp's profitability on sales to hospitals and the community (paragraphs 223 to 226)*

65. The Director finds that Napp earns a far higher margin on sales of MST to the community than it does on sales of its other products to the NHS: see Table 8 in the Decision. According to the Director, in broad terms MST community sales achieve a gross margin of around [...] [in excess of 80] per cent. Napp's total NHS sales earn a margin of around [...] [between 40 and 60] per cent, meaning that NHS sales other than MST earn a margin of around [...] [between 30 and 50] per cent (paragraph 224).

66. As to Napp's argument that it is normal for pharmaceutical companies to earn high margins on their most successful products in order to pay for the research and development of emerging products, or to subsidise less successful products, the Director considers that the system of patent protection allows companies a period in which to earn above-competitive margins as a reward for pharmaceutical innovation. When patent exclusivity is lost, it is to be expected that prices and/or market share will drop as a result of competitive entry. The lack of successful entry in this case is in part due to Napp's exclusionary practices in the hospital segment of the market (paragraph 225). The Director further finds that, taking account of the fact that Napp enjoyed patent protection from 1980 to 1992, Napp has had considerable time and opportunity to recoup its initial investment and compensate it for the risk it has taken (paragraph 233).

— *Comparison of Napp's margins with those of its competitors (paragraphs 226 to 229)*

67. According to the Director, Napp makes a gross margin of [...] [in excess of 80] per cent on its sales of MST to the community. This compares with a gross profit margin of [...] [less than 70] per cent for Napp's next most profitable competitor. In order to take account of the fact that Napp

manufactures MST tablets, while its competitors contract out the manufacture, and the possibility that Napp's operations may be more efficient, the Director has calculated Napp's gross profit margin, using the average costs of its next most profitable competitor, in order to ensure that any comparison is made on the basis most favourable to Napp. Even when calculated on this basis, according to the Director, Napp's prices imply margins of 80.5 per cent compared to [...] [less than 70] per cent for the next most profitable competitor. This further supports the conclusion that Napp's prices to the community are excessive and not subject to normal competitive constraints (paragraphs 228 and 229).

68. Finally, the Director rejects Napp's argument that the PPRS prevents Napp from charging excessive prices. The PPRS is a portfolio constraint and does not seek to ensure that the prices of individual products are not set at excessive levels (paragraph 230).

69. For those reasons, the Director concludes that Napp has maintained excessively high prices and margins on the sale of MST in the community segment of the market without effective competition from successful new entry. According to the Director, this is due, at least in part, to Napp's exclusionary pricing practices in the hospital segment (paragraphs 151, 194, 225, 228 and 232).

The penalty

70. The Director states in the Decision that he is satisfied that the infringements in relation to discounts to hospitals, and excessive prices in the community, have both been committed intentionally or, at the very least, negligently (paragraphs 241 to 246). Applying his published guidance on the appropriate amount of penalty, the Director concludes that Napp should pay a penalty of £3.21 million.

The Directions

71. The general effect of the Directions given to Napp by letter of 4 May 2001 is to require Napp (1) to reduce the NHS list price of MST tablets by at least 15 per cent; and (2) to sell MST tablets to hospitals in the United Kingdom at a price of not less than 20 per cent of the (reduced) NHS list price for the product strength in question. Transitional arrangements were made in respect of Napp's existing contracts.

III – PROCEDURE BEFORE THE TRIBUNAL

72. By request dated 11 May 2001, Napp sought interim relief to suspend the Directions pursuant to Rule 32 of the Tribunal Rules. On 22 May 2001 the President suspended the operation of the Directions by consent, Napp having undertaken to compensate the NHS for losses incurred as a result of not reducing the NHS List price for MST between the date of the interim order and any final order of the Tribunal: see [2001] CompAR 1.

73. Napp's notice of appeal was lodged with the Registry on 29 May 2001 accompanied by a number of witness statements and over 4000 pages of supporting documents and correspondence exchanged with the Director during the administrative procedure. Notice of the appeal was published in the London, Edinburgh and Belfast Gazettes on 1 June 2001 and also on the Tribunal's website (www.competition-commission.org.uk) pursuant to Rule 13(1) of the Tribunal's Rules. No requests to intervene in the proceedings were received.

74. The first case management conference was held on 25 June 2001. At this hearing the date for the filing of the Defence was set for 11 July 2001, and the hearing fixed to commence on 24 September 2001. Napp was invited to clarify certain arguments under the Human Rights Act 1998, and to prepare a list of what it considered to be the main issues on the appeal, relating those issues to the voluminous documentation provided. Napp also agreed to provide the Director with certain items of information, and to disclose documents relating to certain factual allegations made in the notice of appeal, as requested by the Director by letter of 15 June 2001.

75. By letter of 9 July 2001 the Director sought an extension of two and a half days for the filing of his defence. That extension was granted by order of the President of 10 July 2001 following a short judgment setting out why the Tribunal was reluctant to accede to applications for extensions of time for filing pleadings: [2001] CompAR 21.

76. On 11 July 2001 the Tribunal returned to Napp a voluminous bundle of authorities relating to the Human Rights Act which had been sent by Napp on 2 July 2001 without any satisfactory accompanying argumentation and without having regard to the *Practice Direction (Citation of Authorities)* [2001] 1 WLR 1001.

77. The Defence was lodged at the Registry on 16 July 2001. The annexes to the Defence included witness statements from a further seven witnesses. A further case management conference was fixed for 30 July 2001.

78. By letters of 20 and 24 July 2001 Napp gave notice of its intention to apply at the case management conference for various orders striking out or disallowing all or parts of the defence and/or the Decision and the Directions, and excluding the witness statements. The main basis of the application was that the defence departed from, or enlarged upon, or contradicted, the Decision and that the witness statements should have been produced earlier. Having heard argument at the case management conference on 30 July, the Tribunal delivered a judgment on Napp's application at a further case management conference held on 8 August 2001: [2001] CompAR 33.

79. In that judgment (at paragraphs 46 to 47) the Tribunal left open the question whether, in the defence, the Director's case on excess pricing had shifted from that made in the Decision, but held that that was not a matter for striking out. On the issue of the witness statements, the Director withdrew the evidence of one of the witnesses and the evidence of another witness was excluded by the Tribunal. The Tribunal reserved for later decision whether it was in fact prepared to consider the further evidence annexed to the Defence (paragraphs 83 to 92 of the judgment).

80. At the same case management conference on 8 August 2001 the Tribunal gave further directions and asked the parties to endeavour to reach agreement as to what material was commercially confidential. The Tribunal also invited the parties to indicate whether further disclosure was sought and which (if any) witnesses the parties wished to cross examine. Napp did not seek further disclosure or apply to cross-examine any witness. The Director sought to cross-examine Mr John Brogden, the Managing Director of Napp Pharmaceuticals Limited, on his witness statements. Napp did not avail itself of the possibility, suggested by the Tribunal in its judgment of 8 August 2001, of serving a reply to the defence.

81. On 31 August 2001 the Tribunal wrote to the parties indicating those issues on which the Tribunal considered time at the hearing could profitably be concentrated. The Tribunal further asked Napp to draw to its attention any documents from Napp at Board or senior management level which discussed or referred to the objectives, strategy or policy considerations taken into account by Napp in setting its prices in the periods referred to in the Decision.

82. Napp replied by letter of 10 September 2001 enclosing a bundle of some 21 documents. The Tribunal having drawn attention to the fact that with one exception the documents did not relate to the period after 1997, it transpired that Napp's solicitors, Herbert Smith, had not themselves inspected Napp's files, but that Napp's in-house legal department had done so. On 25 September, during the hearing, Mr Bryan Lea, the Head of Napp's Legal Department, filed a witness statement to the effect that he had thoroughly reviewed all Napp's files which were potentially relevant and was confident that the Tribunal's request had been complied with.

83. At Napp's suggestion the Tribunal had agreed at the case management conference of 8 August 2001 to receive a short factual statement, agreed if possible, explaining the operation and work of PCGs and PCTs. It did not prove possible to agree such a statement, and the Tribunal rejected a voluminous and largely unexplained bundle of documents lodged by Napp on 7 September 2001. Eventually both parties submitted short statements outlining their respective positions as regards PCGs/PCTs.

84. In its letter of 31 August 2001 the Tribunal further invited the parties to prepare a short statement indicating to what extent they agreed or disagreed on the calculation of the alleged gain to Napp from the alleged infringements (on the hypothesis, denied by Napp, that any such infringements were established) indicating the different assumptions made. It proved difficult to reach any such agreement, but an agreed note of the respective calculations and the reasons for the differences was handed to the Tribunal on the last day of the hearing.

85. The Applicant's skeleton argument, a document of some 80 pages, was lodged with the Tribunal on 17 September and the Director's skeleton argument of some 35 pages was lodged with the Tribunal on 21 September 2001. Oral argument in the case was presented on 24, 25, 26 and 28 September. As the Director had requested, Mr John Brogden gave evidence on oath on 24 September and was cross-examined.

86. In accordance with the Tribunal's request, the parties were able to agree what material was commercially confidential and not to be discussed in open court. Certain commercially confidential material was disclosed to Napp's solicitors and counsel only, with a view to enabling the latter to decide whether to apply for formal disclosure of the material in question. No applications were made for further disclosure.

87. Following the hearing, further written submissions were made, at the Tribunal's request, principally as regards (i) the relevance or admissibility of the documents disclosed pursuant to the Tribunal's request of 31 August 2001; and (ii) whether Napp's prices fell below direct costs in 1998 or earlier (see the letters of the parties of 5, 15, 17 and 22 October 2001).

88. We comment, for the benefit of those conducting future appeals, that the procedure in this case did not go entirely according to the plan envisaged in the Tribunal's *Guide to Appeals under the Competition Act*, probably for three reasons: the notice of appeal was not as focussed as we would have wished, the Director sought to introduce a good deal of material and argument that was not in the Decision, and some of the supplementary materials supplied by Napp on such matters as the Human Rights Act and PCGs/PCTs were not in a form which we could easily absorb. We entirely appreciate the difficulties of the subject matter, the pressure of time, and the fact that all concerned are on a learning curve as regards the procedures to be followed in appeals under the Act, but we hope that the principles of the *Guide* can be closely followed in future cases.

89. Napp requests the Tribunal to:

- set aside the Decision in whole or in part;
- set aside or vary the Directions;
- to set aside or reduce the penalty;
- declare that Napp's conduct does not infringe the Chapter II prohibition;
- order the Director to pay Napp's costs of and incidental to the appeal;
- order such further or other relief as the Tribunal may consider appropriate.

90. The Director requests the Tribunal to:

- dismiss Napp's appeal;
- order Napp to pay his costs;
- order, pursuant to Rule 27 of the Tribunal's Rules, that interest be payable on the penalty.

IV – THE BURDEN AND STANDARD OF PROOF

91. This is the first appeal under the Act against an infringement decision, so we address at the outset the issue of the burden and standard of proof where penalties are imposed under section 36 of the Act.

92. Article 6 of the European Convention on Human Rights and Fundamental Freedoms (ECHR) which is given further effect in domestic law under the Human Rights Act 1998, provides:

> "Right to a Fair Trial
>
> 1. In the determination of his civil rights and obligations or of any criminal charge against him, everyone is entitled to a fair and public hearing within a reasonable time by an independent and impartial tribunal established by law. Judgment shall be pronounced publicly ...
> 2. Everyone charged with a criminal offence shall be presumed innocent until proved guilty according to law.
> 3. Everyone charged with a criminal office has the following minimum rights:
>   (a) to be informed promptly, in a language which he understands and in detail, of the nature and cause of the accusation against him;
>   (b) to have adequate time and facilities for the preparation of his defence;
>   (c) to defend himself in person or through legal assistance of his own choosing or, if he has not sufficient means to pay for legal assistance, to be given it free when the interests of justice so require;
>   (d) to examine or have examined witnesses against him and to obtain the attendance and examination of witnesses on his behalf under the same conditions as witnesses against him;
>
> ..."

93. Both parties accept that proceedings under the prohibitions imposed by the Act which may lead to the imposition of a penalty under section 36 involve a "criminal charge" or a "criminal offence" for the purposes of Article 6 of the ECHR.

94. From that starting point, Napp argues that it is entitled to the presumption of innocence in proceedings before the Tribunal, which represent the first occasion upon which the "criminal charge" against Napp falls to be determined by an independent and impartial tribunal within the meaning of Article 6(1). Napp further argues that the Director must rebut the presumption of innocence and discharge the burden of proof to the criminal standard: see Clayton & Tomlinson *The Law of Human Rights* (2000) paragraphs 11.115 to 11.119.

95. The Director argues that the fact that the present proceedings involve a criminal charge for the purpose of the ECHR does not mean that they are to be equated with criminal proceedings under English law, or that the rights that apply in criminal proceedings automatically apply to a case under the Act: see the decision of the Court of Appeal in *Han v Commissioners of Customs and Excise*, [2001] 4 All ER 687. As regards the burden of proof, the Director accepts that it is incumbent upon him to establish the infringement, and that the persuasive burden of proof remains

on him throughout. However, that does not necessarily prevent the operation of certain evidential presumptions for example, that sales below direct cost are presumed to be abusive: see *R v Lambert* [UKHL] 37 [2001] 3 WLR 206, paragraphs 34, 87 et seq, and 150 et seq.

96. As regards the standard of proof, the Director argues that the appropriate standard is the balance of probabilities. There is no requirement, under the ECHR, of proof beyond reasonable doubt: Sir Richard Buxton, *The Human Rights Act and the Substantive Criminal Law* [2000] Crim LR 331. The balance of probabilities is a sufficiently flexible standard to require that the Tribunal (or Director) should be more sure before finding serious allegations proved than when deciding less serious matters: per Lord Nicholls in *In re H* [1996] AC 563 at 586-587. The criminal standard of proof beyond reasonable doubt would not be appropriate in relation to the kind and range of issues this Tribunal has to determine under the Act.

97. At the Tribunal's request, counsel for the Director dealt with the position as regards the standard of proof in Scots Law, citing *1st Indian Cavalry Club Ltd and Chowdhury v Customs and Excise Commissioners* [1998] STC 293 and *Mullan v Anderson* [1993] SLT 835. He also dealt with the standard of proof before the European Courts under Articles 81 and 82 of the EC Treaty, citing notably Case T-7/89 *Hercules Chemicals NV v Commission* [1991] ECR II-1711, at paragraph 59, Cases 29-30/83 *Compagnie Royale Asturienne des Mines SA and Rheinzink v Commission* [1984] ECR 1679 at paragraph 20, and the opinion of Judge Vesterdorf, acting as Advocate General, in Cases T 1-15/89 *Rhône-Poulenc and others v Commission* [1991] ECR II-867 at p.954.

98. As we have already stated in our interim judgment of 8 August 2001, we agree that the Director's concession that these proceedings are "criminal", for the purposes of Article 6 of the ECHR, is properly made: see Case C-235/92P *Montecatini v Commission* [1999] ECR I-4575, paragraphs 175 and 176. That is particularly so since penalties under the Act are intended to be severe and to have a deterrent effect: see the Director's statutory *Guidance as to the appropriate amount of the penalty*, (OFT 423, March 2000) issued under section 38(1) of the Act.

99. The fact that these proceedings may be classified as "criminal" for the purposes of the ECHR gives Napp the protection of Article 6, and in particular the right to "a fair and public hearing within a reasonable time by an independent and impartial tribunal established by law" (Article 6(1)), to the presumption of innocence (Article 6(2)), and to the minimum rights envisaged by Article 6(3) including the right "to examine or have examined witnesses against him and to obtain the

attendance and examination of witnesses on his behalf under the same conditions as witnesses against him" (Article 6(3)(d)).

100. In our view it follows from Article 6(2) that the burden of proof rests throughout on the Director to prove the infringements alleged.

101. However, as the Court of Appeal held in *Han,* cited above, to which we referred in our judgment of 8 August 2001, the fact that Article 6 applies does not of itself lead to the conclusion that these proceedings must be subject to the procedures and rules that apply to the investigation and trial of offences classified as criminal offences for the purposes of domestic law: see Potter LJ at paragraph 84, and Mance LJ at paragraph 88 of that judgment.

102. Neither the ECHR itself nor the European Court of Human Rights has laid down a particular standard of proof that must be applied in proceedings to which Articles 6(2) or (3) apply, and still less that the standard should be that of "proof beyond reasonable doubt", which is not a concept to be found in the domestic systems of many of the signatory States (see Sir Richard Buxton, cited above, at pp. 338 and 339).

103. In our view it follows that neither Article 6, nor the Human Rights Act 1998, in themselves oblige us to apply the criminal standard of proof as established in domestic law in cases where the Director seeks to impose a financial penalty in respect of alleged infringements of the Chapter I or Chapter II prohibitions under the Act.

104. In our view the standard of proof to be applied under the Act is to be decided in accordance with the normal rules of the United Kingdom domestic legal systems. Neither party has cited to us any decided domestic cases which suggest that, in circumstances such as these, the criminal standard should be applied, nor invited us to apply by analogy certain civil situations where traditionally the criminal standard of proof is required (e.g. committal proceedings).

105. Infringements of the Chapter I and Chapter II prohibitions imposed by sections 2 and 18 of the Act are not classified as criminal offences in domestic law, in contrast, for example, to the criminal offences created under sections 42 to 44. Under section 38(8), penalties are recoverable by the Director as a civil debt. Directions are enforceable by civil proceedings under section 34. In our view the structure of the Act points to the conclusion that under domestic law the standard of proof

we must apply in deciding whether infringements of the Chapter I or Chapter II prohibitions are proved is the civil standard, commonly known as the preponderance or balance of probabilities, notwithstanding that the civil penalties imposed may be intended by the Director to have a deterrent effect.

106. We add that in many cases under the Act the factual issues before this Tribunal will often relate to such matters as determining the relevant market, whether dominance exists, and assessing whether conduct characterised as an "abuse" is economically justified. Issues of that kind involve a more or less complex assessment of mainly economic data and perhaps conflicting expert evidence. It seems to us more likely that Parliament would have intended us to apply the civil standard of proof to issues of this kind, rather than the time-honoured criminal standard of "proof beyond reasonable doubt".

107. In our view it follows from the speech of Lord Nicholls (with whom Lord Goff and Lord Mustill agreed) in *Re H*, cited above, at pp.586 to 587, that under the law of England and Wales there are only two standards of proof, the criminal standard and the civil standard; there is no 'intermediate' standard. The position is the same in the law of Scotland and Northern Ireland. Within the civil standard, however, the more serious the allegation, the more cogent should be the evidence before the court concludes that the allegation is established on the preponderance of probability: see Lord Nicholls speech in *Re H*, citing notably *In re Dellow's Will Trusts* [1964] 1 WLR 451, 455 and *Hornal v Neuberger Products Ltd* [1957] 1 QB 247, 266.

108. Since cases under the Act involving penalties are serious matters, it follows from *Re H* that strong and convincing evidence will be required before infringements of the Chapter I and Chapter II prohibitions can be found to be proved, even to the civil standard. Indeed, whether we are, in technical terms, applying a civil standard on the basis of strong and convincing evidence, or a criminal standard of beyond reasonable doubt, we think in practice the result is likely to be the same. We find it difficult to imagine, for example, this Tribunal upholding a penalty if there were a reasonable doubt in our minds, or if we were anything less than sure that the Decision was soundly based.

109. In those circumstances the conclusion we reach is that, formally speaking, the standard of proof in proceedings under the Act involving penalties is the civil standard of proof, but that standard is to be applied bearing in mind that infringements of the Act are serious matters attracting severe

financial penalties. It is for the Director to satisfy us in each case, on the basis of strong and compelling evidence, taking account of the seriousness of what is alleged, that the infringement is duly proved, the undertaking being entitled to the presumption of innocence, and to any reasonable doubt there may be.

110. That approach does not in our view preclude the Director, in discharging the burden of proof, from relying, in certain circumstances, from inferences or presumptions that would, in the absence of any countervailing indications, normally flow from a given set of facts, for example that dominance may be inferred from very high market shares (Case 85/76 *Hoffman-La Roche v Commission* [1979] ECR 461, paragraph 41); that sales below average variable costs may, in the absence of rebuttal, be presumed to be predatory (see the opinion of Advocate General Fennelly in Cases C-395/96P and 396/96P *Compagnie Maritime Belge v Commission* [2000] ECR I-1442 at paragraph 127); or that an undertaking's presence at a meeting with a manifestly anti-competitive purpose implies, in the absence of explanation, participation in the cartel alleged: *Montecatini v Commission*, cited above, at paragraphs 177 to 181.

111. Presumptions of this kind simply reflect inferences that can, in normal circumstances, be drawn from the evidence: they do not reverse the burden of proof or set aside the presumption of innocence: *Montecatini* at paragraph 181. Being essentially evidential in character, such presumptions are hardly equivalent to statutory 'reverse onus' provisions of the kind considered in *R v Lambert*, cited above. But even in the case of such a statutory provision, Article 6(2) of the ECHR does not prohibit a permissive or evidentiary presumption from which a trier of fact may (as opposed to must) draw an inference of guilt: see again *R v Lambert*, notably Lord Steyn at paragraph 40, Lord Hope at paragraphs 87 to 91 and Lord Clyde at paragraphs 150 to 158. If a defendant undertaking seeks to rebut the presumption in question, the legal burden of proof remains on the Director to show that an abuse is established.

112. Whether or not section 60 of the Act is to be construed as requiring us to follow the case law of the Court of Justice and the Court of First Instance on issues such as the burden and standard of proof, we believe that the approach we have outlined above is in line with the approach of those Courts. There is no doubt that in proceedings under Articles 81 and 82 of the Treaty, the burden of proof rests on the Commission (see *Montecatini* at paragraph 179). As far as the standard of proof is concerned, the European Courts, faced with the different traditions of the Member States, have simply indicated that the infringement should be demonstrated to the "requisite legal standard" (à

suffisance de droit), but there is no doubt that, in general, those Courts require convincing proof that the alleged infringements have been committed in the form of a "firm, precise and consistent body of evidence": see Cases 29 and 30/83 *CRAM and Rheinzink v Commission* cited above, paragraphs 16 to 20; Cases C-89/85 etc *Ahlström Osakeyhtiö and others v Commission* [1993] ECR I-1307, paragraph 127. We have no reason to suppose that the standard of proof we propose to follow is any different from that followed in practice by the courts in Luxembourg.

113. We observe, finally, that in the present case, much of the above discussion is somewhat academic. As appears in more detail from our findings below, we do not think that it makes any material difference to the outcome in this particular case whether we apply the domestic civil standard in the way described above, or the domestic criminal standard as traditionally expressed.

V – OTHER PROCEDURAL ISSUES

The Director's witness statements

114. In paragraphs 64 to 92 of our judgment of 8 August 2001 we pointed out that the Act and the Tribunal's Rules envisage that further evidence could be given and documents produced before the Tribunal, and that there was no absolute bar, under the ECHR or otherwise, to that being done in a proper case. While indicating that, in general, the discretion to take account of new evidence relied on by the Director should be exercised sparingly, we held that the interests of fairness may well indicate that such new evidence should be allowed, particularly where it consists, in essence, of matters going to rebut allegations made by an applicant in the notice of appeal. We therefore declined to exclude at that stage the evidence of five of the Director's witnesses, although we excluded one statement, and a further statement was withdrawn by the Director.

115. Napp has, however, contended that the Tribunal should only take account of the five remaining witness statements in so far as they are favourable to Napp, and not take into account material to Napp's detriment which could have been, but was not, made available in the administrative procedure. Otherwise, says Napp, the administrative procedure envisaged by the Act can be circumvented and Napp's rights of defence jeopardised.

116. As we indicated in our judgment of 8 August 2001 (paragraphs 72 to 79) it is of obvious importance that, in the administrative procedure, the provisions of Rule 14 of the Director's Rules (see paragraphs 24 and 25 above) are properly observed.

117. If and when a matter moves to the judicial stage before this Tribunal, what was previously an administrative procedure, in which the Director combines the rôles of "prosecutor" and "decision maker", becomes a judicial proceeding. There is, at that stage, no inhibition on the applicant attacking the Decision on any ground he chooses, including new evidence, whether or not that ground or evidence was put before the Director. The Tribunal, for its part, is not limited to the traditional rôle of judicial review but is required by paragraph 3(1) of Schedule 8 of the Act to decide the case "on the merits" and may, if necessary and appropriate, "make any other decision which the Director could have made": paragraph 3(2)(e). If confirming a decision, the Tribunal may nonetheless set aside a finding of fact by the Director: paragraph 3(4) of Schedule 8. Unlike the normal practice in judicial review proceedings, the Act and the Tribunal Rules envisage that the Tribunal may order the production of documents, hear witnesses and appoint experts (see Schedule 8, paragraph 9 of the Act, and Rule 17 of the Tribunal's Rules) and may do so even if the evidence was not available to the Director when he took the decision: see Rule 20(2) of the Tribunal's Rules.

118. In elucidation of these provisions, we refer to the statement made in the House of Commons by the then Minister for Competition and Consumer Affairs (Mr Griffiths) during the passage of the Competition Bill on 18 June 1998 (Hansard Col 496):

> "It is our intention that the tribunal should be primarily concerned with the correctness or otherwise of the conclusions contained in the appealed decision and not with how the decision was reached or the reasoning expressed in it. That will apply unless defects in how the decision was reached or the reasoning make it impracticable for the tribunal fairly to determine the correctness or otherwise of the conclusions or of any directions contained in the decision. Wherever possible, we want the tribunal to decide a case on the facts before it, even where there has been a procedural error, and to avoid remitting the case to the director general. We intend to reflect that policy in the tribunal rules.
>
> This is an important aspect of our policy, and I shall explain the rationale behind our approach. The Bill provides for a full appeal on the merits of the case, which is an essential part of ensuring the fairness and transparency of the new regime. It enables undertakings to appeal the substance of the decision including in those cases where it is believed that a failure on the part of the director general to follow proper procedures has led him to reach an incorrect conclusion. The fact that the tribunal will be reconsidering the decision on the merits will enable it to remedy the consequences of any defects in the director general's procedures."

119. As we have already said in our judgment of 8 August 2001, if, at the judicial stage, an applicant launches an attack which places under close scrutiny particular aspects of the Decision, in principle we do not think that the Director should be denied a reasonable opportunity to reply by adducing rebuttal evidence in support of the points already made in the Decision. Thus we do not accept

Napp's principal submission that nothing may be relied on before the Tribunal unless it was relied on in the administrative procedure.

120. Nor do we accept Napp's submission that it (Napp) is entitled to rely on the Director's new evidence but that we (the Tribunal) must close our eyes and ears if the witness on whom Napp relies states something unfavourable to Napp's case. Napp has had the opportunity to cross-examine the Director's witnesses, and/or apply for orders for disclosure. In four days of argument before the Tribunal Napp has had every opportunity to make any point it wishes as to the evidence in question and has itself relied strongly on the evidence of Messrs Hartley and Penrose, and to a lesser extent that of Mr Blake. We do not see any ground on which Napp should be permitted to "have its cake and eat it".

121. As regards the individual witness statements in question, Mr John Brownlee is head of the PPRS branch in the Department of Health. His evidence goes to rebut certain assertions made by Napp in the notice of appeal as to the position of the Department in this case and the way the PPRS is said to work. We see no grounds for excluding this evidence.

122. Mr John Hartley is Head of Sales and Marketing at Link. The essence of Mr Hartley's statement is to rebut various assertions made by Napp in the notice of appeal regarding the factors Link would take into account in its decisions on prices to hospitals, the importance to Link of the hospital sector, and the effect on Link of Napp's pricing in the hospital segment. Having initially sought to exclude Mr Hartley's evidence, in the event counsel for Napp relied upon it strongly. In addition, Mr Hartley supports Napp's case as regards the Directions. In our view Mr Hartley's evidence and the documents he produces are fairly introduced and relevant to a number of issues in the case.

123. Mr Mark Connolly is the Marketing Director of the Prescription Medicine Division for BIL. His evidence is relevant mainly to the reasons for BIL's withdrawal from the market, which are relied on by the Director at paragraphs 173 to 176 of the Decision, but contested by Napp. We think this evidence is fairly introduced as rebuttal evidence but the point is academic since, as will be seen below, we do not need to express a view on the matters dealt with by Mr Connolly.

124. Mr Roger Penrose is the NHS and Development Manager for BIL. His evidence rebuts Napp's attack on BIL's competence, deals with the importance to BIL of the hospital sector, explains the history of discounting in the market from 1994 until BIL's withdrawal in 2000, and comments on

the follow-on effect alleged by Napp. Although largely relating to events before the alleged period of infringement, Napp relies strongly on Mr Penrose's evidence on at least one point, namely that it was BIL rather than Napp which initiated price cutting after 1994. We see no proper basis for excluding Mr Penrose's evidence, although it is not essential to our analysis of Napp's conduct during the period of infringement.

125. Mr Stephen Blake is a solicitor working for the Legal Division of the OFT. As far as relevant, his evidence updates the Tribunal on potential new entrants to the market, and is not seriously contested.

126. In all these circumstances, we see no reason not to take the Director's five witness statements into account in deciding this case on the merits, whether in Napp's favour or otherwise, to the extent that those witness statements are relevant to the issues which we have to decide.

The documents disclosed following the Tribunal's request of 31 August 2001

127. Napp argues that the documents disclosed by Napp following the Tribunal's request of 31 August 2001 are inadmissible, save to the extent that they support Napp's case. Napp argues that they are not relied on in the Decision and relate to a period prior to the infringement alleged. In addition Napp questions the inferences to be drawn from these documents: see Napp's letter of 5 October 2001.

128. The Tribunal Rules, particularly Rule 17, give this Tribunal wide powers to make directions to secure the just, expeditious and economical conduct of the proceedings (see Rule 17(1)). Rules 17(2)(d) and (k) provide for the production and disclosure of documents, while Rule 17(3) provides that the Tribunal may do certain things of its own motion, in particular putting questions, inviting further submissions and asking for further material, including asking, under Rule 17(3)(d), "for documents or any papers relating to the case to be produced". As is, we believe, well known, the Tribunal's Rules are modelled on the Rules of Procedure of the Court of First Instance of the European Communities (OJ 2001 C34/39): see Articles 64 and 65 of those Rules.

129. We decided to ask for our attention to be drawn to the documents referred to in the Tribunal's request of 31 August 2001 in view of the fact that, in its notice of appeal, Napp was asserting to us the factors that were or would be taken into account by Napp in setting its pricing policy, but as far

as we could see without referring to any documents tending to show what matters Napp had actually taken into account at the material time. We therefore asked for documents relating to the objectives, strategy or policy considerations taken into account by Napp in setting its prices in the periods referred to in the Decision to be drawn to our attention. The documents concerned were promptly supplied without objection on Napp's part.

130. The Tribunal having requested the documents pursuant to its powers under the Tribunal Rules we cannot see that the documents are "inadmissible" solely by virtue of the fact that they did not figure in the administrative procedure. Rule 20(2) of the Tribunal Rules provides expressly that documents may be submitted whether or not they were available to the respondent when the disputed decision was taken. Whether it would be proper or fair to permit the Director to rely on those documents is in our view a matter for the Tribunal's discretion, which we discuss later in this judgment: see paragraphs 311 et seq, below.

The "Ermakov" issue

131. At the stage of our interim judgment of 8 August 2001, Napp argued, and has since continued to argue, that the Director's case during those proceedings has shifted significantly away from the case as made in the Decision. This is particularly so, says Napp, in respect of the Director's case on excess pricing but other matters are complained of as well. In our interim judgment we held that it was not a matter for striking out, but an issue to be decided in our final judgment.

132. Napp now argues on the basis of *R v Westminster City Council ex parte Ermakov* [1996] 2 All ER 302 (CA), followed for example in *Nash v Chelsea Royal College of Art* (Burnton J, [2001] EWHC Admin 538), that the Director should not be permitted to change the reasons for his Decision before the Tribunal, nor add supplementary reasons, given in particular that the Director is a specialist decision maker. In *Ermakov*, the Court of Appeal decided that, in certain proceedings under the Housing Act 1996, the decision maker should be held to the reasons given in his original decision, in the interests of fairness and efficient decision making: see Hutchison LJ at pp. 315 to 317.

133. On this point, for the same reasons that we consider that our discretion to allow the Director to submit further evidence should be exercised only sparingly, we accept Napp's basic submission that, in principle, the Director should not be permitted to advance a wholly new case at the judicial stage, nor rely on new reasons. To decide otherwise would make the administrative procedure, and

the safeguards it provides, largely devoid of purpose; the function of this Tribunal is not to try a wholly new case. If the Director wishes to make a new case, the proper course is for the Director to withdraw the decision and adopt a new decision, or for this Tribunal to remit.

134. However, given the powers of this Tribunal, it seems to us the analogy with *Ermakov* does not go as far as Napp submits. In those circumstances it is virtually inevitable that, at the judicial stage, certain aspects of the Decision are explored in more detail than during the administrative procedure and are, in consequence, further elaborated upon by the Director. As already indicated, these are not purely judicial review proceedings. Before this Tribunal, it is the merits of the Decision which are in issue. It may also be appropriate for this Tribunal to receive further evidence and hear witnesses. Under the Act, Parliament appears to have intended that this Tribunal should be equipped to take its own decision, where appropriate, in substitution for that of the Director. For these reasons, while we accept the force of the general principle that lies behind *Ermakov*, the analogy is not exact.

135. In the present case, for the reasons given in more detail below (see paragraphs 428 to 442), we have reached the view that Napp's allegations as to the Director's alleged "change of case" do not in fact have the significance that Napp alleges as far as the Director's findings of infringement are concerned. As will be seen, we do not think that there is anything in the *Ermakov* line of reasoning which precludes us from determining this appeal on the merits in the light of all the material now before us.

Human Rights and general issues of unfairness

136. Napp argues, in an amended version of paragraphs 5.61 to 5.72 of the notice of appeal, which was submitted after the Tribunal had sought clarification of Napp's case on this aspect, that the Director's conduct of the investigation was unfair and failed to observe the requirements of Article 6 of the ECHR. Napp submits that the Director acted as both prosecutor and judge in investigating and reaching the Decision, and in deciding what evidence, including exculpatory evidence, might be disclosed to Napp; that the Director failed to disclose to Napp all the evidence available to him which he should, or could, have obtained; that the Director failed to collect sufficient evidence, or relied on material having no evidential value, or ignored relevant evidence; and that the Director failed to accord Napp the possibility of testing the evidence by cross-examination.

137. As we have just indicated, we accept that both Article 6(1) and (2) of the ECHR apply to proceedings potentially involving a penalty imposed for a breach of the Chapter I and Chapter II prohibitions. We also accept that there is force in the argument that the administrative procedure before the Director does not in itself comply with Article 6(1), notably because the Director himself combines the roles of investigator, prosecutor and decision maker. However, as we have already indicated in paragraph 74 of our judgment of 8 August 2001, that in itself involves no breach of Article 6 because the Director's administrative Decision is subject to full judicial control on the merits by this Tribunal: see also now the decision of the House of Lords in *Magill v Porter* [2001] UKHL 67, judgment of 13 December 2001, per Lord Hope at paragraphs 87 to 94. In those circumstances we do not find that the procedure, taken as a whole, is unfair. It has not been suggested that this Tribunal is not "an independent and impartial tribunal" for the purposes of Article 6(1) of the ECHR.

138. As to the procedural requirements governing the administrative stage, we have already drawn attention to Rule 14 of the Director's Rules, which provides, in effect, for the "right to be heard" and for "access to the file". Under these provisions the Director must put to the defendant undertaking the essential facts and matters on which he relies. It goes without saying that the Director may not rely, in establishing his case, on anything that has not been disclosed to the defendant undertaking. It is also well established that, subject to the protection of internal documents (Rule 30(1)(f)) and confidential information as defined by Rule 30(1)(c) – essentially business secrets and information relating to the private affairs of an individual – the whole of the Director's file must be available for inspection by the undertakings concerned: see Case T-30/91 *Solvay v Commission* [1995] ECR II-1775, appeal dismissed Case C-288/95P [2000] ECR I-2391. The availability of the file enables the undertaking to defend itself, notably by seeking exculpatory material.

139. In the revised version of its notice of appeal, Napp complains of the Director's failure to disclose documents relating to the conduct of other firms who are or were supplying sustained release morphine in the United Kingdom; the views of the Department of Health on the case; evidence of discounts offered on other pharmaceutical products; and documents relating to the chronology of the discounting of oral sustained release morphine.

140. As we understand it, very extensive disclosure took place during the administrative proceedings, albeit that certain documents – not relied on by the Director – were not disclosed to Napp because

commercial confidentiality had been claimed by third parties pursuant to Rule 14(6)(a) and Rule 30(1)(c) of the Director's Rules. A Schedule listing all the documents in the Director's possession, identifying those which had not been disclosed in whole or part, was supplied to Napp. Upon the lodging of the appeal, the Director disclosed further documents to named external advisers of Napp, who gave undertakings to observe the confidentiality of the documents in question. Material relating to the discounting of products other than oral sustained release morphine was disclosed by the Director in the defence. The witness statements of Mr Hartley and Mr Penrose before the Tribunal contained a great deal of further material about the commercial strategies pursued in relation to Zomorph and Oramorph, respectively.

141. We understand that these further steps have largely resolved any dispute there may have been as regards disclosure. Despite having the opportunity during these proceedings to apply to the Tribunal for the disclosure of further documents, or classes of documents, Napp has made no such application. Nor was any specific complaint made, during argument at the hearing, that material documents were still being withheld, or that Napp's defence was being hampered as a result.

142. In these circumstances, we are wholly unable to find either that any documents were wrongfully withheld from Napp in breach of Rule 14 of the Director's Rules, or that Napp has suffered any prejudice as a result of the application of Rules 14(6)(a) and 30(1)(c) in this case. In particular, given the very full argument that Napp has advanced by reference to the relatively vast amount of material now before the Tribunal, we see no grounds for suggesting that there has been any breach of Napp's right to 'a fair trial' for the purposes of Article 6(1), as far as the disclosure of material documents is concerned.

143. It is true that where, in the course of the administrative procedure, the Director refuses disclosure under Rules 14(6)(a) and 30(1)(c), there is no provision under the Act which permits that issue to be adjudicated upon until the matter reaches the judicial stage before the Tribunal. The same is true of proceedings before the Court of First Instance. However, once the matter does reach the Tribunal, the case is fully argued "on the merits", the Tribunal having the power to take its own decision, or remit the matter to the Director. It is at that stage that the Tribunal is in a position, by the exercise of its powers under Rules 17 to 21 of the Tribunal Rules, to ensure that the rights of the defence are respected as regards the disclosure of documents. That is, in effect, what has occurred in the present case, as far as documents are concerned.

144. In our view the same approach applies to the cross-examination of witnesses. The Director's Rules do not envisage the cross-examination of witnesses during the administrative stage. However, there is power to apply to cross-examine at the judicial stage before the Tribunal. In the present case, Napp did not apply to cross-examine any witness under Rule 17 or seek any witness summons under Rule 21. In those circumstances we see no basis for arguing that Napp's rights of defence have been breached by the absence of cross-examination during the administrative stage.

145. We do not accept that the Director had any duty to collect, and make available to Napp, any further material, nor did Napp make any application to the Tribunal in that regard during the appeal.

146. We add, generally, that the three evidential issues to which Napp's submissions on this part of the case are principally directed are (a) whether hospital discounting was, as Napp suggests, initiated by Farmitalia and BIL; (b) why BIL left the market in 2000; and (c) Mr Mountain's view of the competitive strategy of Link. As will be seen below, neither (a) nor (b) are matters upon which we need to make specific findings. As regards (c), Mr Mountain was available, at the Tribunal's request, at the oral hearing and Napp could have cross-examined him then had they wished to do so.

147. The remaining arguments advanced by Napp in this part of the case seem to us to go to the weight of the evidence rather than to issues of procedure. We therefore turn to deal with the merits.

VI – DOMINANCE

Relevant market

148. Napp's notice of appeal does not expressly question the Director's detailed analysis of the relevant market at paragraphs 45 to 93 of the Decision, other than to remark, without elaboration, in Annex I, paragraph 16, that the Director's approach to the relevant market is "factually and legally flawed". In paragraphs 3.48(ii) and 3.49, and footnotes 47 and 48 of the notice of appeal, Napp suggests that Durogesic, a strong opioid analgesic delivered in an adhesive patch, offers strong competition to Napp. Mr Brogden also makes that point in his second witness statement. Napp does not, however, put forward an alternative market definition, nor say what its share of any alternative market might be.

149. Paragraph 3(1) of Schedule 8 of the Act requires us to determine the appeal on the merits "by reference to the grounds of appeal set out in the notice of appeal." In our view, Napp's notice of appeal does not sufficiently put in issue the definition of the relevant market as one of the grounds of appeal, nor set out the arguments in support of any such ground, as required by Rule 6(5) of the Tribunal Rules and the Tribunal's *Guide to Appeals under the Competition Act 1998*, paragraph 5.10. We take the view that the Tribunal is not bound to consider grounds that are inadequately presented in the Notice of Appeal. In our view, the Director rightly objected to the inclusion of the relevant market in the list of issues served by Napp on 30 July 2001, and we understood counsel for Napp to accept, during the hearing, that the relevant market was not pursued as an issue in this case.

150. It is, therefore, only by way of precaution that we find that Napp's scattered references to Durogesic in the notice of appeal do not suffice to put in question the correctness of the Director's analysis, at paragraphs 53 to 70 of the Decision, which excludes non-morphine products (of which Fentanyl, sold under the name Durogesic, is one) from the relevant market. The evidence there set out is to the effect, notably, that Durogesic is used in practice when patients are intolerant to oral morphine, or for some other reason oral morphine is unsuitable; that the two products are not regarded as substitutes; that Durogesic has certain practical disadvantages when compared to oral morphine; that the price of Durogesic does not appear to constrain the price of MST; and that it is not clear whether Durogesic has in fact had any adverse impact on sales of MST: see paragraphs 56 to 64 of the Decision.

151. The references in the documents to which Napp draws our attention – without however developing any clear argumentation in the notice of appeal – do not in our view convincingly address the matters relied on by the Director in the Decision. Certain of the references relied on by Napp e.g. Dr Hunt (document A21 at paragraph 25), Professor Hanks (document A23 at paragraph 14) and Dr Forster (document A26 at paragraph 15) are at best inconclusive as, in our view, is the material referred to by Mr Brogden. Other documents to which Napp refers are in our view too general to be useful.

152. We are therefore satisfied that for the purposes of these proceedings the relevant market is the supply of sustained release morphine tablets and capsules in the United Kingdom, as the Director concludes at paragraph 93 of the Decision.

Dominant position

153. Napp argues in the notice of appeal that it is not dominant in any relevant market, because the PPRS is effective to prevent Napp from being able to abuse any dominance it might otherwise enjoy, at least in respect of the abuses alleged in this case. Napp argues, in particular, that the PPRS prevents Napp from engaging in excessive pricing. In addition, the Department of Health could regulate the offering, by PPRS companies, of discounts against the NHS list prices. The fact that the Department does not choose to do so is irrelevant.

154. The Director submits that Napp is dominant by virtue of its market shares alone, which are in excess of 90 per cent. That dominance is reinforced by the barriers to entry referred to in the Decision. The PPRS does not go to rebut dominance at all. That scheme controls the overall profit that a supplier of branded pharmaceuticals may earn from the NHS but is not directed at anti-competitive abuse. It does not affect discounting to hospitals. Napp's argument confuses the question of dominance with the separate question of whether, in the light of the PPRS, Napp's prices in the community segment are an abuse of its dominant position.

155. We agree with the submissions of the Director.

156. According to the classic test, a dominant position under Article 82 of the Treaty:

> "relates to a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of consumers."

Case 85/76 *Hoffman-La Roche v Commission* [1979] ECR 461, paragraph 38.

157. The Court also said at paragraph 39:

> "The existence of a dominant position may derive from several factors which, taken separately, are not necessarily determinative but among these factors a highly important one is the existence of very large market shares."

And at paragraph 41:

> "Furthermore although the importance of the market shares may vary from one market to another the view may legitimately be taken that very large shares are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position."

158. In *Hoffman-La Roche* the Court held that market shares ranging between 84 and 90 per cent over three years "prove the existence of a dominant position" (paragraph 60). In *AKZO* the Court held that the test in *Hoffman-La Roche* was satisfied where an undertaking had maintained a stable market share of about 50 per cent over five years [1991] ECR II-3359, paragraph 60.

159. In the present case Napp's overall market share in the relevant market has been in excess of 90 per cent for many years. It is currently around 96 per cent, and over 90 per cent, in the community and hospital segments of the market respectively. In addition, various further factors reinforce barriers to entry and Napp's "first mover advantage", as pointed out in paragraphs 102 to 108 of the Decision. None of these facts are contested by Napp.

160. Applying the concept of a dominant position in Community law to the Chapter II prohibition, which we are required to do by section 60 of the Act, the foregoing considerations suffice, in our view, to establish that Napp enjoys a dominant position within the meaning of section 18(1) of the Act, without it being necessary, at this stage of the analysis, to rely on the further matters to which the Director refers at paragraphs 114 to 118 of the Decision.

161. As regards the PPRS, that scheme regulates by voluntary agreement the maximum profits to be made by any scheme member in respect of branded licensed medicines sold to the National Health Service, and in some cases the maximum prices that may be charged for medicines covered by the scheme. Under section 33 of the Health Act 1999, the Secretary of State has various powers to give directions if the scheme is not effective, including the power to prevent a manufacturer from raising prices without the Secretary of State's approval. Sections 34 to 38 of that Act provide for statutory regulation of prices and profits in respect of those pharmaceutical companies which are not members of the voluntary scheme. Napp has not challenged the essence of the description of the PPRS at paragraphs 125 to 135 of the Decision.

162. As the Decision points out at paragraphs 125 to 130, the essential feature of the PPRS is that it imposes a limit on the rate of return (measured as a percentage return on capital employed on sales) that a company can earn on its sales of branded prescription medicines to the NHS. That profit limit is applied across all the products that a company sells to the NHS and is not applied to each product individually. Under the terms of the current PPRS, companies are allowed a rate of return on capital (ROC) of 21 per cent from home sales of NHS medicines with an upward margin of tolerance of 40 per cent. Companies exceeding the margin of tolerance (i.e. with an ROC over

29.4 per cent) are required to repay any excess to the Secretary of State. The scheme sets out rules on the allocation of costs and capital and has specific rules for the treatment of research and development and promotion costs. The scheme also requires participating companies to provide an annual financial return so that the Secretary of State is able to monitor participating companies' returns.

163. Under the terms of the PPRS, companies are free to set the NHS list prices of new branded products involving new molecules, although any resultant profits in excess of the ROC ceiling laid down by the scheme would be repayable to the Secretary of State. In the case of drugs which, like MST, are a new formulation of an existing chemical entity (i.e. morphine sulphate), their initial price is subject to confirmation by the Secretary of State. Once prices are set, the PPRS restricts increases. In some circumstances, however, companies may "modulate" their prices by increasing some prices and decreasing others, provided that the overall effect is cost neutral to the NHS. Periodically the Department of Health has negotiated an across the board price cut on all branded medicines sold to the NHS. In the context of the current PPRS a price cut of 4.5 per cent was negotiated to take effect from 1 October 1999. However, companies were permitted to lower some prices more than others, provided the overall effect was that of a 4.5 per cent price cut.

164. In our view the case law on the existence of a dominant position, cited above, directs our attention to the competitive situation in the market place, and in particular to whether the allegedly dominant undertaking is able to "prevent effective competition being maintained on the relevant market". As seen from the foregoing, the PPRS does not have a direct effect on Napp's freedom to conduct itself as it wishes in the market for oral sustained release morphine. As regards the issue of dominance, the effects of the PPRS are at most remote and indirect, in that the scheme might in some circumstances constrain Napp from increasing the price of MST (an issue not relevant here) and may similarly constrain Napp's profits on its range of NHS branded medicines taken as a whole, as distinct from MST in particular. In our view neither of those indirect effects go to the threshold question of whether Napp has the degree of power in the market place necessary to bring the Chapter II prohibition potentially into play.

165. The fact that the initial price set for MST in 1980 *may* have been constrained by the PPRS (see paragraph 408 below), and has been reduced since in the context of across the board reductions agreed under successive schemes, could, perhaps, be relevant to the Director's allegation that the community price for MST was excessively high, as could, perhaps, Napp's argument that the

portfolio based approach of the PPRS is to be preferred, when it comes to determining whether the price of MST is excessive for the purposes of the Chapter II prohibition. But those arguments which in any event we reject at paragraphs 406 et seq below, go to the question of *abuse*, and not to the prior question of the existence of a dominant position.

166. On the issue of discounts to hospitals, the current PPRS does not contain any provisions on discounts or any means of regulating Napp's discounts. As far as we can see, neither the current scheme nor its predecessors has or had any bearing on the question whether discounts have been used to exclude competitors, as the evidence of Mr Brownlee makes clear.

167. In Case T-228/97 *Irish Sugar v Commission* [1999] ECR II-2969 the Court of First Instance rejected the appellant's plea that its policy on offering certain rebates was in accordance with the policy of the Irish government in the following terms:

> "If anti-competitive conduct is required of undertakings by national legislation or if the latter creates a legal framework which itself eliminates any possibility of competitive activity on their part, Articles 81 and 82 do not apply. In such a situation, the restriction of competition is not attributable, as those provisions implicitly require, to the autonomous conduct of the undertakings ... Articles 81 and 82 may apply, however, if it is found that the national legislation does not preclude undertakings from engaging in autonomous conduct which prevents, restricts or distorts competition ..."

(paragraph 130).

168. In our view nothing in the PPRS affects Napp's autonomous conduct in such a way as to deprive Napp of its dominant position, as the Director found in paragraphs 122 to 136 of the Decision. Moreover, on Napp's argument virtually the entire pharmaceutical industry of the United Kingdom would be outside not only the scope of the Chapter II prohibition but also Article 82 of the Treaty. The decisions of the Commission cited by the Director at paragraph 137 of the Decision are contrary to that point of view.

169. For these reasons we are satisfied that Napp has a dominant position in the supply of tablets and capsules of oral sustained release morphine in the United Kingdom.

VII – ABUSE: DISCOUNTS TO HOSPITALS

170. In dealing with the issue of abuse, we follow the structure of the Decision in dealing first with discounting to hospitals, and then with excessive prices in the community segment of the market. We remind ourselves, at the outset, however, of the Director's fundamental submission that the

hospital segment of the market is the only viable point of entry into the market as a whole. Hence the alleged abuse in the hospital segment, while a discrete abuse and significant in its own right, is also, says the Director, a means to an end, namely the preservation of Napp's prices and market share in the much larger community segment of the market. Although we analyse the two abuses separately, the connection between the hospital and community segments must be borne in mind throughout this judgment.

A. ARGUMENTS OF THE PARTIES

Napp's arguments

171. Napp does not dispute the cost and market share figures put forward by the Director, nor the fact that Napp offers MST to hospitals at prices below direct costs, accepted in this case as a proxy for average variable costs. Napp, however, argues that its conduct is not abusive, on the basis of what appear to be seven main arguments.

172. Napp submits, first, that its discounts are the result of normal competition in the market.

173. Napp states that until 1991, it offered only modest discounts to hospitals. From 1991 onwards first Farmitalia, and then BIL, started offering much cheaper prices to hospitals. In consequence, "Napp simply aimed to match the prices they were offering". According to Napp, prices fell below average direct cost at some time in 1998 (a date disputed by the Director who says it was 1996), but it was not Napp which led prices down. Moreover, discounting to hospitals is consistent with normal commercial practice: see the evidence of Mr Tebby, a hospital pharmacist in Leeds, and various statements said to have been made by officials of the Department of Health.

174. Secondly, and more fundamentally, Napp submits that its sales below cost to hospitals are incrementally profitable on what Napp describes as a 'net revenue' basis.

175. According to Napp, its Internet Survey shows that, for each unit of oral sustained release morphine sold to a hospital, a supplier can expect to sell 1.35 "follow-on" units of its brand of oral sustained release morphine in the community(see the report by Nera, *Key Market Evidence in the Supply of Slow Release Morphine*, 16 October 2000, document A19). According to a further Nera report entitled *Napp: Analysis of OFT Decision on Abuse*, 29 May 2001 (document A107), even at Napp's highest level of discount, "the overall transaction" (i.e. the sale of MST to hospitals at the

hospital price plus the sale of "follow on" units to the community segment at the community price) is profitable. Such transactions cover not only Napp's average variable costs, but also Napp's average total cost: see Table 2.2 of document A107. Even assuming that one unit of hospital sales led to the sale of only 0.25 follow-on units in the community, Napp would still be covering its average total costs: see Table 2.3 of document A107. Even at the reduced NHS prices required by the Directions, the hospital prices currently charged for MST would be profitable for Napp (i.e. cover average total costs), once the follow-on sales are taken into account, so long as one unit sold in a hospital generated at least 0.30 units of follow-on sales in the community sector: Table 2.4 of document A107. It would require a linkage of only 0.04 follow-on units for Napp to cover its direct costs.

176. According to Napp, it is this "externality" of the "follow-on" effect, where one loss-making sale may generate other, profitable sales, which distinguishes this case from the decision of the Court of Justice in *AKZO*. According to Napp, a comparable case would be if the suppliers of razors sold them very cheaply but made their profits on razor blades. The Director's own guidance in *Assessment of Individual Agreements and Conduct* (OFT 414, September 1999) confirms that a "net revenue test" is perfectly acceptable in principle. Even a modest follow-on effect is sufficient for Napp's purposes, whether or not hospital discounting 'expands the market', or leads to additional GP prescriptions (which it does).

177. In support of its argument, Napp relies on the evidence of Mr Paul Manners, Managing Director of Napp Pharmaceutical Holdings Limited, who states at paragraph 60(ii) of his witness statement of 13 October 2000 annexed to the notice of appeal:

> "Napp considers that it makes sense to discount MST substantially to win hospital contracts, to take account of the fact that there is some linkage, albeit one that it is difficult to quantify, between sales in hospitals and sales in the community. Given that, under the PPRS, Napp can charge prices for its community sales which generate a profit margin of some [...] [in excess of 80]%, Napp does not need to stimulate many sales in the community to justify a substantial discount of its prices to the hospital sector. Thus Napp can afford to discount its prices to hospitals substantially, even on the basis of a fairly modest assumed linkage between hospitals and community sales, and the hospital sales will still be profitable.
>
> In short, we did not believe that, by discounting our prices to the extent that we did to win hospital contracts, we would be making losses; instead we believed that, if we were successful in winning contracts, we would thereby make extra sales, because we could expect to sell extra units of MST in the community segment, by virtue of the "linkage" referred to in paragraph (ii) above. We assumed that all bidders were

evaluating the opportunities in the same way, and were willing to offer discounts on the same basis."

178. Furthermore Mr John Brogden, Managing Director of Napp Pharmaceuticals Limited, states at paragraph 20 of his witness statement of 25 May 2001, also annexed to the notice of appeal:

> "Moreover, I have at all material times believed that Napp's discounts to hospitals represented a fair and normal means of competition: Napp was keen to win hospital contracts, in recognition of the follow on benefits which they bring, in terms of community sales. I believed that other suppliers would also recognise those benefits and, indeed, I believed that that was why other firms (first Farmitalia, then Boehringer Ingelheim and now Link) were offering such low prices to hospitals."

179. According to Napp, the documents disclosed as a result of the Tribunal's order of 31 August 2001 are entirely consistent with the assumption that at least for the later 1990s onwards Napp was competing with BIL in the hospital segment on a net revenue basis in order to obtain the "linked" sales in the community segment. This was a rational strategy, and cannot be regarded as abusive simply because it may make it more difficult for a new entrant to succeed.

180. It cannot be suggested that Napp did not know of the linkages between the hospital and community segments, nor factor them into their pricing, as shown by the evidence of Mr Brogden and Mr Manners cited above. Mr Brogden's e-mail of 10 June 1996, and the e-mails relating to 1999 and 2000 at Annex 2 to the defence, disclosed in answer to the Director's request of 15 June 2001, confirm this. Mr Brogden's letter to the Director of 24 September 1999 was an "overview" but does show *a* "follow-on" effect. A small but significant linkage is sufficient for Napp's purpose.

181. Thirdly, Napp argues that similar "linkages" accrue to other suppliers, such that it is rational for them to compete with Napp on the same basis.

182. The fact that BIL and Link have been prepared to sustain below cost prices for long periods shows that those suppliers too believe in "the follow-on effect", otherwise they would have had no incentive to stay in business (document A107, paragraphs 1.1.2 and 1.3 to 1.4). The fact that BIL did not, apparently, secure the benefit of such linkages and left the market was, Napp suggests, due to failings in BIL's market strategy and had nothing to do with Napp's alleged 'aggression', which Napp denies.

183. That the benefit of such linked sales is available to Link is confirmed, says Napp, by a letter to the OFT by Mr Steven Mountain, the managing director of Link dated 3rd November 2000 (OFT document 255) where he says:

> "Proof of this link [sc. between hospital and community] can be seen in the sales of Zomorph capsules over the last year where the ratio of hospital sales volumes to community sales volumes is 1:4. Link only has a hospital sales team. We do not call or advertise to GPs at all, and so the only way that there are any sales of Zomorph capsules into the community is through hospital influence via referral and the other methods outlined above.
>
> The MST ratio is currently 1:8 and so it can be seen following conversions that a hospital has an immediate and direct influence over around 50% of community usage. The ratio for Zomorph capsules sales will rise further over time as hospital influence filters through to the community…
>
> We do not dispute Napp's second point that Napp makes money overall out of loss leading into hospital. For every 1 pack they sell into hospital we can see that immediately they would sell 4 into the community, and in the long term 8. …"

184. In addition to this letter, upon which Napp strongly relies, Tables 2.5 and 2.6 in document A107 seek to show that, on a ratio of 1:1.35, Link could match Napp's MST prices to hospitals and still break even if its average total costs were three times those of Napp. Napp's figures, handed in at the hearing, show that a follow-on linkage of between 0.10 and 0.51 would suffice to cover Link's costs. According to Nera, "once Napp's hospital prices are considered as "system prices" by including the profitable follow-on community sales, the discounted hospital prices are profitable even for a small producer such as Link ..." (A107, p.17).

185. According to Napp, the witness statements of Mr Penrose and Mr Hartley, also confirm the existence of the linkages, and make it clear that a net revenue approach is a natural way of competing. Contrary to the Director's suggestion, the follow-on effect is sufficiently predictable to be relied on. The matters referred to at paragraphs 152 to 155 of the Decision do not establish the contrary: that evidence is unspecific and pre-dates the Health Act reforms of 1999. The Link documents produced by Mr Hartley clearly show that Link is aware of the linkage between the hospital and community sector and exploits it. Indeed in permitting Napp to price below average cost under paragraph 2(d) of the Directions, the Director himself implicitly recognises the existence of the linkages in question.

186. Moreover, says Napp, these linkages are reinforced by the development of PCGs/PCTs, which incentivize both hospital buyers and GPs to take more account of the overall cost of patients'

treatment when making prescribing decisions. These effects, says Napp, were already being felt by January 2000, just as BIL was leaving the market, and have been successfully exploited by Link, as shown by Mr Mountain's letter of 3 November 2000 and the evidence of Mr Hartley. Napp particularly criticises the Director for failing to take account of Mr Mountain's letter in the Decision, despite Napp's comments on that letter at the second oral hearing during the administrative procedure. In fact, Link's sales have grown substantially since May 2000, another fact not taken into account by the Director. Napp states, however, "for the avoidance of doubt" that it is not suggested that the linkage is entirely automatic, in the sense that no further effort is required on behalf of the supplier. According to its skeleton argument, what Napp means by 'automatic' is that "a supplier need expend no more effort than one would reasonably expect of a competent supplier" (paragraph 85).

187. Fourthly, Napp submits that the Decision is based on events in the period prior to March 2000, and does not address the very different market situation prevailing after that date.

188. Napp submits that the situation changed fundamentally following the withdrawal of BIL and the emergence of Link as Napp's principal competitor. Unlike BIL, Link does not always participate in tenders but goes direct to purchasing authorities and hospitals. According to Napp, Link has won three regional contracts. In two cases it has been placed on the regional list without having tendered, and in the third case the NHS PASA terminated Napp's contract mid-term to allow Link to bid. It appears that Link in fact undercuts Napp, at least on some contracts, so there is no question of price matching on the part of Napp. Since Napp learns of Link's activities after the event, there is an asymmetry of information which is in favour of Link, not Napp. According to Napp, the recent developments of PCGs/PCTs strongly favour Link.

189. As to the Director's argument that switching costs represent an obstacle to Link, Napp says that there is no proper quantification of such costs, and Mr Hartley's evidence suggests that these are not a "material obstacle to the use of linkages as a viable entry mechanism". The same is true of promotion costs. The advent of PCGs/PCTs is likely to eliminate the problem of switching costs in hospitals since it is the overall cost in the community/hospital combined which will become determinative.

190. Nor is it possible, says Napp, to draw any adverse conclusions about Link's profitability without knowing how costs are allocated within Link. The Director now accepts that Link is doing well

and not in danger of going out of business. APS Berk, Lanacher and CeNeS are potential new entrants. BIL's statements as to why it left the market are self-serving and dubious.

191. Fifthly, Napp argues that it has not foreclosed the community segment of the market as alleged by the Director.

192. Napp accepts "that it is well established that GP's prescribing decisions are influenced by hospital prescribing" (notice of appeal, paragraph 3.27). However, in choosing a brand of oral sustained release morphine, GP's will not, according to Napp, be influenced to any substantial degree by the mere fact that a new brand of oral sustained release morphine is used in hospitals. According to the Internet Survey, and the evidence of Dr. Forster (document A26, paragraph 20) most patients are initiated by the GP, without the involvement of the hospital doctor, and the GP will go mainly by his own experience. Although accepting that the influence of hospital prescribing habits is likely to be more important in the case of new drugs (document A26, paragraph 26), Napp submits that there is no evidence to quantify to what extent the sale of a new brand of oral sustained release morphine to hospital will itself contribute to the establishment of a "reputation" for that brand in the community segment of the market, nor to what extent the making of hospital sales is better than other available means of establishing such a reputation (e.g. direct promotion and marketing of the brand to GP's and community nurses, and general promotional activities, such as the sponsoring of medical conferences and the sponsoring of training for healthcare professionals). Napp submits that, even for new entrants, hospital sales do not represent the only means by which a new entrant may establish a reputation in the community segment of the market.

193. Sixthly, Napp argues that it has had no intention to eliminate competition.

194. According to Napp, the selective nature of Napp's discounts represent a competitive response to a competitive situation. The Director himself, in the Directions, accepts that there is likely to be a substantial difference between the community price and the hospital price.

195. In particular, there is no evidence of ill-will or predatory intent on the part of Napp during the period of the alleged infringement, notably vis-à-vis Link. Even by December 2000, Napp had not formulated a policy on how to respond to Link (see the documents at Annex 2 to the Defence). Similarly, there is no evidence, during the period of the infringement, of Napp's alleged 'aggression'. Link's documents annexed to Mr Hartley's witness statement suggest that they did

not expect Napp to retaliate in hospitals nor lower their prices in the community. Nor can the Director be permitted to prove an anti-competitive intent on the basis of the material disclosed in response to the Tribunal's request, since that material was not relied on in the Decision, and predates the period of infringement.

196. Seventhly, argues Napp, there is no sufficient causal connection between Napp's conduct and any alleged harm in the market place.

197. Given the structure of the market Napp could not reasonably have been expected to act any differently than it did and was responding to "circumstances beyond its control". Napp's only alternative would have been to cede the market to its competitors, which would have been wholly unreasonable and is not something required by the Chapter II prohibition. Moreover, had Napp not competed in the way it did, it would have risked losing all or most of its main hospital contracts, and thus its association with hospitals and its ability to use hospitals for testing new drugs. Moreover, there is no distortion of consumption (because the products are prescribed on medical grounds) and no discrimination between customers (because there is only one customer, the NHS).

198. In all those circumstances, concludes Napp, it has committed no abuse. A dominant undertaking is entitled to compete on the merits, and defend its own interests, provided its conduct is reasonable and proportionate. In *AKZO*, there was express evidence of intention to eliminate a competitor, and/or the absence of any economic rationale other than ousting a competitor. That is not the case here, notably because of the follow-on effect and Napp's legitimate reliance on the net revenue test. Similarly the decision of the Court of Justice in *Compagnie Maritime Belge* does not decide that "matching prices" is per se bad. It all depends on the facts, and neither *Compagnie Maritime Belge*, nor the decision of the Court of First Instance in *Irish Sugar*, both cited below, are in point here. In the present case, Napp's conduct has been reasonable and proportionate, within the bounds of normal competition on the merits, and with no intention to eliminate a competitor.

The Director's arguments

199. The Director relies on the facts and matters in the Decision. He points out that Napp is "superdominant", and remains so 20 years after the launch of MST. Napp's discounts to hospitals in the present case go far beyond the norm and have "significantly and very consciously" raised barriers to entry, in order to prevent entry into the hospital segment and protect Napp's price and

market share in the community segment. Pursuant to *AKZO*, the burden is on Napp to rebut the presumption of abuse to which its below-cost sales give rise. According to the Director, Napp's arguments based on 'follow-on effect' and 'linkages' fail to rebut that presumption.

200. As to "follow-on effect", the Director submits that the Internet Survey does not support the conclusion that every one unit of sustained release morphine sold in hospital will automatically generate 1.35 units sold in the community. Even accepting that the 15 per cent finding of the Internet Survey could be accepted "as a crude estimate at a national level over time" of a follow-on effect, resulting from hospital prescriptions and referral letters combined, the Director continues to maintain that any alleged follow-on effect is neither mechanistic, nor predictable, as found in paragraphs 152 to 154 of the Decision. In any event, says the Director, suppliers of oral sustained release morphine do not in practice compete for a "package" of hospital plus directly-linked community sales.

201. The Director accepted (transcript Day 3, p.17) that the likelihood was that, from Napp's point of view, there was some direct follow-on effect, where patients initiated on MST in hospital are subsequently prescribed MST in the community, such that Napp's hospital sales are, as a result, incrementally profitable, on average across the country over time, although at a ratio much smaller than 1:1.35, and not necessarily for each sale or even each region. However, according to the Director, the main commercial value to Napp of its below-cost sales to hospitals is not this narrow 'follow-on effect', but the exclusion of competitors from the essential gateway to the profitable community segment.

202. As a matter of principle, submits the Director, the net revenue test is not an answer to an allegation of abuse where the selling practices of a dominant firm operate as a means of foreclosure. He submits, on the basis of *Compagnie Maritime Belge* and *Irish Sugar*, cited below, that a superdominant undertaking such as Napp is not entitled to engage in a policy of price cutting aimed at impeding competitors entering one part of the market, while at the same time charging higher prices in another part of the market where there is no competitive threat. According to the Director, Napp's admitted policy of price matching is abusive, because of its exclusionary effect, irrespective of whether Napp has carried out a policy of undercutting. In this case hospital switching costs substantially erase the opportunities for Napp's rivals to gain hospital sales by offering still lower prices.

203. Furthermore, the Director emphasises, as he did in the Decision, that Napp's discounted prices to a level below direct costs are only granted on the dosage strengths where Napp faces competition, that is to say 10mg, 30mg, 60mg and 100mg, where the discounts are significantly greater than in respect of those dosage strengths where there is no competition (5mg, 15mg, 200mg). It also grants a higher discount of [...][in excess of 90] per cent where the regional contract is to be awarded exclusively. No cost savings have been put forward to justify this higher discount.

204. In any event, submits the Director, the net revenue test is not a legitimate defence because of the advantages which Napp has over its rivals, which gives rise to asymmetry in the market place as between Napp and its competitors, as the Director found in the Decision. As to the extent of foreclosure, the Decision (paragraph 181) indicates that Napp has foreclosed the principal and probably the only means of entry to the market. Paragraph 251 of the Decision indicates that the policy indirectly impeded competition in the whole of the relevant market. The approach at paragraphs 166 and 167 of the Decision is an alternative approach.

205. As regards BIL's reasons for withdrawing from the market, the Director maintains the position he took in the Decision and relies on the witness statements from Mr Connolly, and Mr Penrose to rebut Napp's assertions regarding BIL. With respect to Link, the Director contends that Link's market share is still negligible and that Link has not been making a profit due to the very low hospital prices, coupled with the very high promotional spend which is necessary to enter the market. According to the Director, there is no indication that the Health Act reforms of 1999 had any effect on the market share of MST or its price in the community during the period of the infringement, as stated in paragraph 121 of the Decision. There is nothing relevant about PCGs/PCTs in the notice of appeal, nor is it alleged in the notice of appeal that the market situation after 1 March 2000 was any different from the situation beforehand. According to the Director, there is only one potential new entrant and that at least two other companies have been deterred from entering the market by Napp's conduct.

206. Finally, says the Director, Napp was clearly aware of the exclusionary effect of its conduct and intended to eliminate competitors. That can be inferred from the evidence referred to in the Decision and also from the documents disclosed to the Tribunal.

B. THE RELEVANT LAW

207. In Case 85/76 *Hoffman-La Roche v Commission* [1979] ECR 461, which concerned a system of loyalty rebates operated by the dominant firm which made it difficult for competitors to enter the market, the Court of Justice stated at paragraph 91:

> "The concept of abuse is an objective concept relating to the behaviour of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition."

208. In Case 322/81 *Michelin v Commission* [1983] ECR 3451, which also involved a rebate system that tended to tie dealers to the dominant company, the Court said at paragraph 57:

> "A finding that an undertaking has a dominant position is not in itself a recrimination but simply means that, irrespective of the reasons for which it has such a dominant position, the undertaking concerned has a special responsibility not to allow its conduct to impair genuine undistorted competition on the common market."

209. In *AKZO* (Case C-62/86 *AKZO Chemie v Commission* [1991] ECR I-3359), where the dominant firm offered prices discounted below cost in order to force a competitor out of business, the Court held:

> "[70] Article 82 prohibits a dominant undertaking from eliminating a competitor and thereby strengthening its position by using methods other than those which come within the scope of competition on the basis of quality. From that point of view, however, not all competition by means of price can be regarded as legitimate.
>
> [71] Prices below average variable costs (that is to say, those which vary depending on the quantities produced) by means of which a dominant undertaking seeks to eliminate a competitor must be regarded as abusive. A dominant undertaking has no interest in applying such prices except that of eliminating competitors so as to enable it subsequently to raise its prices by taking advantage of its monopolistic position, since each sale generates a loss, namely the total amount of the fixed costs (that is to say, those which remain constant regardless of the quantities produced) and, at least, part of the variable costs relating to the unit produced.
>
> [72] Moreover, prices below average total costs, that is to say, fixed costs plus variable costs, but above average variable costs, must be regarded as abusive if they are determined as part of a plan for eliminating a competitor. Such prices can drive from the market undertakings which are perhaps as efficient as the dominant undertaking but which, because of their smaller financial resources, are incapable of withstanding the competition waged against them."

210. *AKZO* was followed in Case T-83/91 *Tetra Pak v Commission* [1994] ECR II-755), on appeal, Case 333/94P *Tetra Pak v Commission* [1996] ECR I-5951 ("*Tetra Pak II*"). The Court of First Instance, applying the criteria set out in *AKZO*, found that certain of Tetra Pak's prices were below direct variable costs, and in one case below average variable cost (paragraph 151), and had no other economic rationale other than ousting Tetra Pak's principal competitor (paragraphs 147 to 151, and 188 to 192 of its judgment). On the subsequent appeal the Court of Justice held at paragraphs 41 to 44:

> "41. In *AKZO* this Court did indeed sanction the existence of two different methods of analysis for determining whether an undertaking has practised predatory pricing. First, prices below average variable costs must always be considered abusive. In such a case, there is no conceivable economic purpose other than the elimination of a competitor, since each item produced and sold entails a loss for the undertaking. Secondly, prices below average total costs but above average variable costs are only to be considered abusive if an intention to eliminate can be shown.
>
> 42. At paragraph 150 of the judgment under appeal, the Court of First Instance carried out the same examination as did this Court in *AKZO*. For sales of non-aseptic cartons in Italy between 1976 and 1981, it found that prices were considerably lower than average variable costs. Proof of intention to eliminate competitors was therefore not necessary. In 1982, prices for those cartons lay between average variable costs and average total costs. For that reason, in paragraph 151 of its judgment, the Court of First Instance was at pains to establish – and the appellant has not criticised it in that regard – that Tetra Pak intended to eliminate a competitor. ...
>
> 44. Furthermore, it would not be appropriate, in the circumstances of the present case, to require in addition proof that Tetra Pak had a realistic chance of recouping its losses. It must be possible to penalise predatory pricing whenever there is a risk that competitors will be eliminated. The Court of First Instance found, at paragraphs 151 and 191 of its judgment, that there was such a risk in this case. The aim pursued, which is to maintain undistorted competition, rules out waiting until such a strategy leads to the actual elimination of competitors."

211. In Cases T-24-26 and 28/93 *Compagnie Maritime Belge v Commission* [1996] ECR II-1201, on appeal Cases C-395 and 396/96P *Compagnie Maritime Belge v Commission* [2000] ECR I-1365 ("*Compagnie Maritime Belge*"), a liner conference, Cewal, was found to have abused a dominant position on certain shipping routes between Europe and West Africa, by selectively lowering its freight rates to match the rates charged by its main independent competitor for ships sailing on the same or similar dates, a practice known as 'fighting ships'. It was not shown that the members of Cewal had incurred losses, only a reduction in profits. The Court of First Instance held at paragraph 146:

"[146] As has already been pointed out, it has been consistently held that whilst the fact that an undertaking is in a dominant position cannot deprive it of entitlement to protect its own commercial interests if they are attacked; and whilst such an undertaking must be allowed the right to take such reasonable steps as it deems appropriate to protect those interests, such behaviour cannot be allowed if its real purpose is to strengthen this dominant position and thereby abuse it (in particular, *BPB Industries and British Gypsum v Commission*)."

The Court of First Instance held that the purpose of the practice was to eliminate the conference's only competitor, and that, in any event, the response by Cewal to the situation which it faced was not reasonable and proportionate (paragraphs 147 and 148).

212. In his opinion ([2000] ECR I-1365) on Cewal's appeal to the Court of Justice, Advocate General Fennelly referred to paragraphs 71 and 72 of *AKZO*, and said at paragraph 127:

"127. Apparently, therefore, sales below average variable (or short-run marginal: *AKZO*, paragraph 70) costs are in effect presumed to be abusive. While it is usually rational to sell above average variable costs, because that permits some return on capital, where the market will not bear a higher price, it is not usually rational to sell below average variable costs. Marginal costs need not be incurred and business has no interest in incurring them so as to make a loss. A dominant firm would be permitted, however, to rebut this presumption by showing that such pricing was not part of a plan to eliminate its competitor."

213. After considering that even prices above average variable costs, yet still below average total or long-run marginal costs, (see *AKZO*, paragraph 72), must be considered abusive where it is established that they are part of a plan to eliminate a competitor, Mr Fennelly went on to consider the case where a dominant undertaking prices above average total costs. He concluded at paragraph 132:

"132. I would, on the other hand, accept that, normally, non-discriminatory price cuts by a dominant undertaking which do not entail below-cost sales should not be regarded as being anti-competitive. In the first place, even if they are only short lived, they benefit consumers and, secondly, if the dominant undertaking's competitors are equally or more efficient, they should be able to compete on the same terms. Community competition law should thus not offer less efficient undertakings a safe haven against vigorous competition even from dominant undertakings. Different considerations may, however, apply where an undertaking which enjoys a position of dominance approaching a monopoly, particularly on a market where price cuts can be implemented with relative autonomy from costs, implements a policy of selective price cutting with the demonstrable aim of eliminating all competition. In those circumstance, to accept that all selling above cost was automatically acceptable could enable the undertaking in question to eliminate all competition by pursuing a selective

pricing policy which in the long run would permit it to increase prices and deter potential future entrants for fear of receiving the same targeted treatment."

214. Dealing with the specific facts of *Compagnie Maritime Belge*, Mr Fennelly commented at paragraph 137:

> "137. In all these circumstances, the Court of First Instance committed no error of law in finding that the response of Cewal members to the entrance of G&C was not 'reasonable and proportionate'. To my mind, Article 86 cannot be interpreted as permitting monopolists or quasi-monopolists to exploit the very significant market power which their superdominance confers so as to preclude the emergence either of a new or additional competitor. Where an undertaking, or group of undertakings whose conduct must be assessed collectively, enjoys a position of such overwhelming dominance verging on monopoly, comparable to that which existed in the present case at the moment when G&C entered the relevant market, it would not be consonant with the particularly onerous special obligation affecting such a dominant undertaking not to impair further the structure of the feeble existing competition for them to react, even to aggressive price competition from a new entrant, with a policy of targeted, selective price cuts designed to eliminate that competitor. Contrary to the assertion of the appellants, the mere fact that such prices are not pitched at a level that is actually (or can be shown to be) below total average (or long-run marginal) costs does not, to my mind, render legitimate the application of such a pricing policy."

215. In its judgment in *Compagnie Maritime Belge* the Court of Justice held at paragraphs 112 to 120:

> "112. It is settled case-law that the list of abusive practices contained in Article 86 of the Treaty is not an exhaustive enumeration of the abuses of a dominant position prohibited by the Treaty (Case 6/72 *Europemballage and Continental Can v Commission* [1973] ECR 215, paragraph 26).
>
> 113. It is, moreover, established that, in certain circumstances, abuse may occur if an undertaking in a dominant position strengthens that position in such a way that the degree of dominance reached substantially fetters competition (*Europemballage and Continental Can*, paragraph 26).
>
> 114. Furthermore, the actual scope of the special responsibility imposed on a dominant undertaking must be considered in the light of the specific circumstances of each case which show that competition has been weakened (Case C-333/94 P *Tetra Pak v Commission* [1996] ECR I-5951, paragraph 24)."

After referring to the specific circumstances of the maritime transport sector, the Court continued:

> "117 It follows that, where a liner conference in a dominant position selectively cuts its prices in order deliberately to match those of a competitor, it derives a dual benefit. First, it eliminates the principal, and possibly the only, means of competition open to the competing undertaking. Second, it can continue to require its users to pay higher prices for the services which are not threatened by that competition.

...

119. It is sufficient to recall that the conduct at issue here is that of a conference having a share of over 90% of the market in question and only one competitor. The appellants have, moreover, never seriously disputed, and indeed admitted at the hearing, that the purpose of the conduct complained of was to eliminate G&C from the market.

120. The Court of First Instance did not, therefore, err in law, in holding that the Commission's objections to the effect that the practice known as 'fighting ships', as applied against G&C constituted an abuse of a dominant position were justified. ..."

216. Finally in Case T-228/97 *Irish Sugar v Commission* [1999] ECR II-2969 ("*Irish Sugar*"), which concerned notably the legality of certain border rebates, the Court of First Instance held (at paragraph 114) that in determining whether a pricing policy is abusive under Article 82 of the Treaty:

> "it is necessary to consider all the circumstances, particularly the criteria and rules governing the grant of the discount, and to investigate whether, in providing an advantage not based on any economic service justifying it, the discount tends to remove or restrict the buyer's freedom to choose his sources of supply, to bar competitors from access to the market, to apply dissimilar conditions to equivalent transactions with other trading parties or to strengthen the dominant position by distorting competition (*Hoffman-La Roche*, paragraph 90; *Michelin*, paragraph 73). The distortion of competition arises from the fact that the financial advantage granted by the undertaking in a dominant position is not based on any economic consideration justifying it, but tends to prevent the customers of that dominant undertaking from obtaining their supplies from competitors (*Michelin*, paragraph 71). One of the circumstances may therefore consist in the fact that the practice in question takes place in the context of a plan by the dominant undertaking aimed at eliminating a competitor (*AKZO*, paragraph 72; *Compagnie Maritime Belge Transports*, paragraphs 147 and 148)."

C. FINDINGS

Preliminary analysis

217. We observe, first, that the events described in the Decision cover the period before, and the period after, 1 March 2000 when the Act came into force. It goes without saying that there can be no infringement of the Chapter I and Chapter II prohibitions on any date earlier than 1 March 2000, notwithstanding that the Act received Royal Assent on 9 November 1998. Nonetheless, in a case such as the present it is impossible to understand the situation as it was during the period of alleged infringement – in this case the 13-month period from 1 March 2000 to 30 March 2001 – without also understanding how that situation arose as a result of facts arising before 1 March 2000. In our

view it is relevant to take facts arising before 1 March 2000 into account for the purpose, but only for the purpose, of throwing light on facts and matters in issue on and after that date.

218. Turning first to the market situation as it was from 1 March 2000 onwards, it is common ground that Napp's overall market share by volume in the relevant market (community and hospital segments combined) was stable at 95 per cent, as indeed it had been for many years. In the community segment, which itself represents 86 to 90 per cent of the whole, Napp's market share was 96 per cent. Again, that had been the case for many years. In the hospital segment, which accounts for only 10 to 14 per cent of the total market, but has a particular strategic importance as a point of entry, Napp's market share during the period of infringement was on average some 92 per cent. In that sector, Napp's market share increased from 77 per cent in 1997 to 90 per cent in 1999, and then to nearly 93 per cent in the first quarter of 2001, largely at the expense of BIL (see Table 3, at paragraph 28 above).

219. In these circumstances, there is no doubt in our minds that, from 1 March 2000, Napp had 'a special responsibility not to allow its conduct to impair genuine undistorted competition', as held by the Court of Justice in *Michelin* [1983] ECR 3451, at paragraph 57. It is well established that such a special responsibility may deprive a dominant undertaking of the right to adopt a course of conduct that would be unobjectionable if adopted by a non-dominant undertaking (Case T-111/96 *ITT Promedia v Commission* [1998] ECR II-2937, paragraph 139), but the actual scope of that special responsibility must be considered in the light of the specific circumstances of each case: *Compagnie Maritime Belge* [2000] ECR I-1365 at paragraph 114. We for our part accept and follow the opinion of Mr Advocate General Fennelly in *Compagnie Maritime Belge*, cited above, that the special responsibility of a dominant undertaking is particularly onerous where it is a case of a quasi-monopolist enjoying "dominance approaching monopoly", "superdominance" or "overwhelming dominance verging on monopoly" [2000] ECR I-1365 at paragraphs 132 and 137. In our view, Napp's high and persistent market shares put Napp into the category of "dominance approaching monopoly" – i.e. superdominance – and the issue of abuse in this case has to be addressed in that specific context.

220. As far as the history of the matter is concerned, there now seems little dispute. From the launch of MST in 1980, until Farmitalia entered the market in 1991, Napp's prices to hospitals were discounted only slightly from Napp's standard NHS list price. When Farmitalia, and later BIL, offered discounts to hospitals, Napp matched those prices. It appears that, after the (re)launch of

Oramorph in 1994, BIL offered higher discounts to hospitals, which Napp matched. Each time BIL came back with a higher discount, Napp matched again. As a result, by 1996 Napp's discounts to hospitals were some [...] [in excess of 90] per cent if Napp was the sole supplier. For the purposes of this judgment we are prepared to assume that the policy of offering higher discounts to hospitals was originally initiated by BIL. Similarly, it is unnecessary for us to make any finding on whether there were occasions on which Napp undercut BIL. For the purposes of this judgment, it is sufficient to find that Napp pursued a policy of matching BIL's prices.

221. By at the latest 1998 (or 1996 as contended by the Director) it is common ground that, on four strengths of tablets, 10mg, 30mg, 60mg and 100mg, Napp's prices were below the direct cost to Napp, i.e. materials and labour. According to Table 5 of the Decision, during the period of the infringement the average prices and average direct costs of these tablets were:

	Average direct costs (£ per pack of 60)	**Average hospital price (£ per pack of 60)**
10mg		
30mg	...	...
60mg		
100mg		

222. As stated in paragraph 191 of the Decision, in many instances during the period of infringement the actual price offered to hospitals on those four strengths was even further below the average direct cost, as the following figures show.

	Average direct costs (£ per pack of 60)	**Typical actual hospital prices (£ per pack of 60)**
10mg		
30mg	...	...
60mg		
100mg		

223. According to Annex 4 of the Defence, which has not been contested, these lower prices, representing a discount of some [...] [in excess of 90] per cent, applied during the period of the infringement in 11 out of the 17 contracting regions there shown. Napp has not contested the

statement, at paragraph 191 of the Decision, that such prices are well below direct costs, by up to [...] [in between 30 to 50] per cent, and do not even cover raw material costs.

224. The above prices below direct costs are offered by Napp on strengths where Napp has faced competition, initially from BIL. The suggestion, at paragraph 146 of the Decision, that the price of the 5mg tablet has been above direct cost but below total delivered cost has not been pursued before us so we do not deal with it. As regards the other two strengths, 15mg and 200mg, it is not suggested by the Director that prices have fallen below costs. The strengths offered by Link, who entered the market in 1997, are 10mg, 30mg, 60mg, 100mg and 200mg, with the 10mg and 30mg being the largest selling lines.

225. On the uncontested facts the situation that presents itself in this case is therefore that of a virtual monopolist that has been selling at prices well below direct cost, and doing so selectively on those tablet strengths where it has faced competition (with the apparent exception of the 200mg tablet where Link has a competing product).

226. At paragraph 71 of *AKZO*, cited above, the Court of Justice said:

> "[71] Prices below average variable costs (that is to say, those which vary depending on the quantities produced) by means of which a dominant undertaking seeks to eliminate a competitor must be regarded as abusive. A dominant undertaking has no interest in applying such prices except that of eliminating competitors so as to enable it subsequently to raise its prices by taking advantage of its monopolistic position, since each sale generates a loss, namely the total amount of the fixed costs (that is to say, those which remain constant regardless of the quantities produced) and, at least, part of the variable costs relating to the unit produced."

227. The Court of Justice subsequently held in *Tetra Pak II*, cited above, at paragraphs 41 and 42:

> "Prices below average variable costs must always be considered abusive. In such a case, there is no conceivable economic purpose other than the elimination of a competitor, since each item produced and sold entails a loss for the undertaking.
>
> ...
>
> For sales of non-aseptic cartons in Italy between 1976 and 1981 ... prices were considerably lower than average variable costs. Proof of intention to eliminate competitors was therefore not necessary."

228. On the basis of *AKZO* and *Tetra Pak II*, and having regard to our duty under section 60(2) of the Act to secure, so far as compatible with Part I of the Act, that there is no inconsistency between the principles we apply and the principles laid down by the Court of Justice, in our judgment it follows,

on the foregoing facts alone, that Napp has abused its dominant position in offering prices below average variable costs to hospitals contrary to the Chapter II prohibition, as the Director found in the Decision, without it being necessary to find that Napp had a specific intention to eliminate competition. In view of the fact that the *AKZO* approach was laid down in a case where the dominant undertaking had only 50 per cent of the market, it seems to us that it is only in the most exceptional of circumstances that a similar approach should not be applied in cases of "superdominance" where the undertaking concerned has around 95 per cent of the market.

229. It is true, however, that in paragraph 127 of his opinion in *Compagnie Maritime Belge*, Advocate General Fennelly stated that while sales below average variable costs (for which in this case direct costs are considered to be a proxy) are "in effect presumed to be abusive", he went on to say that "a dominant firm, would be permitted to rebut this presumption by showing that such pricing was not part of a plan to eliminate its competitor". In view of the remarks at paragraphs 132 and 137 of his opinion, we doubt whether Mr Fennelly would necessarily have taken the same approach on this point had he been considering a case, such as the present, of a virtual monopolist selling well below direct costs. Nonetheless, as a precaution we consider in this judgment whether it is shown that Napp had no plan or intention to eliminate competition, so as to bring itself within the exception to the *AKZO* test envisaged by Mr Fennelly.

230. In that connection we begin by considering Napp's fundamental argument that the *AKZO* and *Tetra Pak II* approach is not the right starting point in this case because, properly understood, Napp's hospital sales did not "generate a loss" because of the "follow-on effects". That issue has to be considered also in the light of *Compagnie Maritime Belge* and *Irish Sugar*, cited above, which show that even if the prices of a dominant firm remain above costs, and simply match the price of a competitor, there may still be an abuse, at least where a superdominant firm is concerned, if the reduced prices in question are made on a selective basis and have no economic rationale other than the elimination of competition.

Napp's "net revenue" defence

231. Napp's core argument, shortly stated, is that its hospital sales have in fact always been profitable when one takes account of the 'net revenue' resulting from both the sale in the hospital and the 'follow-on' sales in the community to which the hospital sales give rise. This 'linkage' says Napp, is equally available to its competitors.

Clarification of terms

232. Some confusion has arisen in this case as a result of the varied use of terminology, principally by Napp, in such expressions as "follow on effect", "follow on units", "follow on benefits", "linked sales", "linkages", "hospital influence", "referral business" and "reputational links". We therefore begin by attempting to clarify the meanings of these terms. In our view it comes down to two rather different concepts which can be best expressed under two headings, namely the 'narrow follow-on effect' alleged by Napp, and 'hospital influence' respectively.

— *The narrow follow-on effect alleged by Napp*

233. As appears from paragraphs 148 and 149 of the Decision, Napp's case before the Director was that the Internet Survey (document A18) showed that on average in about 15 per cent of cases the brand of oral sustained release morphine prescribed by the GP in the community is determined by the hospital doctor's choice of brand. Using a multiplier of 9 (since the community sector is 9 times the size of the hospital sector), Napp concluded that each sale in the hospital would lead to the sale of 1.35 'follow-on' units in the community segment. On the basis of the various calculations carried out by Napp's economic consultants, Nera (document A29), Napp then argued that its hospital sales were profitable if one took into account this 'follow-on effect'. In other words, if one took the net revenue, from both the hospital sale and the 'follow-on' community sale combined, Napp was making a profit overall. Napp described this 'follow-on' effect as 'largely mechanistic' (see e.g. paragraph 34 of Napp's outline notes of oral submissions on the second Rule 14 notice). Napp distinguished this 'mechanistic' follow-on effect from the more broadly based and largely unquantifiable 'reputational links', which occur when the use of a particular brand of oral sustained release morphine in a hospital tends to establish that brand in the minds of GPs. The 'follow-on effect' thus relied on by Napp seems to have been understood by the Director as referring to a situation where a patient has been initiated on a particular brand in the hospital (i.e. there has been a supply in the hospital), and the GP then repeats the prescription when the same patient comes out of the hospital: see footnote 67 to paragraph 111 of the Decision.

234. As far as we can see, references in the Decision (e.g. in paragraphs 111, 150, 152 to 155, 157 and 158, 160, 165, and 166) to a "follow-on effect" are references to a follow-on effect in this narrow sense. However, Napp in argument has often used the expressions 'follow-on effect' or 'follow-on

linkages' or simply 'linkages' in a wider sense that in our view approximates more to the broader notion of 'hospital influence'.

— *Hospital influence*

235. In the course of this appeal, it has become apparent that the term 'follow-on effect' is not one that is in fact used by Napp or its competitors, but appears to have been coined by Napp's advisers for the purposes of this case.

236. Mr Brogden, the managing director of Napp Pharmaceuticals Limited and a businessman with long experience, told us that he had first come across the expression 'follow-on effect' when reading the papers for this case (Day 1, p.38). What Mr Brogden told us about was "hospital influence", or in his words "what I refer to as the hospital influence, what is now described as the follow-on business" (Day 1, p.48).

237. As we understand it, "hospital influence" is a phrase used in the pharmaceutical industry to describe the whole range of ways in which the fact that a drug is used in hospitals may affect the prescribing habits of GPs. This will include, in particular, what Mr Brogden referred to in a memo of 20 June 1994 as "referral" business, which is where a hospital doctor writes a referral letter recommending to the GP that the patient be prescribed a particular brand of drug. When such a referral letter is written, it may or may not be the case that the patient has been initiated onto the drug in the hospital. However, whether or not the patient has actually been prescribed the drug in hospital, the fact that the hospital stocks a particular drug will strongly influence the content of such referrals. More generally, the fact that a branded drug is used in hospitals will positively influence GPs to prescribe that brand.

238. In this judgment we use the phrase 'hospital influence' to include all the ways in which hospitals influence GPs' prescribing habits, including those cases where a patient is initiated in hospital and then returns to the community (the narrow follow-on effect), or the hospital specialist writes a referral letter, or use in hospitals enhances the reputation of the brand, or the hospital serves as a focus for disseminating information about the brand among GPs, pharmacists or nurses in the community. As we have said, when Napp has referred to "linkages" or "follow-on linkages", it has often seemed to us that Napp is really referring to "hospital influence" in this wide sense.

The follow-on effect as alleged by Napp

239. Dealing first with the follow-on effect in the narrow sense alleged by Napp, the Director, at paragraph 150 of the Decision, accepted "that there is a follow on effect between hospital and community sales and [that] Napp's figure of 15 per cent may serve as a crude estimate of this effect at a national level and over time", although he did not accept that such follow-on effect was mechanistic, or that it was equally available to Napp's competitors (paragraphs 152 to 159).

240. The Director, however, pointed out, in the defence, that closer analysis of the Internet Survey shows that the 15 per cent figure relied on by Napp for its "follow-on effect" comprised *both* cases where the hospital doctor wrote a prescription which was dispensed in the hospital, i.e. there was a *sale* in the hospital, and cases where the hospital doctor merely wrote a referral letter (e.g. after a patient had been referred to him for a consultation) recommending that the GP put the patient on to a particular brand of oral sustained release morphine but without writing a prescription which was dispensed in the hospital. Hence, argued the Director in the Defence, one could not use the figure of 15 per cent for working out a 'follow-on' ratio between *sales* to hospitals and *sales* to the community because the 15 per cent did not relate to *sales* in hospitals. He also challenged the 15 per cent figure on the ground that patients who had been initiated in hospital (e.g. cancer patients) would on average be treated in the community for a shorter time than other (non-cancer patients) initiated by their GP. For this reason also the 1:1.35 follow-on ratio could not be relied on.

241. These points have caused difficulty, first because neither point is taken in the Decision and, secondly, because, when the Director accepted the figure of 15 per cent at paragraph 150 of the Decision, he did not make clear that he did so on the basis that that figure includes both cases where a patient is actually supplied with MST by the hospital, *and* cases where the hospital doctor simply writes a referral letter without a supply in the hospital. The definition of 'follow-on effect', in footnote 67 of the Decision, would not appear to include the latter case.

242. Having examined the underlying material, it does appear to us from the Internet Survey (document A18) and the Nera reports (documents A19, A29 and A107) that the Director is right in his contention that the figure of 15 per cent is based on the question in that Survey "What proportion of your sustained release patients were initiated by you versus initiated by hospital/ recommendation?". In other words, that question refers *both* to cases where the patient is initiated

in hospital (i.e. there is a hospital sale), and where there is merely a hospital recommendation (but not necessarily a hospital sale). In Nera's report of 16 October 2000 (A19) Nera makes it clear that they are referring to "approximately 14.6 per cent of patients [who] consume a brand of SRM *heavily influenced* by the brand chosen originally by the hospital doctor ("follow-on linkages") (p.1), by reference to "a branded prescription *or referral letter*" (p.4) [emphasis added by the Tribunal].

243. We have no evidence as to what extent hospital doctors write referral letters recommending MST or issue prescriptions in circumstances where the patient is not supplied with MST by the hospital itself. In the absence of such evidence, it is difficult to rely on the Internet Survey as support for the proposition that, for every 1 unit *sold* in a hospital there is a "follow-on" sale in the narrow sense of 1.35 units *sold* in the community, because the 15 per cent figure includes cases where there is no *sale* in the hospital.

244. Similarly, it would seem to us over simplistic to use a multiplier of 9 to arrive at the ratio of 1:1.35, since a certain proportion of sales in a hospital (or hospice) will be to patients who do not return to the community, or who do so only for a relatively short time. Since we were told that hospitals themselves stock relatively small amounts of morphine, and that a hospital's individual purchases are small, it could turn out that any follow-on effect in the narrow sense alleged by Napp is rather small, but we simply have insufficient evidence about it. Napp's argument that the GP may, in any event, switch the patient from the brand prescribed in the hospital to his own preferred brand, supports the further conclusion that any such follow-on effect is not "mechanistic".

245. For these reasons we do not think it can be assumed that there is a follow-on effect of a narrow or mechanistic kind at a ratio of 1:1.35 as suggested by Napp.

246. However, the fact that we have examined these new points not made in the Decision does not in our view lead to procedural complications because the Director accepted in argument that in view of Nera's figures, only a relatively small follow-on effect in the narrow sense alleged by Napp would be sufficient to cover at least Napp's average variable costs. As we understood it, the Director was prepared to accept that on average, over time across the country, Napp's hospital business would be incrementally profitable, were it permissible to look at hospital and community sales together. Napp contends that this concession is sufficient for the purposes of its argument.

247. However, we have concluded that any such "incremental profitability" flowing from a follow-on effect in the narrow sense alleged by Napp, does not assist Napp's case.

248. In the first place, there is simply no evidence that Napp ever took into account any follow-on effect when setting or carrying out its pricing policy.

249. Thus, when replying to enquiries from the OFT in his letter dated 24 September 1999 to the Director, Mr Brogden said "Our experience over the last decade has shown that there is little correlation between discounting in hospitals and sales of MST in the Community" (OFT 1, p.38). That reply does not suggest that Napp was in fact taking into account, in setting its prices, what it later submitted to the Director was a 'mechanistic' follow-on effect since any such effect is effectively denied by Mr Brogden in that letter. Moreover that letter contains no reference to any 'follow-on' effect at all, in circumstances where it would be an obvious point to make in explanation of the rationale for Napp's pricing policy. Mr Brogden was not able satisfactorily to explain to us why no follow-on effect had not been mentioned in that letter, and we did not find his reference, in the witness box, to annex 3 of the same letter, to be persuasive: the whole thrust of the letter to the Director of 24 September 1999 was that there was no reliable or mechanistic follow-on effect.

250. By letter of 15 June 2001, following certain allegations by Napp in the notice of appeal as to how it set its prices to hospitals, the Director requested Napp to produce any documents which showed what factors Napp took into account in setting its prices for MST to the hospital sector (specifically in relation to certain particular contracts awarded in 1999 and 2000). Napp replied by letter of 4 July 2001 stating that

> "it had not located any documents which discussed follow on linkages and which suggested that on their face or from their context that such linkages are or should be taken into account in setting hospital tender prices."

Contrary to Napp's suggestion in argument, we do not find that the documents enclosed with that letter give rise to any inference that, in setting its tender prices, Napp took account of a follow-on effect in the narrow sense alleged by Napp.

251. When a dominant undertaking selling below cost contends that its policy is not motivated by an intention to eliminate competition but is based on some other, legitimate, commercial rationale, the best way for that undertaking to defend itself is by producing contemporary internal documents

showing that such a rationale did in fact form the basis of the company's policy at the material time. In the present case, Napp did not choose to do so, either in answer to the allegations made by the Director, or in the notice of appeal.

252. Even in reply to the Tribunal's request dated 31 August 2001 (see paragraphs 81 and 82 above), Napp has been unable to produce any document referring to or explaining the rationale for its hospital pricing policy for the period of four years from 1997 to the date of the Decision in March 2001. That period includes the period when, according to Napp, its prices to hospitals first went below direct costs, as well as the whole period of the infringement. Napp does not strike us as a naive or badly managed company. If its pricing policy had in fact been seen by Napp in the way that its economic consultants suggest, we would have expected the company's internal documents to demonstrate that.

253. As regards the documents which Napp did produce in reply to the Tribunal's request, relating to the period prior to 1997, those documents do not show that Napp ever took into account during that period the narrow follow-on effect which Napp now alleges: see paragraphs 315 et seq below.

254. While expert's reports are often relevant and helpful to understanding the issues with which this Tribunal has to deal, we find in this case that the idea of a 'follow-on' effect in the narrow or mechanistic sense relied on by Napp flows not from any internal documents from Napp but from the work done by Napp's economic advisers for the purposes of the present case. In our view such work does not carry matters any further forward in the absence of any evidence that Napp in fact took the theory upon which it is based into account in setting its prices: see *Tetra Pak II*, in the judgment of the Court of First instance, [1994] ECR II at p. 843.

255. In our view, what Napp was well aware of was not any follow-on effect in the narrow sense, but the strategic importance of hospital business, and the hospital influence thereby acquired, as the gateway to the community segment. Thus when Mr Brogden told us that Napp believed its hospital sales were profitable as a result of unquantifiable "follow-on business", what in our view he really meant was that the loss-making hospital business was still worthwhile for Napp if one took into account all the possible ways, notably referral letters, in which the influence of the hospital could lead on to sales in the community. In our judgment, for Mr Brogden, the "follow-on effect" was really the general and unquantified advantage to Napp of retaining for itself such "hospital influence", notably as a means of protecting its market share in the community segment.

256. In our judgment, that is confirmed by the documents disclosed in answer to the Tribunal's request of 31 August 2001, which we discuss at paragraphs 315 et seq below, and by the references to links between the hospital and community segments that could benefit Zomorph, to be found in the documents disclosed in answer to the Director's letter of 15 June 2001.

257. Moreover, in our judgment the 'net revenue' defence advanced by Napp, whether on the basis of the 'linkages' which may result from hospital influence, or on the basis of some narrow follow-on effect, is in any event conceptually and factually wholly misconceived, for the reasons we now give.

Conceptual problems with Napp's net revenue test

258. In our view, Napp's net revenue argument, whether based on the narrow "follow-on effects" alleged by Napp, or on the "linkages" resulting from hospital influence, has at least three conceptual weaknesses, taking into account the particular circumstances of the present case.

259. The first conceptual weakness is that the net revenue test, as applied simplistically by Napp, provides no yardstick for distinguishing between what is legitimate, and what is abusive, behaviour on the part of a dominant undertaking. For instance, a monopolist driving away new entrants by predatory pricing is likely to maximise his net revenue by so doing, for example by avoiding loss of market share and erosion of prices in the profitable market where he holds a monopoly. Yet plainly such behaviour does not cease to be abusive merely because it is profitable for the monopolist to engage in it. In our judgment, therefore, a "net revenue approach" cannot, standing alone, constitute a defence to a charge of abuse by a dominant undertaking, unless it is accompanied by clear evidence that there was no intention or effect of foreclosing the market and impairing competition.

260. This point may be illustrated by the circumstances of the present case. In this case (i) Napp is a virtual monopolist with a market share of 93 per cent in the hospital segment; (ii) the hospital segment is a key gateway to the community segment; and (iii) Napp is also a virtual monopolist in the community segment with a market share of 96 per cent. Let it be assumed, in Napp's favour, that there is some sense in which its loss-making hospital sales can be considered to be profitable for Napp if one takes into account the revenue from sales in the community segment which follow from hospital influence, for example, referral letters written by hospital doctors to GPs. However,

if those loss-making hospital sales also have the effect of excluding competitors, the very conduct which is profitable to Napp on a net revenue basis has at the same time the effect of eliminating competition. That in turn, protects Napp's revenues in the community segment. To then argue that the below-cost pricing in the hospital segment is justified by the revenues from the community segment is the equivalent of saying that anti-competitive behaviour which protects Napp's virtual monopoly can be justified on the basis of the profits made from the monopoly which the anti-competitive behaviour is designed to protect. The argument is circular, as the Director points out at paragraphs 151 and 195 of the Decision.

261. To put the point another way, in most cases of predatory pricing, the predator is willing to forego short-term profits, in the hope of recouping its losses on subsequent, more profitable, sales. In some cases the recoupment may take the form of raising prices again once a competitor is eliminated; in other cases it may simply be that it is well worth the cost of short-term losses in order to protect the profits that flow from a large market share. As the Director submitted in the present case, the fact that Napp's below-cost pricing in the hospital sector enables it to make money from 'follow-on' sales in the community sector merely signifies that the particular form of 'recoupment' available to Napp is more direct and more immediate than it is in other cases of predatory pricing.

262. For these reasons it seems to us that Napp's "net revenue approach" cannot displace the *AKZO* test as the correct starting point for the analysis of the abuse here in question. At best arguments based on a 'net revenue test' *may* be relevant to show that the dominant undertaking had "no plan to eliminate competition" so as to fall within the exception to the *AKZO* test recognised by Advocate General Fennelly, but not otherwise.

263. The second conceptual weakness in Napp's argument is its contention that hospital and community prices are 'system prices'. In our view that argument depends on establishing that what is being sold to the buyer is indeed a 'system', as might, at least theoretically, be the case of the sale of razors and razor blades, or photocopiers and toner cartridges. However, as *Canon KK v Green Cartridge Co* [1997] AC 728 (HL) makes clear, an essential aspect of the legitimate use of system pricing is that the buyer is in a position to evaluate the life-time, or system-wide costs, and so make a rational choice between competing possibilities (see the speech of Lord Hoffmann at pages 737 to 738). Here, that is not the case. During the period of infringement in this case, there were two separate groups of buyers, the hospital authorities, and the GPs respectively, rather than a single

buyer. Neither group of buyers was motivated to any significant extent to take account of the cost implications, for the other group, of his decisions, or had the information to do so rationally. In this case, it seems to us, what Napp has done is exploit not the connection, but the *disconnection* between purchasing decisions taken by the different component parts of the NHS, thereby maintaining widely different prices to the different purchasers concerned. That, in our view, is the exact opposite of "system pricing" as it is properly understood.

264. Even if, in the future, the activities of PCGs/PCTs may begin to alleviate the lack of any connection between the different NHS purchasing decisions with which we are concerned in the present case, it seems to us, on the evidence, that it may be some time before the prescribing decisions of individual GPs, and the purchasing decisions of hospital authorities, can sensibly be described as forming part of a "single system". They certainly did not do so during the period of infringement: see paragraphs 301 et seq below.

265. The third conceptual weakness in Napp's argument based on "follow-on effects" or "linkages", is that it presents only a small part of the total picture which needs to be examined. For the reasons already given, one cannot simply arrive at the conclusion that Napp's pricing to hospitals is in some sense "incrementally profitable", and stop there as if that shows conclusively that there is no abuse. First, in order to rebut the *AKZO* presumption, it is necessary to examine the market circumstances, in order to show that the pricing below average variable costs in question does not have the object or effect of eliminating competition. Secondly, as *Tetra Pak II*, *Compagnie Maritime Belge* and *Irish Sugar* show, the exact scope of the "special responsibility" of a dominant or superdominant undertaking has to be determined in the particular circumstances of each case. In our view, in the light of that case law, one cannot conclude that the Chapter II prohibition is not infringed merely on the basis of some kind of 'incremental profitability' without examining the effect of Napp's conduct on competition, how far Napp enjoys advantages over its competitors, and the evidence as to Napp's intentions. Napp's 'net revenue' approach does not address any of those matters.

266. The three conceptual weaknesses identified above lead us to the conclusion that Napp's net revenue approach in this case is wholly insufficient, in itself, to rebut the *AKZO* presumption that Napp's hospital prices below direct costs are abusive. That conclusion is reinforced by considering the specific market circumstances of this case from the point of view of the effect of Napp's

hospital pricing policy on competition, the alleged 'asymmetry' between Napp and its competitors, and finally, Napp's intentions. To those matters we now turn.

The effect of Napp's hospital pricing policy on competition

267. We accept, first, the Director's findings, at paragraphs 111 to 113, and 162 to 164 of the Decision, that hospitals play a central role in facilitating entry to the relevant market and represent a key strategic entry point for new competitors. The reason is that there are high barriers to entry to the community segment of the market, but much lower barriers to entry in the hospital segment.

268. The barriers to entry to the community segment are explained at paragraphs 104 to 113 of the Decision, which Napp has not seriously disputed (see paragraph 30 above). In brief, those barriers arise because Napp continues to have a high reputation among GPs. That reputation is a particularly strong influence in respect of products such as strong opioids, which are controlled drugs, where GPs are risk averse and reluctant to experiment with new products of which they have no direct experience. In addition – and subject to the effect of PCGs/PCTs which are not material for present purposes (see paragraphs 305 and 306 below) – GPs are not price sensitive and do not, individually, use morphine in large quantities. Promotional effects direct to individual GPs are likely to entail high sunk costs with little prospect of success, at least without the backing of hospital influence.

269. On the other hand, hospital purchasers are price sensitive, and much more willing to assess the relative efficiency of different brands and new products. As the Decision indicates, once the hospital agrees to purchase a particular brand, the supplier stands a chance of entering the community market. That is so first, because where a GP continues the patient on the brand on which he was initiated in hospital, he gains first-hand experience of the product. Secondly, hospital doctors may recommend a particular brand in their referral letters because they have become familiar with it in hospital. Thirdly, the fact that a brand is used in the hospital represents an independent endorsement of the brand, and influences GP prescribing practices (paragraphs 111 and 112, and 162 to 164 of the Decision). Link's evidence now adds a fourth possibility, namely that, once a hospital contract is gained, hospital authorities may themselves be prepared to be used as a channel of communication to dispense information about a new product to GPs, nurses and pharmacists in the community.

270. The importance of hospital influence is confirmed by Mr Roger Penrose, of BIL, who stated in his witness statement dated 12 July 2001 that:

> "The overall strategic importance of obtaining hospital usage was obvious, and was commonly accepted in the industry. It meant that the key pain management specialists (clinicians and nurses) would be endorsing our product in particular whenever clinicians referred out patients by brand, or specialist nurses, in constant contact with hospital practices, gave prescribing advice to GPs this could potentially have a major influence on the GPs prescribing habits." (paragraph 34)

271. Mr Mountain of Link put the matter even more forcefully when he explained in his letter of 3 November 2000 (OFT III, p. 1338) to the OFT, that

> "The reality is that hospital influence on the community prescribing is incredibly strong"

and that

> "the influence of the hospital in this market is profound".

Among the reasons Mr Mountain gives are that palliative care teams working in the community have been trained in hospitals, GPs invariably follow the hospitals' advice in referral letters, and GPs will be anxious to secure consistency of treatment as between primary and secondary care.

272. According to the witness statement of Mr Hartley of Link:

> "Link depends entirely on achieving a successful 'conversion' of a hospital to Zomorph as the basis for establishing a reputation and sales in the surrounding community segment of the market. This can only really be appreciated when one considers the way in which we inform GPs and retail pharmacists about our product." (paragraph 28)

Mr Hartley goes on to explain that Link's strategy is first of all to secure a hospital contract. Once that contract has been won, Link does not market directly in the community segment but seeks to persuade the hospital authorities to inform GPs, retail pharmacists and others that the switch to Zomorph has taken place, explaining the advantages, and if possible recommending that it should be prescribed as "Zomorph capsules". In addition Link's team spends time at the hospitals carrying out training for the personnel who will be using Zomorph on a day-to-day basis.

273. The evidence before us is that hospitals are the key, and indeed the only, viable point of entry from which a new competitor may aspire to penetrate the community segment because of the strength of the barriers to entry already mentioned. In our view, in this particular market, attempts to sell sustained release morphine direct to GPs without a significant hospital presence are likely to be

expensive and fruitless, and we reject any suggestion by Napp to the contrary. We have no reason to doubt the statement of Mr Mountain in his letter to the OFT of 3 November 2000 where he said, with reference to hospitals,

"There is only one way into this market and Napp have the key to the gate"

274. In addition, although a significant presence in the hospital segment is a *necessary* condition for subsequently being able to penetrate the community segment, the evidence is that a hospital presence is not, in itself, *sufficient*. The experience of BIL was that, for whatever reason, a certain presence in the hospital segment did not, in fact, lead on to a significant market share in the community. We accept Mr Hartley's evidence, referred to above, that if and when Link gains a hospital contract, it is necessary to invest considerable further promotional effort in training the staff in its correct usage of the drug, in educating hospital consultants to specify Zomorph or slow release morphine capsules (as distinct from tablets) in referral letters, and in persuading the hospital authorities to inform GPs, nurses and pharmacists in the community about Zomorph as an alternative to MST. Napp itself accepts, in its skeleton argument, that such efforts will be necessary. In addition, switching costs for busy GPs, including the additional costs of learning new titrations, are likely, in our view, to add to the difficulties of entering the community segment.

275. Against that background, we accept the Director's argument that Napp's policy of matching competitors' prices in the hospital segment significantly hinders competition by adding an additional, strategic, barrier to the already high barriers to entry.

276. First, Napp does not dispute that it is impossible for another supplier to sell into hospitals unless they match the price of MST. Since Napp's prices are below, and in many cases, well below, direct costs on those tablet strengths where it faces competition, Napp's policy constrains its competitors to suffer substantial losses on their sales to hospitals. Mr Hartley's evidence is to the effect that Link has been making losses on Zomorph since it entered the market in 1997, as stated in paragraph 179 of the Decision. In our view, that evidence has not been effectively challenged, and we accept it.

277. The fact of having to match Napp's prices at below direct cost, probably for a long period, is likely to be a deterrent to a would-be entrant, or to be a reason for a new entrant to decide, after a period, to withdraw. At best Napp's policy of selling at below direct cost constitutes a substantial

additional hurdle to be overcome by a new entrant, who already faces the development and promotional costs associated with launching a new product, as well as the need to overcome Napp's strong first mover advantages, and the other barriers to entry we have already mentioned.

278. In addition we accept that the hospital faces substantial switching costs in moving away from MST. It is necessary to train doctors and nurses to administer the new drug and about its properties, as well as adapting the hospital computer systems. Mr Brogden in his oral evidence accepted that there is a substantial "hassle factor" involved in any change which is likely to favour the incumbent supplier, (Day 1, pp.44 and 45).

279. Moreover, even if another supplier matches the price of MST, in many cases the hospital has little incentive to switch its business to that supplier at all, because the value of the total annual purchases of slow release morphine by an individual hospital are now so small that it is hardly worth while doing so. On this point, Mr Hartley states at paragraph 44 of his witness statement:

> "The unique barrier that we face as a company trying to become known in this market place is Napp's practice of offering extreme discounts to hospitals making their product almost free. At the levels of discount in question the average hospital spend on MST tablets comes to something under £500 a year."

280. Even if a competitor were to undercut Napp's extremely low prices, and virtually give its products away, the savings to a hospital are now so small that the hospital would still have little incentive to switch. As Mr Hartley points out, the level of cost saving that Link is able to offer hospitals resulting from a switch to Zomorph is almost negligible, and has to be weighed against the significant switching costs they would have to bear. Mr Brogden's e-mail of 10 June 1996 makes the same point: "the total value of the purchases by an individual hospital are now so small as to largely negate any desire or reason for a hospital to move away from MST CONTINUS". This factor of "switching costs" (mentioned at paragraph 158 of the Decision) means that even if a new entrant is prepared to match or indeed undercut Napp's prices and sustain prolonged losses in the hospital segment for a substantial period, entry to the market is effectively blocked because Napp's policy of pricing below direct cost deprives the hospital of any incentive to switch.

281. Since the hospital segment is virtually the only point of entry into the community segment, it also follows that Napp's policy of pricing below direct cost has tended to foreclose not only the hospital segment, but also the possibility of new entry into the community segment as well. As the Director says at paragraph 166 of the Decision, the direct extent of that foreclosure can be measured by

adding Napp's share of the hospital segment to that part of the community segment which is directly foreclosed by the follow-on effect of hospital prescriptions (or referral letters) which directly refer to MST. That alone gives a direct foreclosure of some 24 to 27 per cent of the relevant market (paragraphs 160 and 167 of the Decision).

282. It is true that a substantial proportion of patients are prescribed MST by their GP without the intervention of the hospital doctor. It is also true that paragraph 167 of the Decision gives the impression that the Director considered that up to 40 per cent of the relevant market was foreclosed taking into account the "reputation effect". Nonetheless it seems to us that the Director is correct in saying, at paragraph 251 of the Decision, that the effect of Napp's pricing policy has been indirectly to impair competition in the whole of the relevant market. In our judgment, had it not been for Napp's low prices to hospitals other competitors would have gained hospital contracts from which they could have been expected to succeed, over time, in penetrating the community segment of the market, as a result of the "hospital influence" thereby acquired. Once such penetration began to be achieved, we see no reason why the availability of an alternative, cheaper, product to MST should not progressively have come to the attention of GPs, including those GPs who were accustomed to initiate patients without the intervention of a hospital doctor.

283. The point here is not simply that the use of a new brand of sustained release morphine in hospitals is likely to enhance the product's general reputation which, as Dr Forster accepts (A26, at paragraph 26), is more likely to be the case with new drugs. The point is that entry into the hospital segment gives a new competitor access to the only effective means of penetrating the community segment, at least initially, through hospital prescriptions repeated in the community, referral letters, and the dissemination of information by the hospital authorities, as well as general reputational effects. Napp has denied these possibilities to competitors by means of its hospital pricing policy. In those circumstances Napp can, in our judgment, fairly be said to have effectively, albeit indirectly or potentially, foreclosed the community segment of the market as a whole by blocking, to a substantial extent, the only viable point of entry.

284. We do not need to make a specific finding as to why BIL left the market, having decided to do so in February 2000 just before the Act came into force. It is sufficient to note that, during the period of infringement, and 20 years on since the launch of MST, Napp has continued to have 93 per cent of the hospital segment. There is only one other competitor, Link. Link, we were told at the hearing has, after some four years of effort, obtained some 22 hospital contracts out of a potential

of about 400. Although Link's share of the hospital segment has grown since the Director's investigation started from 1.7 per cent in 1999 to 4.3 per cent in 2000 and 7.3 per cent in the first quarter of 2001, that is no doubt partly due to BIL's departure. We regard Link's position as little more than a toehold – acquired at considerable loss over several years – in the face of Napp's share of 93 per cent in that segment. Link's share of the total market (hospital and community segments together) was just under 4 per cent by the first quarter of 2001, while Napp still had over 95 per cent of the total.

285. Neither the fact that Link has remained in the market, nor that there is, apparently, at least one confirmed new entrant in the foreseeable future (and perhaps other possibilities) mean that the barriers to entry and hindrance to competition faced by actual or potential competitors to Napp during the period of infringement were not substantially greater than they would have been but for Napp's policy of pricing below direct costs. In any event, it is unnecessary to wait until competition has actually been eliminated in order to establish an abuse: see *Tetra Pak II* at paragraph 44 of the judgment of the Court of Justice.

286. In a situation where the barriers to entry protecting an incumbent monopolist are already high, even a modest raising of further barriers by the pricing actions of that monopolist is potentially a serious matter. In this case, it seems to us that the effect of Napp's pricing policy in hindering competition has been significant. We accept the Director's view, expressed at paragraph 159 of the Decision, that it is not normal for a mature product such as MST to have actually increased its share of the hospital segment from 80 per cent in 1997 to 93 per cent in 2000. Even during the period of infringement, Napp increased its market share in the hospital segment from 91.9 per cent to 92.7 per cent.

287. More generally, it seems to us that the Director was right to conclude, at paragraphs 159 and 172 of the Decision, that it is not normal for pioneer brands to retain such a high market share, in either the hospital or community segment, for so long after patent expiry. The table presented by the Director at Annex 7 of the defence, by way of correction to Table 3.1 to Nera's Report of 29 May 2001, *Napp: Analysis of OFT Decision on Excess Pricing for MST* (A 106), shows, in general, substantial falls in market share following the expiry of a patent, often within two years of generic entry, although admittedly there is one unexplained exception shown in that table. Similarly, in the light of the comments made by the Director at Annex 8 of the defence, it does not seem to us that Napp's paper *Evidence on Other Therapeutic Markets* (A 112) establishes that it is normal for a

pharmaceutical product coming out of patent to maintain both its existing price *and* a virtual monopoly market share for prolonged periods. On the contrary, in our view, after patent expiry, one would normally expect some fall in price, or market share, or both, as competitive forces come to bear on the previously patented product. In the present case, that has not happened, *either* to Napp's prices, *or* to its market share, in the community segment. It has not happened to Napp's market share in the hospital segment. Even allowing for the fact that in this case Napp's actual or potential competitors represent branded, rather than generic, entry, in our judgment the overwhelming inference from the totality of the evidence is that Napp's prices in the community segment, and its market shares in both the hospital and community segments, have been protected, at least in part, by the foreclosure effects of Napp's hospital discount policy. Nor do we doubt that that was Napp's intention: see paragraphs 307 et seq below.

288. In our judgment the foregoing circumstances are very far removed from the matters considered in paragraphs 4.15 to 4.17 of OFT 414 *Assessment of Individual Agreements and Conduct*. It is true that those paragraphs can be read as suggesting that certain behaviour should not be regarded as predatory where a price cut is incrementally profitable to an undertaking on the basis of a net revenue test. We, for our part, accept that there may be some very limited circumstances in which a dominant undertaking could justify pricing below average variable costs for a short period on a net revenue basis (e.g. to expand the total market). However, it seems to us, for the conceptual and factual reasons we have already given, that any such "net revenue" approach cannot be applied where, as here, the result of the pricing conduct in question is to foreclose the market. In addition, in the present case, it is not in any realistic sense a question of Napp making significant *additional* sales – the classic justification for "loss leading" (see paragraph 194 of the Decision). The situation in the present case is that of a superdominant undertaking pricing selectively and below direct cost in order to *protect* a market share of 95 per cent from new entrants, and doing so as a long-term strategy rather than on a short-term basis. For those reasons we do not think that paragraphs 4.15 to 4.17 of OFT 414 have any relevance in the present case.

Asymmetry: Napp's advantages over its competitors

289. Napp, however, argues, that the 'linkages' between the hospital segment and the community segment which flow from hospital influence are equally available to its competitors. Since there is no reason why its competitors should not also compete on the basis that any losses in the hospital

segment can be made up on subsequent sales in the community segment, Napp submits that there was in fact a level playing field between itself and its competitors.

290. We accept that there is in a broad sense a potential "linkage" between the hospital and community segments in that, in general, "hospital influence" may lead on to sales in the community segment. We do not, however, accept that the existence of such a 'linkage', actual or potential, enables Napp's competitors to compete with Napp on equal terms. Nor, in our view, does the existence of such 'linkages' alter the fact that Napp's low hospital prices tend to eliminate, or at least significantly hinder, competition.

291. During the period of infringement the disparity between Napp's market share and that of its next largest competitor, Link, was 95:4 overall, 96:3 in the community segment and 93:7 in the hospital segment. Those figures do not support the argument that there was a level playing field.

292. The evidence of Nera which Napp has relied on before the Director and on this appeal does not support the argument that significant linkages are automatically available to new entrants. Thus, in Nera's Report of 26 October 2000 *Key Market Evidence in the Supply of Slow Release Morphine* (A19) it is stated at page 12 that:

> "[The data] shows that even where and when Zomorph succeeds in gaining access to hospitals, this has a minimal impact on its market penetration among GPs."

In relation to Oramorph the same report comments (p. 18):

> "there are only limited linkages between hospital and community sales of SRM. Most of the community market that is currently "captive" to MST cannot be won simply by winning some hospital contracts."

293. Mr Brogden in his letter dated 24 September 1999 to the Director, to which we have already referred, said "Our experience over the last decade has shown that there is little correlation between discounting in hospitals and sales of MST in the Community" (OFT 1, p.38). Again, that does not support Napp's subsequent argument that "linkages" are equally available to its competitors.

294. As regards Napp's suggestion that the low prices that BIL was prepared to tender for the regional hospital contracts indicate that BIL was competing for a profitable "package" which included "follow-on" sales in the community segment, Mr Penrose comments in his witness statement:

> "This is utterly mistaken. Where patients were prescribed Oramorph SR in the hospital, we made every effort to maximise the chances that patients would continue to be prescribed it subsequently in the community, but we could never be sure this would actually happen or to what extent. In many cases we found there was no significant follow-on effect."

295. As regards Link, Napp relies on a passage in Mr Mountain's letter of 3 November 2000, (paragraph 183 above) where he acknowledges that "Napp make money overall out of loss leading into hospital" Napp does not, however, quote Mr Mountain's last sentence in that passage:

> "This is why Napp aggressively defend the hospital business, and as a monopoly supplier why their pricing is predatory."

296. It is true that, according to Mr Mountain's letter, the ratio between Link's hospital sales and its community sales is 1:4. However, that figure simply states a fact, namely that Link has four times as many sales in the community segment as in the hospital segment. As Mr Hartley points out, Mr Mountain's letter does not mean that Link can or does operate on the basis that gaining a hospital contract will itself automatically produce consequential referral business in the surrounding community which is profitable when looked at as a package. He explains:

> "on the contrary it is only the application by Link of the various methods described above, which include, above all, harnessing the reputation of the hospital specialists and the PCG officials to communicate with GPs, nurses and retail pharmacists in the community that achieves vital sales growth" (paragraph 37).

297. In our view, the reality is that, in order to obtain any significant sales in the community, Link has to make very significant efforts and investment, (i) to gain a hospital contract in the first place, then (ii) to persuade hospital consultants to recommend Zomorph, and (iii) to persuade hospitals or PCGs/PCTs to inform GPs, pharmacists and community nurses about the product. What in our view Napp's hospital discounting policy does is to make it significantly more difficult for Link (a) to achieve step (i), and (b) to afford, or even justify, the investment necessary for steps (ii) and (iii).

298. In those circumstances, in our view, it is wholly artificial to argue that on quite small "linkages", Link's hospital sales can be incrementally profitable or that any such supposed 'incremental profitability' would be a sufficient basis on which competitors could sustain effective competition to Napp. Whatever the reason for BIL's withdrawal, the fact that they did withdraw provides no support for Napp's argument. The evidence is that Link's business has been loss-making since the

launch of Zomorph in 1997. It cannot be known how long Link could have stayed in the market had it not been for the present proceedings (and see paragraph 44 above).

299. Among the reasons why the potential availability of the "links" mentioned by Mr Mountain do not give rise to a level playing field are the following: (i) Napp has an established flow of profits from the community segment which can subsidise the losses on its hospital business, whereas a new entrant has to start from scratch without that advantage; (ii) Napp is in a position to impose its hospital prices on new entrants, thereby forcing them to incur losses on sales to hospitals over and above the normal costs of development and promotion associated with entering a new market; (iii) Napp as the incumbent supplier benefits from the existence of hospital switching costs which new entrants have to overcome; (iv) the low level of purchases by individual hospitals means that switching costs may prove an insuperable barrier to a new entrant; (v) with its established reputation Napp no longer has to incur additional costs of promotion in order to benefit from hospital influence in the community segment, whereas its rivals have to invest heavily; (vi) Napp has higher prices in the community segment than its rivals and thus can more easily recoup its losses in the hospital segment; (vii) any "linkage" is likely to be more reliable and predictable in the case of MST than other products because of Napp's established reputation; (viii) according to the Internet Survey, 30 per cent of patients with a hospital prescription or referral letter may be switched by their GP to another brand, which is most likely to be MST; (ix) where Napp has procured a sole contract, that will be an additional barrier to a new entrant; and (x) Napp has the benefit of its established position in the community segment in the large proportion of cases where a patient is initiated by a GP without the intervention of a hospital or a referral letter.

300. For these reasons, we reject Napp's argument that the 'linkages' upon which it relies are equally available to Napp's competitors. For the reasons already given at paragraphs 267 to 288 above, in our judgment the fact is that, whatever 'linkages' may exist, Napp's pricing policy to hospitals has succeeded over a significant period in hindering competition and raising barriers to entry to the significant disadvantage of its rivals.

The market since 1 March 2000

301. We do not accept Napp's argument that the Decision takes insufficient account of alleged changes to the market situation during the period of infringement.

302. We note, first, that there is no suggestion that Napp's hospital prices altered in any way during the period of the infringement from 1 March 2000 to 31 March 2001. Those hospital prices remained below direct cost on those strengths (10mg, 30mg, 60mg and 100mg) where Napp faced competition. In 11 out of 17 regions the contract prices were up to [...] [in between 30 to 50] per cent below direct cost, as already stated (paragraph 223 above). The continuation of Napp's below direct cost contract prices during the period of the infringement meant that Link could not bid for any of that hospital business without matching Napp's prices, and thus itself selling at a loss. Similarly, for the reasons already mentioned, the barriers to entry which those prices present to any supplier seeking to enter the market (taking account of switching costs and the small volumes purchased by individual hospitals) remained firmly in place. In all essential respects, therefore, Napp's prices continued to be a barrier to entry throughout the period of the infringement.

303. The evidence before the Tribunal shows that at least two contracts were renegotiated during the period of the infringement, Link being added on a shared basis, but it is not suggested that Napp took the opportunity to raise its prices on those occasions. Link's prices thus had to match Napp's. The evidence at Annex 4 to the defence indicates that certain other contracts were due to come to an end during the period of the infringement and our understanding is that these contracts were continued in Napp's favour at the same low prices. We were told in the context of the application for interim relief that, with few exceptions, Napp's contracts were terminable on three months' notice. We have no doubt that, had it wished, Napp could have ceased to offer prices below direct cost to hospitals during the period of the infringement. Napp chose not to do so.

304. We do not accept Napp's argument that Link's new-found tactic of going straight to hospitals rather than necessarily competing in the tendering process in the way that BIL had done represents a material change in the market situation. Napp's prices still represent a significant barrier to Link whether it approaches individual hospitals or participates in the tendering process. As regards the fact that in two regions Link has apparently succeeded in being added to the regional contract, once again Link has only achieved that by offering the loss-making prices forced upon it by Napp. We are not wholly clear from the evidence whether Link has, in fact, been able to participate in a third regional contract, but even if it has, we have already said that we have no reason to doubt that, as at September 2001, Link was supplying only some 22 hospitals out of a possible 400. Although the rate of growth in Link's market share in the hospital segment has accelerated slightly following BIL's withdrawal, Napp's market share in that segment has increased as well, from 90 per cent in

1999, to 91.9 per cent in 2000 and to 92.7 per cent in Q1 2001. That picture does not suggest to us that there was any material weakening of Napp's dominance during the period of the infringement, nor that the playing field became materially more level in the period since 1 March 2000.

305. As regards PCGs/PCTs, and the Health Act reforms of 1999, no ground of appeal was based on these developments in the notice of appeal, the only significant comments made being under the heading "Prospects for competition" in the factual part of that document. It was not argued in the notice of appeal that PCGs/PCTs, which started to come on stream in 1999 and 2000, had made any material difference to the market for oral sustained release morphine during the period of infringement from 1 March 2000 to 31 March 2001.

306. The material relating to PCGs/PCTs subsequently submitted by Napp, apparently largely taken from various websites, does not in our view take the matter much further. Among the few documents that were submitted to us on an agreed basis, the Kings Fund Tracker Surveys for 1999/2000 and 2000/2001, suggest to us that in the initial period of their operation PCGs/PCTs were likely to concentrate on purchasing policies for those drugs which represent a large proportion of the budget, rather than on drugs such as slow release morphine which according to the Decision (paragraph 121) have a relatively minor impact on their total budgets. It is true that in the documents produced by Mr Hartley of Link there is evidence that in some limited areas PCGs/PCTs may be beginning to have an impact in making GPs more aware of prescribing costs for sustained release morphine, and hospital purchasers more aware of such costs in the community segment. However, there is nothing to suggest that such developments had any material impact during the period of the infringement: see paragraph 121 of the Decision. In particular, during that period, the advent of PCGs/PCTs had no material effect on Napp's prices, nor its market shares, in either the community or hospital segments.

Intention to eliminate competition

307. Since we have found that Napp's policy of pricing below direct costs hindered competition and raised barriers to entry, to the significant disadvantage of its competitors, it is, strictly speaking unnecessary to examine Napp's intentions in order to establish an abuse: see *Tetra Pak II* in the judgment of the Court of Justice at paragraph 42. We do so for completeness.

308. The Director finds, in the Decision, that Napp pursued its pricing policy to hospitals with the intention of eliminating competition: see e.g. paragraphs 145, 181, 196, 201 and 202. He bases that view notably on (a) the fact that Napp's discounts were targeted on those strengths of tablet where Napp faced a competitor; (b) the fact that Napp's highest discounts of [...][in excess of 90] per cent were offered on sole contracts which by their nature were intended to exclude competitors; and (c) the absence of any other credible explanation for a policy of pricing below direct costs for a prolonged period, in circumstances, where Napp was protecting a market share of around 96 per cent in the community segment.

309. We accept the Director's submission that to establish an intention to eliminate competition it is sufficient to show that the undertaking concerned must have been aware or, at least, could not have been unaware, that its conduct was of such a nature as to eliminate competition: see the cases cited at paragraphs 450 and 456 below.

310. On that basis, and in the light of the facts that (a) Napp's discounts below direct costs were targeted selectively only on those tablet strengths where it faced competition; (b) Napp's lowest prices were given on sole contracts; and (c) in our view Napp and its senior executives must have been aware that its discounts had the object or effect of preventing or hindering competitive entry into the market, we are satisfied that the Director was fully entitled to come to the conclusion that Napp's intention was to eliminate competition, on the material before him at the time the Decision was taken.

311. The Director further invites us to take into account, on the issue of intention, the documents disclosed in answer to the Tribunal's request of 31 August 2001, on the ground that they go to the question whether Napp did have an intention to eliminate competition, and in particular to the credibility of Napp's assertions to the contrary. As already indicated, Napp submits that we should disregard these documents except to the extent that they are in Napp's favour (see paragraphs 127 to 130 above).

312. In our judgment, while these documents pre-date the period of the infringement, they explain the origins and motives of Napp's pricing policy. In the absence of any indication that Napp's intentions changed at any later date, and in the face of the company's continued assertion that it possesses no documents any later than 1997 which explain the policy it adopted, they are in our view evidence of what Napp's intentions were during the period of the infringement.

313. To remove any doubt on that point, Mr Brogden explicitly confirmed to us that Napp's policy had remained consistent throughout the 1990s and the period of the infringement. Mr Brogden said, in the context of questions about Napp's strategy as regards Link:

> "I can only say to you from my position that we always had a consistent strategy within the company. As you well know, we were facing aggressive pricing discounts by our competitors and they were constantly lowering their prices in the hospitals, apart from also having lower prices in the community, but they aggressively undercut our prices in hospitals and that has always been the case with the competitors that we have faced. Our strategy over the years to my mind has been absolutely consistent and you will see it, I think, repeatedly in the documents, that our strategy was to match those prices." (Transcript, Day 1, p.19.)

When asked about the absence of documents since 1997, he said:

> MR BROGDEN ... "I do not know whether I am right or wrong on this, but I can only attempt to explain it by the sense that our strategy over the years has not changed, and our strategy in terms of matching the prices that Boehringer created within the hospital market has, to some extent been perpetuated with Link also continuing to aggressively undercut our prices. In that sense there is ...
>
> THE PRESIDENT: So in relation to Link you have been following, broadly speaking, the same strategy that you followed with Boehringer?
>
> A. Yes, sir, broadly speaking, we have been following the same strategy. There are differences, but those are not of our making, and not our strategy.
>
> Q. But the strategy has remained consistent throughout?
>
> A. The strategy has remained consistent throughout, sir. If I may just say ...
>
> Q. Of course.
>
> A. ... because there is an important difference, the one thing that Boehringer seemed to do to my knowledge over the years was consistently submit tenders for the regional health authority contracts. These are the big contracts. It seems, as we have learned from our experience of late, that they [Link] have not consistently done that, but our approach has always been consistent in the sense of trying to match prices and submit tenders to hospitals." (Day 1, p 19)

314. Rule 20(2) of the Tribunal Rules provides:

> "The tribunal may admit or exclude evidence, whether or not the evidence was available to the respondent when the disputed decision was taken and notwithstanding any enactment or rule of law relating to the admissibility of evidence in proceedings before a court."

In the light of that Rule, in our view it is open to the Director to rely on the documents disclosed to the Tribunal even though they were not relied upon by the Director in the Decision (i) as evidence tending to rebut assertions made by Napp in the course of this appeal and (ii) as secondary support for the finding already made by the Director in the Decision, that Napp's intention was to eliminate

competition. Napp has had a very full opportunity to comment on the documents in question. We do not see any unfairness to Napp if we permit the Director to rely on them.

315. An extract from Napp's 1991 year end report states:

> "The launch of SRM-Rotard in tablet strengths of 10mg, 30mg, 60mg and 100mg, in identical colours to MST CONTINUS Tablets, is clearly the most important issue with which we now have to deal... We have agreed internally that we will match (beat, if necessary) their prices to hospitals and hospices."

316. In the period up to the end of 1993 Napp continued that policy on the basis that:

> "Farmitalia's approach has been to concentrate on hospitals and hospices by offering extremely low prices, which we have been forced to match in order to retain this important and influential business." (year-end report for December 1992).

and that:

> "an aggressive pricing policy is essential to prevent the adoption and acceptance of new competitors." (June 1993 mid-year report)

317. Following the launch of Oramorph by BIL, a Napp filenote of 25 March 1994 from Mr Chris Smailes to Mr Brogden and others stated that BIL's discounts were beginning to "hit home". In recommending a "pre-emptive strike mid-contract" Mr Smailes commented:

> "The effect, however, would be to deflate the vital element of Boehringer's promotional strategy and limit their opportunities to give Oramorph SR early success. It would also reaffirm that this is our market and any "would be" competitor may hurt us but will gain nothing for themselves."

318. In a memo dated 2 June 1994, Mr Smailes reported that he had become, "even more acutely aware of the potentially massive threat we face to our MST CONTINUS Tablet business." Mr Smailes proposed to reduce the price of MST in certain hospital regions to at least that of the Oramorph contract price. He concluded:

> "The above action is both immediate and uncompromising as a response to Boehringer's threat, and will hopefully signal to them that we are <u>NOT</u> leaving this market open to them..."

319. In a further memo of 17 June 1994 Mr Smailes undertook a review of the options facing Napp. He stated:

> "Clearly the 90% discount option would send an unequivocal message to Boehringer that there was no place for them in this market. We do not of course know what their

intentions are and can only assume that they would not be prepared to lose money in order to penetrate the market."

Mr Smailes' proposal was to "offer 80% discount prices and review the situation in the light of the outcome." Mr Brogden responded to Mr Smailes' memo on 20 June 1994 in the following terms:

> "I know there is a school of thought that argues that we should 'stuff Boehringer' by quoting substantial discounts, eg, 90%. However, I don't want to simply win the battle and lose the war by getting stuck with such low prices that our hospital sales have no absolute value (other than referral). It's the usual difficult balancing act. I'd be inclined to accept the proposal of 80% made by Chris providing that the contracts come up in such a sequence as to allow us to drop our price if we should fall at the first hurdle. If three <u>significant</u> contracts have to be completed at the same time then I would consider moving to 85%. Incidentally, Arthur, these judgments have to be made in relation to the cost of goods and you should encourage Chris to include these in future."

320. On 18 August 1994 Mr Smailes wrote a follow-up memo indicating that BIL had responded to Napp's reductions on a particular contract price. Mr Brogden's response, dated 19 August 1994, is recorded in manuscript on the memo as follows:

> "Chris I'd be inclined not to prevaricate. Simply match the prices."

321. Napp's December 1994 year-end report noted that:

> "In volume terms MST CONTINUS Tablets have done surprisingly well. Our aggressive stance towards Boehringer's pricing is certainly working although, of course, reducing our overall sales and profit. I have already reported that our discounts are around 80% on tender business ... Perhaps more significantly though we are preventing them from getting a "toe-hold" in the GP market."

322. Napp's mid-year report of June 1995 stated that the "key issue" facing Napp's domestic sales was "price pressure":

> "The cost of a drug is now the prime consideration with many if not most doctors. Unfortunately our major promoted products are highly exposed: MST continues to suffer severe price erosion from Boehringer's efforts. Recently Oramorph SR was offered on contract at 97.5% discount compared with MST."

The report goes on to identify under the heading "Competitor Activity",

> "(i) the continuing need to keep Boehringer at bay. This focuses particularly on the hospital contract market and those retailers supplying hospices."

323. The end of year report of December 1995 noted, under the heading "Major Products":

"The projected decline in cash sales for the tablets is in part due to the continued need for aggressive contract pricing to match Boehringer's (Oramorph SR) ..."

324. An internal email from Mr Brogden of 10 June 1996 explains to others in Napp what he describes as "two essential points" about BIL's pricing practices:

> "1. Perhaps understandably, they [BIL] felt hospital/hospice endorsement was very important to their market entry and aggressively undercut our own contract prices. As you appreciate, hospital endorsement (usage) can influence greatly the general practitioner and to prevent them gaining this foothold we also reduced our contract prices. They have now stabilised at the ludicrous figures you see in the table and whilst they are still half our price, the total value of the purchases by an individual hospital are so small as to largely negate any desire or reason for a hospital to move away from MST CONTINUS.
>
> 2. The above strategy [by BIL] was coupled with lower basic NHS price than MST. There are two reasons. Firstly, many hospitals appreciate the influence that their choice of drug has on the community general practitioner and believe therefore that they have a responsibility to make their choice of product with some regard to what the wider community will have to pay. Thus Boehringer use the lower Basic NHS price to persuade the hospital pharmacist – "not only will you pay less, but by following you the community, general practitioner will also pay less". Secondly, of course, the lower basic NHS price is simply placed in front of the general practitioner as a money saving device against the practice budgets."

325. The June 1997 mid-year report states as follows:

> "Our morphine preparations have done considerably better than anticipated. This reflects the introduction of MXL once-a-day morphine ... We have been very successful in containing our competitors though not without a continued erosion of prices when trying to keep them out of the hospital market."

326. Reading these documents as a whole, they seem to us amply to confirm that the commercial purpose of what Mr Brogden described in his e-mail of 10 June 1996 as the "ludicrous" level of discount was none other than to prevent BIL from gaining a foothold in the hospital segment, primarily because, as Mr Brogden said in that e-mail, "hospital endorsement (usage) can greatly influence the general practitioner". That Napp's policy was throughout "to retain this important and influential business" (December 1992) and thus prevent BIL "from getting a toehold in the GP market" (December 1994) is made explicit by a number of the documents cited above. Those documents thus explicitly confirm that Napp realised the importance of "hospital influence" and saw its policy of discounts to hospitals as part of a strategy to prevent competitors from entering the community segment. As Mr Smailes said in his notes of 25 March 1994 and 17 June 1994, Napp's intention was

> "to reaffirm that this is our market and that any 'would be' competitor may hurt us but gain nothing for themselves."

and

> "to send an unequivocal message to Boehringer that there is no place for them in this market."

327. In our judgment there is no credible evidence that Napp ever saw any justification for its hospital discount policy other than the need to exclude competitors from the hospital segment, and thus prevent them from gaining hospital influence which would, in turn, threaten Napp's market share in the community segment.

328. It is clear from Mr Brogden's memo of 20 June 1994, where he says that he does not want to be "stuck with such low prices that our hospital sales have no absolute value (other than referral)" that Mr Brogden did not see "referral business" as, in itself, a self-standing commercial justification for low hospital prices. That memo further demonstrates Mr Brogden's then view that "these judgments have to be made in relation to the cost of goods." As he told us in evidence, his preference would always have been "to make a profit on the sale of the unit to the hospital in its own right" (Day 1, p.34). In our view, the fact that at some point, in 1996 or, possibly, 1998, Napp's prices went below direct costs, was due entirely to Napp's policy of matching competitors' discounts, whatever the cost, so as to exclude competitors from the vital hospital influence.

329. In the light of all the material before the Tribunal, we do not feel that either Mr Manners, in his witness statement of 13 October 2000, nor Mr Brogden in his witness statement of 25 May 2001, gave us a full account of the reasons why Napp pursued its hospital discounting policy.

330. Mr Manners (see paragraph 177 above) states, in effect, that "it makes sense" for Napp to discount hospital prices because of the high margins it makes in the community segment. As we have pointed out (paragraphs 259 to 262 above), what this argument comes down to is the assertion that the hospital discounts which tend to protect Napp's virtual monopoly in the community segment are justified by the retention of the very high market share, and the high margins, which Napp earns from that monopoly. That argument, in our view, tends to confirm the existence of the abuse rather than justify it. Mr Manners also sought to persuade us that Napp's belief, and by implication its motivation, was that "if we were successful in winning contracts, we could thereby make extra sales". Leaving aside the fact that there were few 'extra' sales to be made, since Napp already had

96 per cent of the community segment, Mr Manners makes no reference to any internal documents which support his description of Napp's hospital pricing policy. Those we have seen in the course of these proceedings confirm that it was not simply a case of "making extra sales", but of a consistent policy of excluding competitors from the hospital segment.

331. Similarly, Mr Brogden told us in his witness statement of 25 May 2001, that "Napp was keen to win hospital contracts, in recognition of the follow-on benefits which they bring, in terms of community sales" (see paragraph 178 above), but made no reference to Napp's internal documents. Those documents in our view show that it was not simply a question of Napp being "keen" to win hospital contracts "in recognition of the follow-on benefits they bring", but rather of Napp's seeking to exclude competitors from the hospital segment. Mr Brogden's witness statement did not, in our view, tell us the whole story.

332. In addition, both Mr Manners and Mr Brogden assert Napp's belief that other suppliers were "evaluating the opportunities in the same way" and offering low discounts to hospitals "in recognition of the benefits that follow-on sales bring in terms of community sales". However, since (i) Mr Brogden asserted to the Director, in his letter of 24 September 1999, that Napp's experience "over the last decade" showed little correlation between hospital and community sales; and (ii) that Napp itself, as we have found, was setting its hospital prices with a view to eliminating competition, we find it hard to determine what Napp thought was in the minds of its competitors. Nothing in that evidence persuades us that Napp's intention was other than the elimination of competition.

333. However, as we have said (paragraphs 307 to 310), the documents disclosed in the course of the proceedings merely confirm the findings as to Napp's intention to eliminate competition already made by the Director in the Decision. We think that the Director would have been fully justified in coming to the same conclusion even without the documents in question.

Conclusion on Napp's net revenue defence

334. On the basis of the foregoing, we find on the facts that, during the period of infringement, (a) Napp's policy of selling to hospitals at prices below direct costs, and on a selective basis, had a significant effect in hindering competition in the hospital and community segments of the market for oral sustained release morphine; (b) existing and potential competitors of Napp seeking to enter,

or gain market share in, the hospital segment and, ultimately, in the community segment of the market, were placed at a significant competitive disadvantage by Napp's hospital discounting policy; (c) Napp's intention was, so far as possible, to eliminate competition by preventing or hindering market entry into both the hospital and the community segments; (d) Napp's primary motivation was not to make "extra sales", nor to make "an incremental profit" in recognition of the "follow-on benefits" accruing from hospital contracts, but to deny to its competitors a key means of entering the market for oral sustained release morphine in the United Kingdom through the gateway of the hospital segment.

335. In those circumstances, we reject Napp's submission that the *AKZO* test is not a proper starting point in this case. MST is sold to hospitals below direct cost. Those sales, when made, generate a loss. Such sales are thus presumed to be an abuse, in accordance with *AKZO* and *Tetra Pak II*.

336. Even assuming in Napp's favour that the *AKZO* presumption is not an irrebuttable presumption, the Director has satisfied us that there are no grounds for rebutting the presumption of abuse stated in *AKZO*. Napp's 'net revenue test' turns out, on examination, to be little more than a circular argument to the effect that it is, in a general sense, "profitable" for Napp to sell at low prices in hospitals in order to deny to competitors a toehold in the hospital segment and the "hospital influence" which might flow from that. Even accepting, at a general level, a "linkage" between "hospital influence" and sales in the community segment, we do not think there is any conceptual or factual reason not to apply the *AKZO* presumption in the circumstances of this case. As seen above, Napp's hospital pricing policy has prevented competitive entry on any significant scale and exploited the advantages available to Napp which are not available to its competitors. Moreover, there is no evidence to bring Napp within the possible exception to *AKZO*, left open by Advocate General Fennelly, to the effect that there was "no plan to eliminate competition". On the contrary, in the present case the evidence establishes that Napp's pricing policy was intended to eliminate competition, and in fact hindered competition to a significant extent.

337. Even if, contrary to our view, the "linkages" relied on by Napp could be prayed in aid to distinguish this case from *AKZO* and *Tetra Pak II*, we remind ourselves that Napp is a superdominant undertaking in both the hospital and community segments with, in consequence, a particularly onerous special responsibility "not to impair further the structure of the feeble existing competition", as Advocate General Fennelly said at paragraph 137 of his opinion in *Compagnie Maritime Belge*. As appears from the Court's judgment in that case, a dominant enterprise with

over 90 per cent of the market may commit an abuse if it selectively cuts prices deliberately to match those of a competitor, even if it is not shown that the undertaking has priced below total costs. In that case the dominant undertaking had eliminated the principal, and possibly the only means of competition open to its sole rival, thereby maintaining higher prices in the area not threatened by competition. There was a market share of over 90 per cent, and an intention to eliminate competition (paragraphs 117 and 118 of the judgment). As Mr Fennelly pointed out in his opinion (at paragraphs 135 and 137) it was a case of a superdominant undertaking which had selectively targeted competitors with discriminatory price cuts, implemented with relative autonomy from costs, with the aim of eliminating all competition.

338. Even on the view of the facts most favourable to Napp, most of the features of *Compagnie Maritime Belge* are present here, even though the factual context is different. Napp is a superdominant undertaking with well over 90 per cent of the market. During the period of the infringement it had only one significant competitor, Link. Napp pursued its hospital pricing policy with the deliberate intention of eliminating competition, as the Director found. That policy was implemented by low prices targeted selectively against those strengths of tablet where Napp faced competition, with higher discounts being given for sole contracts. The policy ensured that the much higher prices and high market shares in the profitable community segment were not threatened by competitive entry through the gateway of the hospital segment. It seems to us, on those facts, that each of the features identified by the Court of Justice in paragraphs 117 and 118 of its judgment in *Compagnie Maritime Belge* are present here.

339. In those circumstances, in our judgment, Napp's 'net revenue test' arguments fall to be rejected, not only on the basis of the principles of *AKZO* and *Tetra Pak II* but also, and in any event, on the basis of the principles of *Compagnie Maritime Belge*. *Irish Sugar*, cited above, further shows that selective discounting by a dominant undertaking, without any economic justification, which tends to eliminate competition, is equally an abuse of a dominant position.

Napp's other arguments

340. It follows from the above that we reject Napp's argument that it has not "had recourse to methods different from normal competition" (*Hoffman-La Roche*, paragraph 91). We accept that in the pharmaceutical sector discounts granted to hospitals by pharmaceutical companies may be substantial. However, nothing in the evidence before us leads us to doubt (i) that discounts of up to

[...] [in excess of 90] per cent are not normal in hospital tenders; (ii) that such discounts have been granted selectively only where Napp has been faced by a competitor; and (iii) that the resulting difference between what the hospital pays and the normal NHS list price is exceptional – in some cases over 2000 per cent – as the Director finds at paragraphs 198 to 200 of the Decision (see Section VIII below). Perhaps more significantly, we do not regard it as "normal" for prices to hospitals to remain below direct costs for many years. For the reasons already given, we find that the below-cost pricing in question was not a 'normal' commercial response but the response of a superdominant undertaking aiming to eliminate competition. Nothing in the structure of the NHS compelled Napp to act as it did.

341. There is no evidence that Napp's selective discounts below direct cost were based on any "economic service" justifying them, such as cost savings, so as to fall within paragraph 114 of the judgment of the Court of First Instance in *Irish Sugar*, cited above. Nor does it seem to us "normal" that a pharmaceutical product out of patent, facing a number of other products considered to be therapeutically equivalent, should have maintained such high market shares, for such a long period, in both the hospital and community segments of the market, as we have already found (paragraph 287 above).

342. As to Napp's argument that it had no commercial alternative but to meet the competition offered by BIL, and later to maintain the same prices in competition with Link, a dominant undertaking is entitled to take reasonable steps to protect its own commercial interests if attacked, but only by means which are reasonable and proportionate. Moreover, the behaviour in question will not be justified if the real purpose of the undertaking is to strengthen its dominant position and thereby abuse it: see the judgment of the Court of First Instance in *Compagnie Maritime Belge* at paragraphs 146 to 148.

343. In our view, these principles are implicit in the "special responsibility" of a dominant undertaking, and even more so when it is a question of "superdominance" amounting to a virtual monopoly. By virtue of the Chapter II prohibition there is thus a certain limit beyond which a dominant undertaking may not go when reducing its prices, purportedly to "meet" competition, particularly when it is defending a market share of around 95 per cent. In a case such as the present, that limit is, at the very least, the point where its prices go below average variable cost, on a selective basis, in order to "see off" the competitor on the particular products where the dominant enterprise is facing competition, leaving other prices unchanged.

344. As *Tetra Pak II* and *Compagnie Maritime Belge* make clear, the freedom of action of a dominant undertaking, particularly a superdominant undertaking is still constrained, even where prices remain above average variable costs, or even above average total costs, if the price cutting is carried out on a selective basis, with the purpose of eliminating a competitor. If that purpose can be achieved by simply matching the competitor's prices, it is no answer to say that there was no undercutting: see *Compagnie Maritime Belge*, at paragraphs 113 to 119 of the judgment of the Court of Justice, and Mr Fennelly's opinion in that case, especially at paragraph 137.

345. For the reasons we have already given, we are satisfied that Napp's conduct went well beyond the limits to which the activities of dominant undertakings are subject by virtue of the Chapter II prohibition. On any view, we do not think that Napp's conduct can be described as "reasonable" or "proportionate", as the Director found at paragraph 202 of the Decision.

346. More specifically, we do not accept that Napp had no commercial alternative but to reduce its prices below direct costs. Even if Napp's hospital prices had remained above average total costs, in our view non-dominant competitors such as BIL or Link would still have faced difficulties in building up a significant market share in view of the high existing barriers to entry already mentioned. It is unlikely, in our view, that Napp would have lost all or even most of its hospital contracts.

347. Nor do we accept Napp's argument that it is placed in an impossible position if there is, legally speaking, a 'floor price' on its discounts to hospitals at the level of average direct costs or average total costs, because, according to Napp, competitors such as Link would be able to undercut Napp, making up their losses on hospital contracts by means of the profits from the community segment generated by the 'linkages' between the two segments.

348. First, we see force in the Director's view, expressed in his letter of 4 May 2001, that discounts offered by competitors would be unlikely to remain at their present levels if Napp's hospital prices were to rise. Link has already suffered considerable losses, which Link would have an incentive to minimise. Moreover, even with the benefit of the "linkages" which Napp asserts, it seems to us, on the evidence, that Link or any other new entrant, may still face some difficulties in establishing itself in either the hospital or the community segments, even on the basis of selling at low prices to hospitals, because of the substantial switching costs in both segments and Napp's existing dominant position.

349. It is also open to Napp to compete on the therapeutic qualities of what is no doubt an excellent product, and on the efficiency of its operations. More importantly, if Link or another new entrant began to secure more hospital business, and thereby threaten Napp's business in the community segment, in our judgment the correct response on Napp's part is not to engage in predatory pricing in the hospital segment, but, if necessary, to reduce its high prices in the community segment. That in our view would be "competition on the merits", which has so far been prevented by Napp's abusive conduct in the hospital segment.

350. As to Napp's point that paragraph 2(d) of the Directions permits Napp to price below average variable costs provided that it maintains the minimum permitted differential of 80 per cent between its hospital and community prices, that provision rightly reinforces our own view that the lawful competitive behaviour for Napp to follow, in response to competition, is to reduce its prices in the community segment. However, we take the view that there is a legal and practical difficulty, as regards paragraph 2(d) of the Directions, and we return to that issue in Section X of this judgment.

351. We observe, finally, that in his conclusion on abuse at paragraph 236(a) of the Decision, the Director has included as part of the abuse, at paragraph 236, subparagraph (i),

> "selectively supplying sustained release morphine tablets and capsules to customers in the hospital segment at lower prices than to customers in the community segment."

Although the Director has, in the Decision, rightly criticised the *extent* of the differential between Napp's prices in the hospital and community segments, it does not seem to us that, in the Decision, the Director has alleged that supplying the hospital segment at lower prices than the community segment is, *of itself*, an abuse. The Director has not addressed to us any detailed argument on this issue, nor made specific reference to subparagraph (i) of paragraph 236. If and in so far as the word "selectively" in subparagraph (i) is intended to add anything, the "selective" nature of Napp's discounts is already referred to in subparagraphs (ii) and (iii) of paragraph 236. It seems to us, therefore, that sufficient grounds have not been shown for upholding paragraph 236(a)(i) of the Decision if and in so far as that subparagraph is intended to identify an element of the abuse not otherwise covered by the rest of paragraph 236(a).

Conclusion

352. For all those reasons, we find that Napp has abused its dominant position in the supply of tablets and capsules of oral sustained release morphine in the United Kingdom by supplying hospitals at excessively low prices in the period from 1 March 2000 to 31 March 2001, as the Director concluded in paragraph 236(a) of the Decision. For the reason just given, we exclude from that finding paragraph 236(a)(i).

VIII — ABUSE: EXCESSIVE PRICES

A: ARGUMENTS OF THE PARTIES

Napp's arguments in the notice of appeal

353. The essence of Napp's case is summarised in the notice of appeal as follows:

> "Napp has not charged excessive prices for MST. The price of MST is set in accordance with the PPRS, and is a reasonable price, having regard to the objects of the PPRS, and the fact that its terms are calculated, inter alia, to provide an appropriate incentive to Napp and to other companies to invest in R&D to secure a new generation of drugs for supply to the NHS." (paragraph 4.1(ii)(a))

Napp relies very largely on Nera's report of 29 May 2001, *Napp: Analysis of OFT Decision on Excess Pricing for MST* (A 106) and a paper of 24 May 2001 prepared by Napp entitled *Evidence on Other Therapeutic Markets,* (A 112).

354. Napp's basic submission is that the PPRS and the Department of Health's powers under the PPRS and the Health Act 1999 are effective to prevent Napp from engaging in excessive pricing or exceeding "the competitive price" for MST. According to Napp, a competitive price for a pharmaceutical product should be one which,

> "… over the life cycle of the product as a whole, provides pharmaceutical firms … with the appropriate incentive to invest in such R&D, education, training and promotion to the extent that consumers collectively are willing to fund such investment. Any such competitive price will take account of the *ex ante* uncertainty as to whether a particular product will succeed." (notice of appeal, paragraph 5.21)

355. According to Napp, these are precisely the factors underlying the PPRS, which thus properly takes into account questions which Nera describes as of "dynamic", as opposed to, "static" efficiency. For many years, Napp has been within the limits on ROC permitted by the PPRS. The Director is

incorrect to suggest, at paragraph 130 of the Decision that the limits set by the PPRS are "not restrictive". The pharmaceutical industry is a relatively high risk industry because of the amount of R&D required and the uncertainty of finding successful drugs. Napp's overall rates of return are well within reasonable limits for an industry of this kind.

356. Napp contends that the Director's alternative view is that competition should drive prices down to reflect long run marginal costs of manufacture, marketing and distribution, and that any price above that level is excessive. Such a view, according to Napp, disregards the particular features of the pharmaceutical industry. That industry is a research-based, innovative industry, in which a few successful "winners" must not only repay their own development and promotion costs, but must also fund the research and development of a large number of other products which do not cover their own costs, as well as ongoing research into new products, very many of which ultimately turn out to be unsuccessful. According to evidence cited by Napp, most pharmaceutical products fail to cover their development costs; it takes on average 10 to 12 years and more than £350 million to develop a new medicine; very few compounds are licensed; and only one in seven licensed compounds are commercially successful.

357. In these circumstances, says Napp, only a "portfolio-based" approach such as that of the PPRS, which assesses profitability across a range of investments made in conditions of "ex ante uncertainty", can evaluate whether a firm is enjoying excessive profitability. According to Napp, both European Community and United Kingdom law recognise the importance of portfolio pricing: see Advocate General Reischl in Case 262/81 *Coditel II* [1982] ECR 3381 at pp 3411, 3412 and Monopolies and Mergers Commission Report, *"The Supply of Recorded Music: a report on the Supply in the United Kingdom of Pre-recorded compact discs, vinyl discs and tapes containing music"* (1994).

358. According to Napp, the Director's response, at paragraph 209 of the Decision, to the effect that the costs of R&D, and of bringing an innovative product to market, can be recovered during the period of patent protection, is far too narrow. According to Napp, its formulation patent on MST never prevented the launch of competing products such as those subsequently launched by BIL or Link. More fundamentally, the Director's reliance on patent protection fails to recognise that, in the pharmaceutical industry, the successful products have to fund not only their own costs, but also the costs of developing the unsuccessful products. The reasonableness of Napp's margins in the community segment cannot be determined without, first, assessing what its initial investment in

MST was, secondly, considering Napp's expected volume of sales, and, thirdly, assessing how much profit Napp needs to make in order to fund its ongoing research activities.

359. Moreover, according to Napp, an adequate return on investment should not be limited to the patent period. The Director's contrary approach reduces the incentive to produce new drugs. By contrast, the PPRS adopts a "smooth pricing profile" which avoids the "bunching" of recoupment on R&D during the life of the patent. The reality is that many drugs which come off patent continue to command high prices and maintain substantial market shares because of legitimate "first mover" advantages.

360. The Director's approach further fails to recognise that, under the PPRS, Napp was obliged to set its price for MST lower than it otherwise could have because of the success of another of its products, Phyllocontin. Under the PPRS Napp had to obtain Department of Health approval for the original price of MST because it was a formulation of an existing chemical molecule, and the Department of Health approved that price as a reasonable price in 1980. Since then, apart from a price increase in 1983, the price of MST has been subject to the general across-the-board reductions agreed between the Department of Health and the pharmaceutical industry of 3.5 per cent, 2.5 per cent and 4.5 per cent in 1985, 1993 and 1999 respectively. In real terms, the price of MST has fallen by some 63 per cent since it was launched in 1980.

361. According to Napp, the fact that the Department of Health does not appear to adopt the Director's approach suggests that the Director's model of how competition should operate in this market is not "unequivocally the best one to use". At the least, the Director should have undertaken his own informed assessment of the optimal balance between considerations of static and dynamic efficiency to determine a competitive price for MST. The Director's approach unjustifiably interferes with the amount the Department of Health has decided it wishes the pharmaceutical industry to spend on R&D in the public interest. There is no good reason for the Director, or the Tribunal, to question the Department of Health's judgment on these issues, particularly since the PPRS has been structured so as encourage innovation, an area where the United Kingdom pharmaceutical industry has been outstandingly successful by international standards.

362. Apart from those arguments of principle, Napp criticises the details of the comparators used by the Director to conclude that Napp's prices are excessive. According to Napp, the comparison of MST with other products is flawed because different brands are not fully equivalent. MST's brand

strength enables it to attract a premium over other brands, as the Director accepts. Nothing in the Director's analysis serves to show that MST's legitimate brand premium is excessive, or by how much. In addition, Napp points out that the Director has miscalculated the price of Morcap SR. Further the Director has misunderstood the nature of Napp's export sales. Napp is merely a contract manufacturer and has no involvement or risk in the marketing of the product outside the United Kingdom. Comparisons with Napp's other NHS products are not meaningful either.

363. Finally, Napp points out that other benchmarks investigated by the Director failed to support his case. A comparison with similar products in other EU member states did not show that Napp's prices were excessive. Nor did an investigation into the return on capital employed earned by Napp reveal that Napp's prices were excessive as compared with other firms. Nothing in Community law, notably Case 27/76 *United Brands v Commission* [1978] ECR 207 ("*United Brands*"), supports the Director's approach.

The Director's arguments in the defence

364. In the defence, at paragraphs 16 and 17, the Director summarised his case in relation to the abuses found to have been committed by Napp:

> "16. In essence, the Director General's case is that Napp charges excessively low and/or discriminatory prices in the hospital segment and thereby sustains very high prices and market share in the community segment of the market. These two aspects are accordingly interlinked. Napp's pricing practices have the effect of placing significant obstacles against the successful entry of competitors, and in consequence serve to preserve its quasi-monopoly position in the community segment of the market and enable it to continue to charge prices for MST higher than could be sustained in the absence of that quasi-monopoly position ie competitive prices …
>
> 17. Accordingly, the Director General does not seek to condemn the prices in the community segment in isolation; in other words, if his case should fail as regards the exclusionary character of Napp's pricing practice in the hospital segment, he does not contend that the prices in the community segment violate the Chapter II prohibition simply because of their absolute level."

365. The Director states at paragraph 84 of the Defence:

> "As stated above, it is the Director General's case that Napp's conduct has had the effect of excluding competitors from the hospital segment, thereby foreclosing the essential gateway for entry to the community segment. As a result Napp has retained its quasi-monopoly position in the community segment and has been able to charge quasi-monopoly prices. In those circumstances, the charging of prices, which are

higher than Napp would be able to charge in a competitive market, constitutes an abuse."

The Director relies on *United Brands*, at pages 301 and 302 of that judgment.

366. As to Napp's specific criticisms of the comparators used, the Director accepts that MST's brand strength will command some premium but contends that Napp's price is still excessive: it is a question of degree. As to Morcap SR, the Director considers that Morcap SR is inappropriate as a comparator. As to export prices, the Director does not claim that Napp's export prices should be the same as domestic prices, but that the "extraordinary scale" of the discrepancy is significant. As regards the comparison with Napp's other products, it is again the degree of the size of differential that is significant, according to the Director.

367. With regard to Napp's arguments as to the need to apply a "dynamic" concept of competition, the Director submits that such arguments cannot serve as a justification for a product to earn a limitless stream of monopoly profits through keeping out competitors. When a monopoly comes to an end, whether due to the expiry of a patent or otherwise, and competitive entry occurs, this will normally have some impact on prices. The PPRS in fact assumes that there is likely to be an impact on prices following the expiry of a pharmaceutical patent. This is why the PPRS prevents "price modulation" where a patent has expired: see the 1999 version of the PPRS, paragraphs 21.3, 21.4 and 21.7. In its *Report on the Supply of Chlordiazepoxide and Diazepam*, (13 February 1973, no.197), the Monopolies Commission found, at paragraphs 223 and 232, that the prices of Librium and Valium were excessive even before the expiry of the relevant patents.

368. According to the Director, the PPRS is irrelevant to this case as it is not concerned with the control of anti-competitive practices, including the charging of a higher price by reason of conduct excluding competitors.

369. The Director rejects Napp's arguments based on Nera's report of 29 May 2001, *Analysis of OFT Decision on Excess Pricing of MST*, and the Napp paper entitled *Evidence on Other Therapeutic Markets*. He argues generally that there are difficulties in making comparisons on the basis of "selective data" with situations which concern different products. However, according to the Director, most branded pharmaceutical products suffer very extensive falls in market share when they come off patent, in some cases within a year of competitive entry: see Annexes 7 and 8 to the defence.

370. As regards the extent of the excess price for MST charged in the community segment, the Director accepts that determining the price which would prevail in competitive conditions is necessarily a matter of economic judgment rather than precise quantification. He draws attention to the methodology adopted by the European Commission in its decision in *United Brands* OJ 1976 L96/1, which was accepted by the Advocate-General on appeal, [1978] ECR at page 312, 338. The Director considers that, on the basis of the evidence before him, he has adopted a conservative approach in concluding that Napp's community prices are at least 15 per cent higher than they would be under competitive conditions. He submits that the Tribunal should accord him a margin of discretion in relation to such decisions: see Case 71/74 *Frubo v Commission* [1975] ECR 563, paragraph 43; and the opinion of Advocate General Warner at p. 597; Cases C-68/94 etc *France and Others v Commission* ("Kali and Salz"), [1998] ECR I-1375, paragraphs 223 and 224.

Napp's submissions on the Director's alleged change of case

371. After service of the defence, Napp sought to argue that the Director's case on excessive pricing in the Decision had been reformulated in paragraphs 16 and 17 of the defence (quoted at paragraph 364 above). According to Napp, the Director should not be permitted to do so, and that part of the defence should be struck out. As has already been mentioned, the Tribunal concluded in its interim judgment of 8 August 2001 that this was not a matter for striking out, and left the ultimate decision on this issue over to this final judgment: [2001] CompAR 33.

372. Napp submits, first, by reference notably to a detailed textual analysis, that in the Decision the Director treated excessive pricing as a discrete abuse from that of the excessively high discounts. According to Napp, what was alleged was a 'stand alone' abuse of excessive pricing in the community segment, regardless of the effects of Napp's prices to hospitals. Now, however, the Director has abandoned his position in the Decision by making the abuse in the community segment *dependent upon* the abuse in the hospital segment. The Director should not be allowed to advance a new case now.

373. Secondly, the Director's reformulation of his case does not establish whether as at 1 March 2000 Napp's prices were "excessive". This is because his analysis does not address what Napp's community prices would have been if Napp had pursued what the Director considered to be legitimate pricing in the hospital segment. Napp's argument is that, even if it had been forced to raise its hospital prices on 1 March 2000, it would then have been faced with a choice as to when to

lower its community prices. Napp might have decided that it was more profitable to maintain its community prices for some time, even though this would have lost market share, before responding with lower community prices. Napp suggests that any reduction in its community prices would most likely have occurred after 30 March 2001.

374. Thirdly, Napp claims that the Director's reformulation of his case assumes that all community sales are affected by its conduct in the hospital sector whereas the Director's case in the Decision was that only 24 to 27 per cent of the community market was directly affected by the hospital conduct through the follow-on effect, plus an indirect "reputation effect". However, it was never suggested in the Decision, contends Napp, that this "reputation effect" had a foreclosing effect on the entirety of the community market: see paragraphs 160 to 167 of the Decision.

375. At the final hearing Napp further argued that the Director's "new case", as made in the defence, must be proceeding on one of two hypotheses: (i) that Napp should have reduced its community prices as of 1 March 2000 because they had been maintained at an excessive level by anti-competitive behaviour prior to that date; or (ii) that, had Napp rectified its hospital prices on 1 March 2000, its prices in the community would have fallen to "competitive" levels. Neither hypothesis is spelt out in the Decision, which alleged an abuse in the community segment regardless of how Napp behaved in the hospital segment. It is not open to the Director to change the Decision now.

376. As to the first hypothesis, Napp argues that, by relying on the fact that Napp's community prices were excessive as the result of its hospital pricing, the Director is forced to rely on that conduct prior to the coming into the force of the Act. Taking into account its hospital conduct prior to 1 March 2000, which was at all times legal, to reach the conclusion that its prices were excessive and unlawful on 1 March 2000, would be to apply the Act retroactively and amounts to an infringement of Article 7 of the ECHR. Moreover, submits Napp, the Director's reformulation of his case requires Napp, quite unrealistically, to attempt an assessment of how the market would have developed prior to 1 March 2000, if Napp had not set its hospital prices as it did from 1994 onwards, in order to determine at what level to set its community prices after the coming into force of the Act. In any event there was no accepted norm for saying that Napp's hospital prices were "anti-competitive" prior to 1 March 2000.

377. As to the second hypothesis, Napp submits that the consequences of Napp raising its hospital prices as at 1 March 2000 have never been examined by the Director. If the matter had been raised in a Rule 14 Notice, Napp would have had to prepare detailed "economic and/or statistical or econometric" evidence in response. In any event, according to Napp, the Director has not demonstrated that Napp would have reduced its community price during the relevant period as a result of any increase in hospital price. Napp lists the following imponderables in support of this proposition: (i) at what price would Napp have been required to offer MST to hospitals? (ii) at what rate would hospitals have switched to competing products such as Zomorph and what effect would the Health Act 1999 reforms have on this process? (iii) at what rate would hospital sales convert to community sales in favour of MST's competitors? (iv) what would have been the optimal moment for Napp to decide to lower its community prices, having regard to the trade-off between maintaining prices at a reduced market share, or reducing margins in order to retain market share? In Napp's view there is no evidence to suggest that Napp would have reduced its prices in the community segment by as much as 15 per cent in the period of the infringement, or indeed at all, even if it had charged higher hospital prices as from 1 March 2000.

378. Napp adds that, in any event, the Director's evidence pre-dates March 2000 and therefore does not take any account of the rapidly evolving pressures in the community brought about by reforms under the Health Act 1999: see notably the documents produced by Napp in answer to the Director's request of 15 June 2001.

The Director's response to the alleged change of case

379. The Director maintains that the abuse of excessive prices alleged in the Decision is a distinct abuse. According to the Director, Napp's exclusionary conduct in the hospital sector enables it to charge unfair prices in the community segment, it does not mean that Napp automatically does so. The distinct abuse here consists in Napp's decision to charge unfair prices as from 1 March 2000.

380. According to the Director the Decision does not expressly state that the Director's case *depends* on establishing the exclusionary character of Napp's conduct, but it does make clear, in paragraphs 211, 225, 228 and 232, that its prices in the community segment are due in part to the exclusionary character of Napp's pricing practice in the hospital sector. Paragraphs 162 and 251 of the Decision show that the whole market was affected by Napp's discount policy.

381. According to paragraph 31 of his skeleton argument for the final hearing, the Director's position is that:

> "The essential significance of Napp's exclusionary conduct (both before and after 1 March 2000) to the finding of excessive prices is that it provides a solid basis on which to conclude that, in the absence of such conduct, there would have been effective price competition in this market as from 1 March 2000."

382. The Director denies that, in order to establish his case, he must rely impermissibly on matters arising prior to 1 March 2000. Matters arising prior to 1 March 2000 merely serve to inform the judgment as to whether the prices charged after 1 March 2000 were above the competitive level.

383. As the Director's case properly understood impugns Napp's prices in the community sector as excessive and an abuse as at 1 March 2000, there is no need to consider either how the market would have developed if Napp had not engaged in exclusionary practices prior to 1 March 2000, nor what the effect would have been had Napp raised its hospital prices on 1 March 2000.

384. The Director rejects Napp's criticism regarding the other two price benchmarks not referred to in the Decision. A comparison of gross profit margins earned by other companies as a whole with those of Napp on MST is unreliable. Similarly, a comparison with international prices is "fraught with difficulty" according to the Director: see the decision of the Restrictive Practices Court *In re Chocolate and Sugar Confectionery reference (foreign evidence)* LR 6 RP 325, at 337B-F. These problems are compounded where different national regulatory regimes exist.

385. Finally, the Director rejects Napp's assertion that he failed to take into account the reforms introduced by the Health Act 1999: see paragraph 121 of the Decision. As late as 6 March 2001, Napp expressly referred in its reply to the second Rule 14 Notice that these changes were a matter for the future (AI, p.432).

B: LAW

386. Section 18(2)(a) of the Act provides that conduct by a dominant undertaking may constitute an abuse, in breach of section 18(1), if it consists in

> "directly or indirectly imposing unfair ... selling prices".

387. Although cases at European Community level concerning unfair selling prices have been few, in *United Brands* the Court said:

> "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 82 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 UBC's 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"

388. In Case 30/87 *Bodson v Pompes funèbres des régions libérées* [1988] ECR 2479, the Court referred to a comparison between the prices charged in circumstances where there was competition, and those charged where there was a local monopoly, as one way of determining whether prices were excessive (paragraph 31).

C: FINDINGS

389. It seems to us that the most convenient approach is to deal first with the issues on the basis of what the Director found in the Decision, and then to examine Napp's arguments about the Director's alleged "new case".

The abuse as found in the Decision

390. In paragraph 203 of the Decision, the Director states that, as a matter of principle a price is excessive for the purposes of the Chapter II prohibition:

> "if it is above that which would exist in a competitive market and where it is clear that high profits will not stimulate successful new entry within a reasonable period. Therefore, to show that prices are excessive, it must be demonstrated that (i) prices are higher than would be expected in a competitive market, and (ii) there is no effective competitive pressure to bring them down to competitive levels, nor is there likely to be."

391. While there may well be other ways of approaching the issue of unfair prices under section 18(2)(a) of the Act, the Director's starting point, as stated in paragraph 203 of the Decision, seems to us to be soundly based in the circumstances of the present case.

392. Measuring whether a price is above the level that would exist in a competitive market is rarely an easy task. The fact that the exercise may be difficult is not, however, a reason for not attempting it. In the present case, the methods used by the Director are various comparisons of (i) Napp's prices with Napp's costs, (ii) Napp's prices with the costs of its next most profitable competitor, (iii) Napp's prices with those of its competitors and (iv) Napp's prices with prices charged by Napp in other markets. Those methods seem to us to be among the approaches that may reasonably be used to establish excessive prices, although there are, no doubt, other methods.

393. The facts set out in paragraphs 207 to 234 of the Decision, establish the following:

- Napp's prices in the community segment are typically around [...] [between 30 to 50] per cent higher than its competitors.
- Apart from certain across-the-board reductions applying to the pharmaceutical industry as a whole under the PPRS, Napp's price in the community segment has remained the same since the launch of MST in 1980, (save, as we understand it, for one increase in 1983) notwithstanding the expiry of its formulation patent in 1992.
- Napp's list price (less wholesale discount) in the community segment of the market is on average over 1400 per cent higher than its price in the hospital segment of the market for 10mg, 30mg, 60mg, and 100 mg tablets, where Napp faces competition.
- At Napp's highest level of discount, the list price in the community segment is on some tablets over 2000 per cent higher than Napp's hospital prices.
- Napp's prices in the community segment are over 500 per cent higher than its prices for export on a contract manufacture basis. As we understand it, MST faces competition in export markets.

— Napp's gross profit margin on sales to the community segment is [...] [in excess of 80] per cent, compared with a margin of around [...] [between 30 and 50] per cent on Napp's other products sold to the NHS.

— Napp's gross profit margin of [...] [in excess of 80] per cent on sales to the community segment compares with a gross profit margin of [...] [less than 70] per cent for Napp's next most profitable competitor. If Napp's manufacturing margin is recalculated on the basis of the costs of its next most profitable competitor, Napp's gross margin becomes [...] [less than 90] per cent compared with that competitor's [...] [less than 70] per cent.

394. As to the facts of those comparisons, Napp criticises the Director for not including the price of Morcap SR. Since Morcap SR does not seem to be actively promoted, and has a negligible market share, we agree with the Director that Morcap SR is not a relevant comparator. The fact that some prescriptions for Morcap SR are for once-daily treatment is a further reason for excluding Morcap SR.

395. Napp has also criticised the inclusion of export prices in the Director's comparisons on the grounds that that business is contract manufacture, which is risk free, and does not carry marketing and promotion costs. Although we accept that there is likely to be some differential in export prices as a result of those two factors, we agree with the Director that that is unlikely, in itself, to explain why prices to the NHS in the community segment are, on some strengths of tablet, over 500 per cent higher than export prices.

396. We therefore conclude that no serious criticism can be made of the detail of the price comparisons relied on by the Director.

397. In our view those comparisons, taken together, amply support the Director's conclusions that Napp's prices in the community segment were, during the period of the infringement, well above what would have been expected in competitive conditions. Thus we agree with the Director's finding, at paragraph 211 of the Decision, that it is only in the community segment, where buyers are less price sensitive, and where there is an absence of effective competition, that Napp can sustain a premium of 40 per cent over competitors. With the exceptions mentioned in paragraph 360 above, Napp's prices have remained unchanged for 20 years, including nearly 10 years since the expiry of Napp's formulation patent. At the same time, Napp has retained a market share of the

community segment of some 96 per cent. Those facts also support the proposition that Napp's community prices, unlike its hospital prices, have not been subject to competitive pressure, as the Director found in paragraph 213 of the Decision.

398. That conclusion is further supported by the fact that where Napp faces competition, in the hospital segment and export markets, Napp's prices are very significantly lower than Napp's prices in the community segment. As the Director found, Napp's prices in the community segment are, depending on the tablet strength, over 500 per cent higher than in the export market and are on average over 1400 per cent higher than in the hospital segment (paragraphs 217 to 222 of the Decision). The following table illustrates how large the price differentials are, taking Napp's 10mg, 30mg, 60mg and 100mg tablets, where Napp faces competition, and the prices for its 5mg, 15mg and 200mg tablets where that is not so to any significant extent:

Napp's prices (£ per pack of 60)

	NHS List price to the community	*NHS price to the community less wholesale discount*	*Average hospital price*	*Lowest hospital price*	*Export price*
5mg	4.30	3.76			
10mg	7.17	6.27			
15mg	12.57	11.00			
30mg	17.22	15.07	...	...	...
60mg	33.58	29.38			
100mg	53.16	46.52			
200mg	106.34	93.05			

399. Similarly the fact that NHS list prices in the community segment are set in regular increasing steps, according to tablet strength, whereas in the hospital and export markets that is not the case, strongly suggests that in those other markets prices vary according to the competitive forces affecting different tablet strengths. Again, that does not appear to be the case in the community segment, as the Director points out at paragraph 220 of the Decision.

400. It is therefore established, on the facts of this case, that during the period of infringement Napp charged significantly higher prices in the community segment than in other markets or segments where it faced competition, and has significantly higher margins in the community segment than its

most profitable competitor. In addition, Napp faced no competitive pressure on its prices in the community segment, had no patent protection, and enjoyed a market share of 96 per cent throughout.

401. The fact that the Director has not chosen to rely on other comparators such as international price comparisons or returns on capital does not in our view lessen the force of the comparators upon which he does rely. Napp itself has not, in the notice of appeal, put forward any other comparators.

402. On those facts we are satisfied that Napp "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", so as to satisfy the test of abuse as laid down by the Court of Justice in *United Brands* at paragraph 249 of its judgment.

403. To put the matter in terms of the principle set out at paragraph 203 of the Decision, in our view the above facts demonstrate (i) that, during the period of the infringement, Napp's prices in the community segment were significantly higher than would be expected in a competitive market; and (ii) that, during the period of the infringement, there was no significant competitive pressure to bring them down to competitive levels, nor was there likely to be over any reasonable time scale.

404. For the reasons we have already given at paragraphs 301 to 306 above, we do not think that there was any significant competitive change in the market circumstances during the period of the infringement as compared with the period prior to 1 March 2000.

405. The fact that the Director has not, in the Decision, precisely quantified by how much he considers Napp's prices in the community segment to be excessive, leaving it over to the Directions to order an appropriate reduction, does not in our view alter the fact that, measured by a number of different yardsticks which all yield the same result, Napp's prices in the community segment were well above the levels to be expected in conditions of normal competition, during the period of infringement.

Napp's defence based on the PPRS

406. To rebut the Director's conclusion, Napp puts forward three main arguments based on the PPRS and the nature of the pharmaceutical industry: (i) that whether the price of MST is excessive

cannot be judged without knowing the size of Napp's initial investment in that product and its expected volume of sales; (ii) that the PPRS is a sufficient control over the price of MST; and (iii) that the Director has failed to take into account the need for "portfolio" pricing: see paragraphs 353 to 361 above.

407. As to the first of these arguments, Napp's original investment in MST was made in the early 1980s in launching and promoting a product which, at the time, represented an important innovation. Napp has provided no figures as to what that initial investment was. In the absence of any indication to the contrary, we would expect that initial investment to have been recouped long ago, as the Director found at paragraph 233 of the Decision. Nera's report of 29 May 2001 *Analysis of OFT Decision on Excess Pricing of MST* is to the same effect "If the OFT had carried out an assessment of the costs associated with the development and launch of MST and the subsequent returns (which it has not) it is likely that it would have found that the product has done more than compensate Napp for their investments" (p.3). We do not think that the Director can fairly be criticised for not having further investigated this point in circumstances where Napp has produced no credible evidence to suggest that its initial investment has not been recouped. We therefore reject any argument that the price of MST might be justified, during the period of infringement, by the initial investment made many years ago.

408. As regards Napp's second argument that the PPRS is a sufficient control on the price of MST, we have no solid information as to the basis on which the Department of Health allegedly approved the initial launch price of MST in 1980. It is common ground that the PPRS principally controls a company's overall ROC and does not, in that connection, concern itself with individual products. On the information provided by Napp, we are unable to evaluate whether, in 1980, the price of MST really was significantly constrained by the success of Phyllocontin, and we note that Napp did receive a price increase for MST in 1983. We note also Mr Brownlee's statement that, under the PPRS, Napp could have increased the price of MST in 1993 but did not do so. In all those circumstances, it is unclear whether the PPRS has ever had a significant effect as regards the original price of MST. In any event, in our view, the effect of the PPRS in the original launch price of MST in 1980 is not relevant to the issue which we have to decide, which is whether Napp has maintained the price of MST above the competitive level contrary to the Chapter II prohibition during the period of infringement after 1 March 2000. In our view it has, for the reasons already given in paragraphs 393 to 405 above.

409. The essence of the third argument put forward by Napp is that, in an industry, such as the pharmaceutical industry, in which relatively few successful drugs must fund the research and development costs of many unsuccessful drugs, and the ongoing research costs of new products yet to be discovered, it is wrong to look at the margins of a single successful product and deem those margins, standing alone, to be excessive. The only sensible approach in such an industry, argues Napp, is to look at the company's prices and profits over a portfolio of products and then judge whether its return on investment is reasonable on that portfolio basis. That is precisely what the PPRS does. Accordingly, says Napp, a company whose ROC is well within the limits of the PPRS cannot be judged to have charged excessive prices on a single product.

410. We note that the PPRS is a voluntary, non statutory scheme. According to the 1999 version, its purpose is to:

> "— Secure the provision of safe and effective medicines for the NHS at reasonable prices.
>
> — Promote a strong and profitable pharmaceutical industry capable of such sustained research and development as should lead to the future availability of new and improved medicines.
>
> — Encourage the efficient and competitive development and supply of medicines to pharmaceutical markets to this and other countries."

411. In our view there are several reasons why Napp's arguments based on 'portfolio pricing' under the PPRS must be rejected.

412. First, as already stated, the PPRS is primarily directed to ensuring that a pharmaceutical company does not exceed the permitted ROC on the totality of its NHS business. The PPRS is not directed to the question whether or not the price of an *individual product* sold in a market where there is dominance is above the competitive level, which is the essential question in the present case. In our view, the fact that a pharmaceutical company is subject to the PPRS does not, of itself, give that company any kind of exemption from the Chapter II prohibition in general, or from section 18(2)(a) in particular, as regards the prices of *individual products*.

413. In so far as Napp argues that its prices for MST cannot be excessive under the Chapter II prohibition simply because it is subject to the PPRS, any such argument has, in our view, no foundation in law or logic. In our judgment that argument, and indeed 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 on other, unspecified, markets comprised in some wider but undefined "portfolio" unrelated to the market in which dominance exists.

414. Secondly, the PPRS is not intended to guarantee a company the right to earn profits up to the limits of the scheme. Thus, as the Director points out, the 1st Report to Parliament on the PPRS (1996) at paragraphs 4.73 and 4.76 states:

> "The PPRS does not guarantee a company a particular level of sales, or a particular level of profit associated with those sales, for a number of reasons…"
>
> "… a company facing competing products may not be in a strong position to increase prices as a way of generating additional revenue, unless it has other products in its portfolio facing little therapeutic competition."

415. As Mr Brownlee points out in his witness statement, an underlying assumption of the PPRS is that member companies comply with the prevailing laws of the United Kingdom. Since 1 March 2000 those laws have included the Competition Act 1998.

416. Thirdly, we agree with the Director's view, at paragraph 209 of the Decision, that a manufacturer with an innovative product cannot demand or expect prices to remain at excessively high levels indefinitely. Indeed, one of the principal purposes of the patent system is to confer a degree of exclusivity, thus enabling companies to recover substantial research and development costs and investment in new medicines: see the 3rd Report to Parliament on the PPRS (1999) at paragraph 1.1(ii). In the present case, it is now 20 years since the launch of MST, and Napp's formulation patent expired 10 years ago.

417. We do not accept that, after such a long period, the price of MST can credibly be defended on a 'portfolio pricing' theory. The evidence we have is that, in the case of many pharmaceutical products, the expiry of a patent leads to competitive (often generic) market entry, with the consequence that the incumbent supplier either lowers prices, or loses market share, or both, perhaps quite rapidly: see paragraph 287 above. In the present case, however, Napp has maintained *both* the price of MST *and* an exceptionally high market share for many years. Neither

the remarks of Advocate General Reischl in *Coditel II*, nor the Monopolies and Mergers Commission Report *The Supply of Recorded Music*, seem to us to be relevant to the present case.

418. Fourthly, the Department of Health has not, as it could have, intervened in this case. We would have expected the Department to have intervened, had it thought that the Director's approach undermined either the objectives of the PPRS, or jeopardised the successful development of the United Kingdom pharmaceutical industry. The Department has, on the contrary, provided Mr Brownlee's witness statement to the Director in which no such views are expressed.

419. Mr Brownlee, in his witness statement, emphasises notably that the PPRS does not contain any requirement for member companies to undertake R&D as a condition of membership of the scheme, and that it is unlikely that companies would do so specifically for the United Kingdom market, which represents only a small proportion of the world market for medicines. He also points out that the PPRS contains no assurance that Napp would not be penalised for an abuse of dominance under the Act as long as it observed the terms of the PPRS, and that no such assurance has been given. Nor does Mr Brownlee accept Napp's argument that it is normal business practice for suppliers of leading brands to maintain their list prices after patent expiry and to offer differential discounts. Mr Brownlee states that the Department of Health expects suppliers to respond to whatever market pressures exist after a patent expires.

420. Fifthly, in our view, the PPRS is not intended to permit a company to maintain excessive differentials on its sales to different parts of the NHS. In the present case, Napp has been able to exploit its dominance to the extent that, on certain strengths of tablet, it can charge on average over 1400 per cent more, when a prescription is dispensed by a community pharmacist, than it can when *the same prescription, for the same patient,* is dispensed in a hospital. We do not think that the PPRS can credibly be put forward as a justification for maintaining, in the community segment, high prices which result in differentials on that scale.

421. Sixthly, in our view, we do not think that arguments based on the PPRS have any application where the lack of competitive pressure on the prices concerned is due, to an appreciable extent, to anti-competitive practices by the dominant undertaking concerned. A key feature of the present case is that Napp's high prices in the community segment do not represent a competitive market outcome but, on the contrary, occur in circumstances where, throughout the period of infringement, Napp's discounts to hospitals substantially hindered competitive entry: see Section VII above. Whatever

the public interest arguments may be for the PPRS, those arguments do not seem to us to be relevant to the justification of an excessive price in circumstances where it is the undertaking's own anti-competitive activities which have, to a material extent, prevented any significant competitive pressure being brought to bear on the price in question. To seek to justify such a price on the basis of the PPRS is in our view to move wholly outside the objectives of the PPRS and to bring the PPRS into potential conflict with the Act.

422. It is clear, from the Decision, that the Director considered that Napp's prices in the community segment were not subject to competitive forces, and that that was due, to a material extent, to Napp's hospital discounting policy. Thus the Director maintained, in the Decision, that Napp's pricing policy "has to be considered as a whole" (paragraphs 142 and 236). In finding that the hospital segment plays a central role in facilitating entry (e.g. paragraphs 111 and 162), and that Napp's hospital discounting policy had hindered competition in that segment (paragraphs 145 to 202) the Director also found that the object and effect of that policy was to protect Napp's prices in the community segment. Thus:

> "These margins [in the community segment] result from a lack of competition in the community segment which, in turn, results from the anti-competitive effects of Napp's discounting behaviour in the hospital segment." (paragraph 151)
>
> "Napp cannot therefore justify a policy of loss leading [in the hospital sector] except in so far as cutting hospital prices below AVC denies a competitor the opportunity to establish itself in the community sector and thereby allows Napp to continue to earn high margins in that sector." (paragraph 194)
>
> "That Napp can earn high compensating margins in the community segment ... is because its discount policy in the hospital segment has hindered competition in the community segment. ... The object and effect of the low pricing in the hospital segment is indeed to protect and take advantage of Napp's near monopolist position [in the community segment]." (paragraph 195)
>
> "It is only in the community segment where buyers are less price sensitive and where there is an absence of effective price competition, partly as a consequence of Napp's conduct, that Napp can sustain a premium of 40 per cent on competitors." (paragraph 211)
>
> "That Napp has sustained these higher margins without stimulating successful new entry is due, at least in part, to its exclusionary pricing policies in the hospital segment of the market." (paragraph 228)
>
> "Napp has maintained excessively high margins on the sale of MST in the community segment of the market without effective competition from successful new entry. This is due, at least in part, to Napp's exclusionary pricing practices in the hospital segment." (paragraph 232)

> "The lack of successful entry in this case is in part due to Napp's exclusionary practices in the hospital segment of the market." (paragraph 225)

423. The same conclusion flows from our own findings in Section VII above. In those circumstances, so it seems to us, the PPRS is wholly irrelevant. In our judgment, the fact that a company does not exceed the limit on ROC allowable under the PPRS across the range of its products, does not constitute a defence to a charge of excessive pricing contrary to the Chapter II prohibition if that price has been maintained above the competitive level and has, to a material extent, been shielded from competition by the anti-competitive practices of the undertaking concerned.

424. This latter consideration does not, in our view, imply that Napp's hospital discount policy is in some sense an "ingredient" of the abuse of excess pricing. The fact that Napp's prices in the community segment were protected by the hospital discount policy is simply one further reason for rejecting Napp's defence based on the PPRS. The abuse of excessive pricing consists of maintaining prices higher than would be expected in a competitive market, in circumstances where there is no significant competitive pressure to bring them down to competitive levels, nor likely to be. In our judgment, the relevance of Napp's hospital pricing to the abuse of excessive pricing in the present case is simply to show that Napp's reliance on the PPRS by way of defence is unfounded.

425. The point that the PPRS has little, if any, relevance since the excessive price complained of in this case has been protected by Napp's hospital discounting policy was canvassed, in one form or another, before the Tribunal, in the course of the appeal. We take that point into account as a further reason for rejecting Napp's reliance on the PPRS, arising out of facts and matters found by the Director in the Decision.

426. The fact that one reason why we reject Napp's reliance on the PPRS is because Napp itself has hindered competition in the community segment by its hospital discounting policy does not in our judgment involve any 'retroactive' application of the Act to some period prior to 1 March 2000. As at 1 March 2000, Napp's prices in the community segment were above the competitive level, and not subject to competitive pressure. The abuse of excessive pricing consists in maintaining those prices at levels above the competitive level as and from that date.

427. It follows, for the reasons already given, that Napp committed the abuse of excessive pricing during the period of infringement found in the Decision.

The Director's alleged "change of case"

428. We do not think that the foregoing analysis is affected by Napp's arguments that the Director has impermissibly "changed his case", notably in paragraphs 16 and 17 of the defence.

429. In the first place, our principal task is to decide the appeal "on the merits". In exercising that jurisdiction, our starting point must be what the Decision itself says. For the reasons already given, we are satisfied that an abuse of excessive pricing by Napp in the community segment may properly be found on the basis of the facts and matters set out in the Decision. In our view, that is the end of the matter.

430. In any event, what the Director stated at paragraph 17 of the defence was that he would not wish to maintain the abuse of excessive pricing in the community segment in circumstances where the Tribunal found that there had been no exclusionary conduct in the hospital segment. Since the Tribunal has found that there *was* exclusionary conduct in the hospital segment the concession set out in paragraph 17 of the defence simply falls away.

431. If, contrary to the above, it is necessary to examine whether the Director did, in the defence, move away from what he said in the Decision, we find as follows.

432. According to the explanation given to us at the hearing of the appeal, the wording in the defence was intended to distinguish the present case, where the allegedly excessive pricing was protected by exclusionary conduct, from a case in the pharmaceutical industry where no exclusionary conduct was alleged. In view of the fact that the pharmaceutical industry is regulated by the PPRS, a case of alleged excessive pricing by a pharmaceutical company, in which there was *no* suggestion of any exclusionary conduct, would, in the Director's view, be a different case, and would require a more detailed and complex analysis than the Director felt it necessary to undertake for the purposes of the present Decision.

433. Looked at in this light, the essence of the Director's position before the Tribunal seems to us to be that, in this case, Napp's defence under the PPRS does not bear examination because, among other reasons, the excessive prices in the community segment have been protected by exclusionary conduct in the hospital segment. That is the point which we have ourselves accepted at paragraphs 421 to 423 above.

434. What in our view the Director was really saying to us was that the hospital pricing abuse created the conditions in which the community pricing abuse could take place, which is not significantly different from what is said in the Decision. If, in the defence, the Director intended to go further and say that the excessive pricing in the community segment was abusive *only* because of Napp's exclusionary conduct in the hospital segment, any such view would have been erroneous in law. Nothing in *United Brands* suggests that the existence of exclusionary conduct is a prerequisite to a finding that prices are excessive contrary to the Chapter II prohibition.

435. However the defence is to be read, we do not accept Napp's argument that the Director's position in the defence implies that he has impermissibly taken account of Napp's actions prior to 1 March 2000 and thus applied the Act retrospectively, contrary to Article 7 of the ECHR. As we see it, neither the Decision, nor the defence, alleges any infringement committed before 1 March 2000.

436. Even if, in the defence, the Director were saying that Napp's prices in the community segment were abusive because they were maintained in the context of Napp's exclusionary pricing policy in the hospital segment, it is not necessary to rely on Napp's conduct prior to 1 March 2000 to establish that, as from 1 March 2000 (i) Napp's prices in the community segment were above the competitive level, and (ii) that such prices were, on and after that date, protected from competition by exclusionary pricing in the hospital segment. Point (i) is established by the matters set out at paragraphs 390 to 405 above and point (ii) is established by the matters set out in section VII above.

437. Thus Napp's contention that it is impossible to know what price it would have charged in the community segment on 1 March 2000, had it not engaged in allegedly anti-competitive conduct prior to that date, is irrelevant. The question is whether the price that Napp was *in fact* charging in the community segment was above the competitive level, whether or not protected by exclusionary conduct, in the period from 1 March 2000 to 30 March 2001.

438. Nor is it necessary, in order to establish the abuse of excessive pricing, to speculate on what might have happened in the market place if Napp had raised its hospital prices on 1 March 2000. Napp did not raise its hospital prices on 1 March 2000 so the issue does not arise. Moreover, we are concerned with what the prices actually were, and not what they might have been in other hypothetical circumstances.

439. The same applies to Napp's argument that, even if it had raised hospital prices on 1 March 2000, it is unlikely that its community price would have been any different during the period of the infringement. Again, the point is that Napp did *not* raise its hospital prices on 1 March 2000. Thus it is impossible to know how competition would have developed in those new circumstances and what the strategies of Napp, its competitors, and the relevant purchasing authorities would have been. We decline to rule out the possibility that Napp would, in these hypothetical circumstances, have reduced its community prices. But we do not need to consider the various hypothetical alternatives because Napp's prices were not, in fact, subject to competitive pressures in the period from 1 March 2000 to 30 March 2001, and remained throughout that period at levels we have found to be excessive.

440. Finally, Napp argues that the case as made by the Director in the defence suggests that Napp's conduct in the hospital segment affected all sales in the community segment, contrary to what is suggested in paragraph 167 of the Decision. As we have already held, the result of Napp's hospital discount policy was to affect, at least indirectly, the whole of the community segment by preventing new entry and the competitive pressure on Napp's prices in the community segment that such new entry would bring: see paragraphs 282 to 283 above. In this respect we do not think that the way the Director pleaded the abuse of excessive pricing in the defence involved a material change to the general thrust of the Decision, as shown by the extracts cited in paragraph 422 above, albeit that paragraph 167 of the Decision is not drafted very satisfactorily.

441. It follows that little, if anything, turns on the wording of the defence, despite the time and effort devoted to argument on this aspect both at the final hearing and at the earlier stage of Napp's application to strike out the defence.

Conclusion

442. For all those reasons, we find that Napp has abused its dominant position in the supply of tablets and capsules of oral sustained release morphine in the United Kingdom by charging excessive prices to customers in the community segment of that market, as the Director found in paragraph 236(b) of the Decision.

IX — THE PENALTY

A: INTENTIONALLY OR NEGLIGENTLY

Arguments of the parties

443. Napp contends, in the alternative, that even if it has committed an infringement of the Act, it did not do so intentionally or negligently and that accordingly, pursuant to section 36(3) of the Act, the Director was not entitled to require Napp to pay him a penalty.

444. Napp argues in the notice of appeal (paragraph 5.57) that in order to establish an infringement committed intentionally or negligently it would have to be shown that Napp was aware, or ought to have known, that its hospital prices were not subject to sufficient constraints by other suppliers to keep them within reasonable limits; that Napp was aware that, or ought to have known, the PPRS was not effective to ensure that its community prices remained within reasonable limits; and that Napp was aware, or ought to have known, that it had resorted to methods of competition which were abnormal and could not be regarded as a form of competition on the merits. Napp argues that there is a relevant analogy with the *mens rea* requirement in cases of theft, citing *R v Ghosh* [1982] 2 QB 1053, HL.

445. Napp further submits, in reliance on the witness statements of Mr Manners and Mr Brogden, that:

> "(i) Napp has at all material times believed that the PPRS was effective to prevent it from charging excessive prices and that, provided that Napp observed the terms of the PPRS, its pricing of MST to the NHS would not be regarded as excessive.
>
> (ii) Napp has at all material times believed that it was normal and acceptable commercial practice for a supplier of a leading brand of a pharmaceutical product, facing competition from new entrants, and with no patent protection, to maintain the NHS list price of its product, and to offer differential discounts to different buyers according to their willingness to pay, in the manner and to the extent that Napp has offered discounts against the list price of MST.
>
> (iii) Napp did not believe that, by offering substantial discounts against the list price of MST to hospital buyers, it would thereby incur incremental losses. It believed that sales of MST to hospital buyers would result in incremental profits to Napp, when account was taken of the effects which hospital sales could be expected to have in maintaining or increasing sales of MST in the community segment of the market. Prior to the commissioning of the Internet Survey at document A18, Napp did not, however, seek to quantify the extent of any such linkages between hospital and community sales. Napp believed that it was normal commercial practice to offer discounts to hospitals which took account of linkages between hospital and community sales. Nor did Napp have any reason to believe

> otherwise: Napp observed that other firms were offering discounts which were suggestive that those other firms were also competing on that basis. Napp did not believe that it could expect to secure greater linkages between hospital and community sales than other suppliers of oral sustained release morphine."

(paragraph 5.58 of the notice of appeal, as substituted.)

446. Napp also submits that the Director failed as the Act requires to address his mind to the question of whether the infringement was committed intentionally rather than negligently, or vice versa, and that the infringement was novel (notice of appeal, paragraph 5.60).

447. In its skeleton argument for the hearing, Napp further contends that changes in the Director's case show that Napp could not reasonably have been expected to have known that its conduct would have anti-competitive effects. According to Napp: (i) the Director has changed his case several times regarding the extent of the foreclosure brought about by Napp's conduct in the hospital segment of the market, (ii) the Director changed his case by abandoning during the administrative procedure the allegation in his first Rule 14 Notice that differential pricing between the hospital and community segments of the market was itself an abuse, (iii) the Director has changed his case in relation to the availability of linkages to Napp and other suppliers, and (iv) Napp used the net revenue test endorsed by OFT 414 (paragraph 4.16) and was entitled to assume that such an approach was lawful.

448. Napp also submits that the reforms introduced by the Health Act 1999 mean that the market remains "in a state of flux". Napp suggests that it was merely responding to "circumstances beyond its control", in the hospital segment to the pressure imposed by the NHS purchasing authorities, and in the community segment to pressure from the Department of Health in the form of the PPRS. Finally, Napp suggests that the circumstances it was responding to are now addressed by the Health Act reforms. Napp should not be punished if those reforms have not yet fully unfolded.

449. The Director submits that the question whether an infringement was "intentional or negligent" under section 36(3) of the Act is a threshold question which "corresponds" to the position under Article 15(2) of Council Regulation 17. In order to cross that threshold, the Director does not have to determine whether an infringement was intentional rather than negligent or vice versa. Once the Director is satisfied that the threshold criteria for imposing a penalty are satisfied, he can then turn to consider the appropriate level of penalty having regard to his guidance issued under section 38

of the Act. Paragraph 7.3 of the Director's *Guidance as to the Appropriate Amount of the Penalty* (OFT 423) ("the *Director's Guidance*") states that "Mitigating factors include: … infringements which are committed negligently rather than intentionally."

450. The Director submits that it is not necessary for an undertaking to have been aware that it was infringing the Act for an infringement to be regarded as having been committed intentionally. It is sufficient that it could not have been unaware that the contested conduct had as its object or effect, or could have had as its effect, the restriction of competition: e.g. by way of example Case T-65/89 *BPB Industries and British Gypsum v Commission* [1993] ECR II-389, paragraph 165; see also: Case T-77/92 *Parker Pen v Commission* [1994] ECR II-549, paragraph 81; Case 100/80 *Musique Diffusion Française v Commission* [1983] ECR 1825, paragraph 112; Case 85/76 *Hoffman La Roche v Commission*, cited above, at paragraph 39.

451. To establish that the infringements in this case were committed intentionally or negligently the Director relies on paragraphs 241 to 246 of the Decision. He also points out that as Napp did not in fact set its hospital prices by reference to any follow-on effect or other objectively justified factor, Napp must have realised that its practice could have an exclusionary effect. As to the specific points made by Napp, the Director argues notably (i) that there was no basis for Napp to assume that the PPRS shielded it from anti-competitive conduct infringing the Act; (ii) Napp must be taken to have been aware that differential discounting to a level below cost can be anti-competitive conduct for a dominant company; and (iii) that such an infringement cannot be considered novel. Finally, in his skeleton argument the Director now relies on certain of the documents disclosed by Napp pursuant to the Tribunal's request of 31 August 2001.

Law

452. The Director's power to require Napp to pay him a penalty in respect of Napp's infringement of the Chapter II prohibition is set out in section 36(2) of the Act. Section 36(3) provides that the Director may impose such a penalty "only if he is satisfied that the infringement has been committed intentionally or negligently by the undertaking". If the penalty is challenged before this Tribunal, in our judgment the Tribunal itself must be satisfied that the infringement was committed "intentionally or negligently".

453. Article 15(2) of Council Regulation no. 17 provides that the Commission may impose fines on undertakings where "either intentionally or negligently they infringe Article 81(1) or Article 82 of the Treaty". In Case C-137/95P *SPO and others v Commission* [1996] ECR I-1611, the Court of Justice held, in effect, that the requirement set out in Article 15(2) of the Council Regulation no.17 that a fine for an infringement of Article 81(1) or 82 may be imposed only if the infringement was committed "intentionally or negligently", is a threshold condition which must be fulfilled in order to impose a fine. However, in determining whether that threshold condition is met, the Commission is not required to decide whether the infringement was committed intentionally or negligently, so long as it is satisfied that the infringement was *either* intentional *or* negligent. Having decided that the threshold is crossed, i.e. that the infringement was *either* intentional *or* negligent, it is then for the Commission to assess the gravity of the infringement, taking into account its duration and all other relevant factors, in accordance with the last sentence of Article 15(2) of Council Regulation no.17, which provides "In fixing the amount of the fine, regard should be had both to the gravity and to the duration of the infringement".

454. It is true that section 36(3) of the Act does not, unlike Article 15(2) of the Council Regulation no.17, expressly refer to the need to take into account, when fixing the penalty, the gravity and duration of the infringement. Under the Act, the matters to be taken into account in fixing the amount of the penalty are required to be set out in the *Director's Guidance* published under section 38. Paragraph 2.12 of that *Guidance* states that the fact that an agreement was committed negligently, rather than intentionally, is to be regarded as a mitigating factor.

455. In our view the slightly different structure under sections 36 and 38 of the Act, as compared to Article 15(2) of Council Regulation no.17, does not constitute a relevant difference between the provisions concerned for the purposes of section 60 of the Act. In those circumstances, and having regard to our general duty under section 60 to apply the Act consistently with the principles of Community law, in our judgment we should follow the decision of the Court of Justice in *SPO and others v Commission*, cited above. It follows that we uphold the Director's submission that, in order to impose a penalty under section 36(3), he has to be satisfied, as a threshold matter, that the infringement was either intentional, or negligent. However, he does not, for the purposes of crossing that threshold, have to determine specifically which it was. He may well have to do so, however, at the subsequent stage of his appraisal when he is considering the gravity of the infringement.

456. As to the meaning of "intentionally" in section 36(3), in our judgment an infringement is committed intentionally for the purposes of the Act if the undertaking must have been aware that its conduct was of such a nature as to encourage a restriction or distortion of competition: see *Musique Diffusion Français*, and *Parker Pen*, cited above. It is sufficient that the undertaking could not have been unaware that its conduct had the object or would have the effect of restricting competition, without it being necessary to show that the undertaking also knew that it was infringing the Chapter I or Chapter II prohibition: see *BPB Industries and British Gypsum*, cited above, at paragraph 165 of the judgment, and Case T-29/92 *SPO and Others v Commission* [1995] ECR II-289, at paragraph 356. While in some cases the undertaking's intention will be confirmed by internal documents, in our judgment, and in the absence of any evidence to the contrary, the fact that certain consequences are plainly foreseeable is an element from which the requisite intention may be inferred. If, therefore, a dominant undertaking pursues a certain policy which in fact has, or would foreseeably have, an anti-competitive effect, it may be legitimate to infer that it is acting "intentionally" for the purposes of section 36(3).

457. As to "negligently", there appears to be little discussion of this concept in the case law of the European Community. In our judgment an infringement is committed negligently for the purposes of section 36(3) if the undertaking ought to have known that its conduct would result in a restriction or distortion of competition: see *United Brands v Commission*, cited above, at paragraphs 298 to 301 of the judgment. For the purposes of the present case, however, we do not need to decide precisely where the concept of "negligently" shades into the concept of "intentionally" for the purposes of section 36(3), nor attempt an exhaustive judicial interpretation of either term.

458. In view of our obligations under section 60 of the Act, and the Community case law relating to Article 15(2) of Council Regulation no.17, we do not think it useful to import into section 36(3) the concept of 'mens rea' as found in domestic criminal law.

Findings on intentionally or negligently

Discounts to hospitals

459. At paragraph 241 of the Decision the Director held that Napp's infringement of the Chapter II prohibition in relation to discounts to hospitals was committed "intentionally, or at the very least

negligently". As we have just held, the Director was not, at this stage of the analysis, obliged to specify whether he considered the infringement to be intentional or merely negligent.

460. The Director was, however, obliged to set out the reasons for his conclusion. After holding, in paragraph 242, that Napp was aware of its strong market position and the high barriers to entry facing rivals, the Director continued at paragraphs 243 and 244 of the Decision:

> "243. Napp was similarly aware of the strategic importance of the hospital segment for new competitors and potential entrants. It must therefore have been aware that its discounts to hospitals would have the effect of reducing the ability of competitors to gain market share in the hospital and community segments of the market, and could lead them to exit the market altogether. That this was Napp's intention is shown the more clearly by the fact that its prices to hospitals were below direct cost and by its having adjusted discounts on particular products and in respect of supplies to particular hospital regions according to the amount of competition it faced.
>
> 244. The Director is satisfied therefore that Napp's conduct had as its object the restriction of competition. He is equally satisfied that Napp was aware that its actions would be, or, at the very least, would be reasonably be likely to be, restrictive of competition, but was still prepared to carry them out. Furthermore, contrary to Napp's representations, Napp cannot have been unaware of the exceptional magnitude of the discounts it was offering to hospitals or of the asymmetry between its position in the market and that of its competitors. It must therefore have been aware that it would not be possible for competitors to engage in similar pricing behaviour over the long term."

461. For the reasons already given in Section VII above, we entirely agree with the Director's findings in paragraphs 243 and 244 of the Decision. In our judgment, it follows from the findings we have already made in section VII above, that Napp's infringement of the Chapter II prohibition in relation to discounts to hospitals was committed intentionally within the meaning of section 36(3) of the Act. The Director himself held that Napp had the intention to eliminate competition: paragraph 236(a), last sentence.

462. As regards the various contrary arguments put forward by Napp, we have already found that Napp itself did not set its hospital prices by reference to any alleged narrow or mechanistic follow-on effect. Whether or not Napp believed that its hospital sales were in some sense "profitable" when the effects in the community segment are taken into account, is in our view irrelevant, since we are satisfied that Napp's intention was to exclude competitors from the hospital segment for as long as possible. We do not accept that Napp believed, or could reasonably have believed, that the conditions of competition were similar as between Napp and its competitors during the period of

infringement. We do not regard sustained pricing below direct cost by a superdominant enterprise enjoying a virtual monopoly 20 years after the launch of the product as in any sense "normal competition" or "legitimate commercial usage", as those terms are understood in Community or domestic competition law.

463. The same applies to selective discounting in the hospital segment by Napp, a superdominant enterprise, with the aim of protecting its monopoly in the community segment. In our judgment nothing in the structure of the NHS compelled Napp to act as it did or give rise to circumstances "beyond its control". The reforms of the Health Act 1999 were not material during the period of infringement. In our judgment, Napp's "net revenue" defence is and always was conceptually flawed and factually unsustainable for the reasons we have already given. We see no novelty in the infringement, given the decisions of the Court of Justice in *AKZO*, *Tetra Pak II* and *Compagnie Maritime Belge*. Napp's arguments as to alleged changes in the Director's case do not alter the overwhelming inference, to be drawn from the evidence as a whole, that Napp's hospital discounting policy was pursued with the deliberate intention of eliminating, or at least severely hindering, competition.

464. In all those circumstances in our judgment the infringement of the Chapter II prohibition consisting in low prices to hospitals was committed by Napp intentionally within the meaning of section 36(3).

Excessive prices

465. At paragraph 246 of the Decision the Director finds:

> "246. Napp has maintained high prices in the community segment of the relevant market in the full knowledge of its own very high market share, its profit margins on such sales, its competitors' prices, the preference for its brand on the part of the GPs, and their lack of price sensitivity. The Director therefore considers that Napp's infringement in respect of its excessive prices to the community was, for the purposes of section 36 of the Act, intentional or, at the very least, negligent."

466. There is little guidance in Community law as to the meaning of "intentionally or negligently" in the context of the exploitative abuse of maintaining unfairly high prices. In our judgment, it must be shown that the dominant undertaking either knew (in the sense that it could not have been unaware), or ought to have known, that it was, without objective justification, maintaining prices

above the levels that would prevail in conditions of normal competition. In this case Napp knew that it had a virtual monopoly in the community segment. Napp also knew that the price of MST was not subject to competitive pressure in the community segment. Napp, however, maintained the price of MST knowing that that price was (i) around 40 per cent above that of its competitors; (ii) on average over 1400 per cent above its price to hospitals on 10mg, 30mg, 60mg and 100mg tablets; and (iii) up to [...] [in excess of 500] per cent above its export prices on those tablets. Napp also knew that its gross profit margin was some [...] [in excess of 80]per cent, well above its average NHS margin.

467. On those facts, in our judgment, Napp at least ought to have known, that (i) it was a dominant undertaking; (ii) it was maintaining prices in the community segment well above competitive levels, and (iii) that those prices were not subject to significant competitive pressure.

468. Although the point is not made in paragraph 240 of the Decision, that conclusion is reinforced by our finding that Napp's pricing in the hospital segment was designed to prevent competitors from entering the market. Since BIL and Link both have (or had) lower prices than Napp in the community segment, Napp must have known that, once those competitors became established, its prices in the community segment would come under pressure. In our judgment, the natural inference is that Napp intended to do everything it could to maintain its community prices at levels above those which would prevail in competitive conditions. That inference is drawn by the Director himself in several places in the Decision, as the citations in paragraph 422 above show.

469. As to whether Napp knew or ought to have known that it had no objective justification for maintaining prices at those levels, Napp argues, in essence, that the abuse of excessive pricing could not have been committed "intentionally or negligently" because it reasonably thought its prices were not abusive so long as they remained within the limits of the PPRS. Furthermore, the Director varied his case in the administrative procedure, initially alleging that Napp's community prices should be aligned with its hospital prices, then alleging that Napp's community prices should be reduced by 20 per cent, and then finally settling on a reduction of 15 per cent. Before the Tribunal, says Napp, the Director has further shifted his case on excessive pricing, now alleging that the abuse in the community segment exists in consequence of Napp's hospital pricing.

470. In our view Napp ought to have realised, on reasonable reflection, that its arguments of objective justification based on the PPRS were unfounded, for the reasons we have given at paragraphs 390

to 427 above. Moreover the fact that the Director's case has developed in the course of the proceedings does not alter the fact that, objectively speaking, Napp maintained prices in the community segment that it at least ought to have known were well above competitive levels and protected from competition. We do not accept that the question of "intentionally or negligently" under section 36(3) of the Act depends on whether or not the undertaking was told by the Director how to conduct its business. In the present case reference to *United Brands*, at paragraphs 248 to 253 of the judgment, cited above, would or should have put Napp on notice of the possibility that it was reaping trading benefits in the community segment "which it could not have reaped if there had been normal and sufficient competition".

471. On those facts, it seems to us, the abuse of excessive pricing was committed by Napp, at the least, negligently, within the meaning of section 36(3) the Act.

472. On the other hand, we consider that there is mitigation available to Napp on the excessive pricing abuse, which we deal with below.

B: THE AMOUNT OF THE PENALTY

The Director's Guidance

473. In the Decision, the Director has set the penalty by reference to the "five step" approach set out in the *Director's Guidance*, published under section 38 of the Act with the approval of the Secretary of State: section 38(4). The Director is obliged by section 38(8) to have regard to that guidance.

474. According to paragraph 1.8 of the *Director's Guidance*:

> "The twin objectives of the Director's policy on financial penalties are to impose penalties on infringing undertakings which reflect the seriousness of the infringement and to ensure that the threat of penalties will deter undertakings from engaging in anti-competitive practices. The Director therefore intends, where appropriate, to impose financial penalties which are severe, in particular in respect of agreements between undertakings which fix prices or share markets and other cartel activities, as well as serious abuses of a dominant position, which the Director considers are among the most serious infringements caught under the Act. The deterrent is not aimed solely at the undertakings which are subject to the decision, but also at other undertakings which might be considering activities that are contrary to the Chapter I and Chapter II prohibitions."

475. According to the *Director's Guidance*, section 2, the first 'step' in fixing a penalty (Step 1) is to apply a percentage rate, up to a maximum of 10 per cent, to the "relevant turnover" of the undertaking. The "relevant turnover" is not a statutory concept but is defined by the Director in his *Guidance* as the turnover in the relevant product market and relevant geographic market affected by the infringement in the last financial year.

476. Paragraphs 2.3 and 2.4 of the *Director's Guidance* state:

> "2.3 The starting point for determining the level of financial penalty which will be imposed on an undertaking is calculated by applying a percentage rate to the "relevant turnover" of the undertaking, up to a maximum of 10%. The "relevant turnover" is the turnover of the undertaking in the relevant product market and relevant geographic market affected by the infringement in the last financial year. This may include turnover generated outside the United Kingdom if the relevant geographic market for the relevant product is wider than the United Kingdom.
>
> 2.4 The actual percentage rate which will be applied to the "relevant turnover" will depend upon the nature of the infringement. The more serious the infringement, the higher the percentage rate is likely to be. Price-fixing or market-sharing agreements and other cartel activities are among the most serious infringements caught under the Chapter I prohibition. Conduct which infringes the Chapter II prohibition and which by virtue of the undertaking's dominant position and the nature of the conduct has, or is likely to have a particularly serious effect on competition, for example, predatory pricing, is also one of the most serious infringements under the Act. The starting point for such activities and conduct will be calculated by applying a percentage likely to be at or near 10% of the "relevant turnover" of the infringing undertakings."

477. The second 'step' (Step 2), according to the *Director's Guidance*, is an "adjustment for duration". Under that step, penalties for infringements which last for more than one year may be multiplied by not more than the number of years of the infringement.

478. Step 3, entitled "adjustment for other factors", is intended, to enable the Director to increase the penalty arrived at under Steps 1 and 2, in particular to achieve the necessary deterrent effect. Paragraphs 2.8 and 2.9 of the *Director's Guidance* provide:

> "2.8 The penalty figure reached after the calculations in steps 1 and 2 may be adjusted as appropriate to achieve the policy objectives, outlined in paragraph 1.8 above, in particular, of imposing penalties on infringing undertakings in order to deter undertakings from engaging in anti-competitive practices. The deterrent is not aimed solely at the undertakings which are subject to the decision, but also at other undertakings which might be considering activities which are contrary to the Chapter I and Chapter II prohibitions. Considerations at this stage may include, for example, the Director's estimate of the gain made or likely to be

made by the infringing undertaking from the infringement. Where relevant, the Director's estimate would account for any gains which might accrue to the undertaking in other product or geographic markets as well as the "relevant" market under consideration. The assessment of the need to adjust the penalty will be made on a case by case basis for each individual infringing undertaking.

2.9 This step may result in a substantial adjustment of the financial penalty calculated at the earlier steps. The consequence may be that the penalty which is imposed is much larger than would otherwise have been imposed. The result of any one of steps 2 or 3 above or 4 below may well be to take the penalty over 10% of the "relevant turnover" identified at step 1, but the overall cap on penalties is 10% of the "section 36(8) turnover" referred to in step 5 below and must not be exceeded."

479. Step 4 enables the Director to adjust the penalty arrived at under steps 1 to 3 in order to reflect other aggravating or mitigating factors. Examples are given in paragraphs 2.11 and 2.12 of the *Director's Guidance*.

480. As far as relevant for present purposes, step 5 in fixing the penalty is to ensure that the amount arrived at steps 1 to 4 does not exceed the maximum penalty permitted under The Competition Act 1998 (Determination of Turnover for Penalties) Order 2000 (SI 2000 no. 309) ("the Maximum Penalties Order"). Under section 36(8) of the Act, "no penalty fixed by the Director under this section may exceed 10 per cent of the turnover of the undertaking (determined in accordance with such provisions as may be specified in an order made by the Secretary of State)". According to Article 3 of the Maximum Penalties Order:

"3. The turnover of an undertaking for the purposes of section 36(8) is:

(1) the applicable turnover for the business year preceding the date when the infringement ended;

(2) where the length of the infringement is more than 12 months, in addition the amount of the applicable turnover for the business year preceding that identified under paragraph (1) which bears the same proportion to the applicable turnover for that business year as the period by which the length of infringement exceeds 12 months bears to 12 months; and

(3) where the length of the infringement is more than 24 months, in addition the amount of the applicable turnover for the business year preceding that identified under paragraph (2) which bears the same proportion to the applicable turnover for that business year as the period by which the length of infringement exceeds 24 months bears to 12 months;

save that the amount added under paragraph (2) or (3) shall not exceed the amount of the applicable turnover for the preceding business year in question."

The Director's approach in the Decision

481. At paragraphs 249 to 254 of the Decision the Director states under the heading "Step 1 – starting point":

> "249. The relevant product market affected by the infringements is the supply of sustained release morphine tablets and capsules in the UK. Napp's turnover in the relevant product market in the year ending 31 December 2000 was £[...] million. The Director has taken this as the relevant turnover for the purposes of calculating the starting point.
>
> 250. The actual percentage rate applied to the relevant turnover depends upon the nature of the infringement. The more serious the infringement, the higher the percentage rate is likely to be.
>
> 251. Napp has supplied sustained release morphine tablets and capsules to hospitals at significant discounts with the object and effect of preventing competitors from increasing their share of the relevant market and deterring new entry. Napp has further targeted its discounts at those areas where it faced or expected competition. The Director considers that Napp's discount policy directly restricted competition in at least a quarter of the relevant market and indirectly impaired competition in the whole of the relevant market. These discounts have therefore seriously disadvantaged Napp's competitors in competing for hospital sales and thereby further restricted and diminished competition in the hospital segment of the market. Furthermore, the hospital segment of the market is of considerable strategic importance for competitors wishing to increase sales in the larger community segment of the market. Hence Napp's discounts to hospitals have restricted and diminished competition in both the hospital and the community segments of the market.
>
> 252. Napp faces very little competition in the community segment of the market and the barriers to entry are high. Napp's prices to the community are typically some 40% higher than those of its competitors and, in most cases, over 1000% higher than the prices it charges to hospitals. They are also between [...] [in excess of 100%] and [...] [less than 700%] higher than its prices for export. In addition, its gross profit margins on community sales are in excess of [...][80%] compared to average NHS margins of around 40%. The result of Napp's conduct is a serious distortion of competition, and a considerable excess cost to the NHS and so to the taxpayer.
>
> 253. Sustained release morphine tablets and capsules are supplied for use in the final product market, rather than as an intermediate good, and the cost is borne by the taxpayer. The effects are therefore widespread.
>
> 254. The Director therefore concludes that, contrary to Napp's submissions, Napp has committed a serious infringement of the Chapter II prohibition and has taken as the starting point for determining the penalty 8% of the relevant turnover."

482. Under "Step 2 – adjustment for duration" the Director makes no adjustment since the infringement lasted little more than a year (paragraph 256 of the Decision).

483. At paragraphs 257 to 260 of the Decision the Director states under the heading "Step 3 – adjustment for other factors":

> "257. The penalty figure reached after the calculations in steps 1 and 2 may be adjusted as appropriate to achieve the Director's policy objectives of reflecting the seriousness of the infringement and deterrence. As regards the latter, the deterrent is not aimed solely at the infringing undertaking but also at other undertakings which might be considering activities contrary to the Act.
>
> 258. The Director considers that it is appropriate to make an adjustment to the penalty in order in particular to achieve his policy objective of deterrence. To achieve this objective, the Director has decided that in the present case the basis for the adjustment should be his estimate of Napp's gain from the infringements.
>
> 259. It is impossible to estimate with certainty how much lower Napp's profits would have been, or would now be, on sales of sustained release morphine tablets and capsules in the UK in the absence of the infringements. It is however clear that prices in the community segment of the market are, and have been throughout the period of the infringement, excessive and typically 40% higher than the prices charged by Napp's competitors. Moreover, it could be expected that were it not for the infringements, not only would Napp's community prices have been lower but the volume and value of its sales in the market as a whole would also have been, and would now be, lower. However, it is likely that Napp's revenues from hospital sales, representing on average 15% of the market by volume and less than 1% by value, have been less than they would otherwise have been.
>
> 260. On the basis of these findings, the Director estimates that Napp's likely gain from the infringements is, at the very least, £2m. The Director considers that this figure probably underestimates Napp's gain from the infringements but is satisfied that it is appropriate in this case to adjust the penalty by this amount in order to meet the Director's policy objectives on penalties. In reaching this conclusion, the Director has had regard both to Napp's turnover on the relevant market and to the fact that Napp's profits are subject to taxation. Following Step 3, the penalty is therefore adjusted to £2.92m."

484. At paragraph 262 of the Decision the Director states under the heading "Step 4 – adjustment for further aggravating and mitigating factors", that that figure of £2.92 million should be increased by 10 per cent since Napp did not alter its pricing policy since it became apparent to it, at least since 25 August 2000, that the Director regarded its behaviour as infringing the Chapter II prohibition. At paragraph 263 the Director states that there are no mitigating factors in this case.

485. Following Step 4, the Director therefore arrives at a penalty in the amount of £3.21 million.

486. Under the heading "Step 5 – adjustment to prevent maximum penalty being exceeded and to avoid double jeopardy" the Director states at paragraph 265 of the Decision:

"265. The final amount of any penalty imposed under section 36 may not exceed 10% of the turnover of the undertaking calculated in accordance with the Competition Act 1998 (Determination of Turnover for Penalties) Order. The UK turnover of Napp Pharmaceutical Holdings Limited in 2000 amounted to £51.2 and in 1999 to £53.9m. The length of the infringement exceeds 12 months by 30 days, so that the turnover for the purposes of section 36(8) of the Act is £51.2m + 30/365 of £53.9m, i.e. £55.6m. The calculated penalty does not exceed 10% of this figure."

Arguments of the parties

487. The essence of Napp's case, advanced in the alternative, is that the penalty should be cancelled or substantially reduced for the following reasons, in addition to those already advanced. (i) The Director has not addressed his mind to whether the infringement was negligent or intentional. (ii) The infringement was novel, taking into account OFT 414 and Community case law. (iii) Napp had a legitimate expectation it would not be penalised as long as it observed the PPRS. (iv) Little if any loss was caused to consumers, in terms of them having to forego goods which they could have purchased under competitive conditions, or by restricting innovation. (v) The persistence of Napp's infringement was in substantial part attributable to the Director's delay in pursuing his investigation and his failure to state his case earlier. (vi) The Director has failed to justify increasing the penalty by £2 million to represent Napp's "gain" from the infringement. (vii) Any "clawback" should not be from a date earlier than 13 March 2001, the date of the third Rule 14 Notice. (viii) Events prior to 1 March 2000, such as the exit of BIL, should not be taken into account in fixing any penalty. (ix) Napp did not initiate any "price war" with Farmitalia and BIL; it was hospital buyers who encouraged Napp to reduce its prices. (x) Napp could not have been expected to know that after the expiry of its patent it should have substantially reduced its list price for MST. (xi) It was reasonable for Napp to believe that provided it observed the terms of the PPRS its community prices would be regarded as reasonable. (xii) It is normal for suppliers of leading brands to maintain NHS list prices after patent expiry and offer differential discounts according to buyers' willingness to pay. (xiii) The Department of Health as the ultimate buyer of MST was well aware of Napp's costs and prices and of the prices of rival products. Department of Health officials do not agree with the Director's assessment. (xiv) Napp fully co-operated with the Director's investigations under the Act and earlier legislation. (xv) The Director was wrong to increase the level of penalty under step 4 by 10 per cent just because Napp continued to contest the case after the issue of the first Rule 14 Notice.

488. Napp also contends that the Director's "change of case" on pricing in the community segment should give rise to a reduction in the penalty of 70 to 75 per cent. According to Napp, the Director no longer advances a 'stand alone' abuse on prices in the community segment but only that the abuse on prices in the community segment results from the abuse on prices in the hospital segment. But, according to Napp, sales to hospitals influence only 25 to 30 per cent of the total market, well below the 40 per cent mentioned by the Director in paragraph 160 of the Decision. Since the community segment accounts for 90 per cent of sales of MST, the penalty attributable to the community segment should be assessed to be 70 to 75 per cent of the whole and reduced by that amount.

489. In any event, Napp contends that any alleged gain it has made is very much less than the figure of £2 million mentioned in paragraph 260 of the Decision. In exhibit "JB 6" to his first witness statement Mr Brogden set out various calculations of Napp's alleged "gain" which calculated the after-tax amount at approximately £1 million, assuming a 15 per cent reduction in the community price and an increase in hospital prices in accordance with the Directions. In these calculations, Mr Brogden assumed a 10 per cent loss of hospital sales, and a modest *increase* in Napp's community sales, resulting from the fall in the price in the community segment.

490. In Annex 9 of the defence, the Director produced various counter calculations which showed that Napp's "gain" properly calculated during the period of infringement was of the order of £2 million. The Director assumed a reduction of 15 per cent in the community price, a loss of volume in hospital sales of some 40 per cent, and a consequential reduction in Napp's market share in the community segment of 12½ per cent, over the first year of the infringement.

491. In response to those calculations, and a request by the Tribunal to the parties of 31 August 2001 to consider a period longer than one year, Napp produced further revised calculations in a letter from Herbert Smith dated 14 September 2001. That letter estimated Napp's after-tax 'gain' at approximately £1.1 million during the period of the infringement, again assuming a 15 per cent reduction in its community prices and an increase in hospital prices in line with the Directions. Napp further assumed an average loss of some 21 per cent of hospital sales in the first year, and a corresponding decline of 2 per cent in community sales. Napp points out, in its skeleton argument, that there would be hardly any 'gain' in the period of infringement if it were not required to reduce its community prices by 15 per cent.

492. The Director, in his defence, rejects Napp's arguments in mitigation and refutes Napp's criticisms of the penalty. He submits that the 10 per cent uplift at 'step 4' was not because Napp contested the case but because Napp did nothing to correct its behaviour despite being on notice that its selective discounting in the hospital segment was abusive.

493. As regards the gain, the Director did not produce the calculations that had been used to arrive at the figure of £2 million referred to in paragraph 260 of the Decision, although he told us in argument that at least some of those calculations were predicated on the 20 per cent price reduction in the community price, as originally suggested in the third Rule 14 Notice, rather than on the 15 per cent reduction required by the Directions. He did, however, produce the calculations just mentioned at annex 9 to the defence showing a gain of £2 million during the period of the infringement. In his skeleton argument the Director further submits, notably, that Napp's "gain" properly understood lasts for more than the 13 months of the infringement. That is because, even if the infringement had been terminated on 30 March 2001, there would be a certain time lag before rivals began effectively to penetrate the market.

494. As far as the parties' calculations of the 'gain' during the period of infringement are concerned, the key points of difference between the parties relate to (a) the assumed rate at which Napp would have lost hospital sales if it had raised its prices in accordance with the Directions on 1 March 2000 and (b) the assumed rate at which, in consequence, Napp would have lost market share, and thus profits, in the community segment. Factor (b) is more important than factor (a).

495. Thus, on (a) Napp assumes that it would lose 20 per cent of hospital contracts in the first 3 months, and lose a further 15 per cent of hospital sales over the following 21 months, giving a loss on average of 21 per cent of hospital sales over the year 1 March 2000 to 28 February 2001. The Director, on the other hand, assumes a loss of 40 per cent of hospital sales over the first twelve months from 1 March 2000.

496. As to (b), Napp assumes that its loss of hospital sales would lead to a loss of 2 per cent of community sales in the first 12 months, assuming a follow-on effect of 15 per cent, building up to 7 per cent over a period of 3 years. The Director, on the other hand, assumes that Napp's loss of hospital sales would lead to a loss of 12½ per cent of community sales over the first 12 months, or 25 per cent over the first 2 years. As to Napp's assumptions, the Director says that with a follow-on effect of 15 per cent, Napp's assumed loss of 35 per cent of hospital sales should lead to a loss

of community sales of 5.25 per cent. It is implausible that the reputation effect would account for only a further 1.75 per cent of the market (over 3 years) to make up Napp's figure of 7 per cent. As to the Director's assumptions, Napp says that the ratio of hospital to community sales suggests a high 'linkage' in favour of Link of about 1:2.8, which undermines the Director's case on the lack of "follow-on effect".

Findings

General observations

497. We observe first, that the Tribunal is not bound by the *Director's Guidance*. The Act contains no provision which requires the Tribunal to even have regard to that *Guidance*.

498. Schedule 8, paragraph 3(2) of the Act, provides that "the tribunal may confirm or set aside the decision which is the subject to the appeal, or any part of it, and may ... (b) impose, or revoke, or vary the amount of, a penalty ... or (e) make any other decision which the Director could have made."

499. It follows, in our judgment, that the Tribunal has a full jurisdiction itself to assess the penalty to be imposed, if necessary regardless of the way the Director has approached the matter in application of the *Director's Guidance*. Indeed, it seems to us that, in view of Article 6(1) of the ECHR, an undertaking penalised by the Director is entitled to have that penalty reviewed *ab initio* by an impartial and independent tribunal able to take its own decision unconstrained by the *Guidance*. Moreover, it seems to us that, in fixing a penalty, this Tribunal is bound to base itself on its own assessment of the infringement in the light of the facts and matters before the Tribunal at the stage of its judgment.

500. That said, it does not seem to us appropriate to disregard the *Director's Guidance*, or the Director's own approach in the Decision under challenge, when reaching our own conclusion as to what the penalty should be. The *Director's Guidance* will no doubt over time take account of the various indications given by this Tribunal in appeals against penalties.

501. We emphasise, however, that the only constraint on the amount of the penalty binding on this Tribunal is that which flows from the Maximum Penalties Order. In the present case the maximum penalty under that Order is £5.56 million, for an infringement by Napp lasting from 1 March 2000

to 31 March 2001. It is clear from that Order that Parliament intended that it is the overall turnover of the undertaking concerned, rather than its turnover in the products affected by the infringement, which is the final determinant for the amount of the penalty. As the Director points out in the *Guidance*, any other approach would mean that abuses by powerful companies in small relevant markets might not be appropriately sanctioned.

502. We agree with the thrust of the *Director's Guidance* that while the turnover in the products affected by the infringement may be an indicative starting point for the assessment of the penalty, the sum imposed must be such as to constitute a serious and effective deterrent, both to the undertaking concerned and to other undertakings tempted to engage in similar conduct. The policy objectives of the Act will not be achieved unless this Tribunal is prepared to uphold severe penalties for serious infringements. As the *Guidance* makes clear, the achievement of the necessary deterrent may well involve penalties above, often well above, 10 per cent of turnover in the products directly concerned by the infringement, subject only to the overall 'cap' imposed by the Maximum Penalties Order. The position in this respect is no different in principle under Article 15(2) of Council Regulation no. 17, albeit that the applicable maximum penalty under that provision is differently calculated.

503. We observe in parenthesis that since 1998 the European Commission has published *Guidelines on the Method of Setting Fines* OJ 1998 C9/3 ("the *Commission's Guidelines*") which have some similarities with, and some differences from, the *Director's Guidance*. The essential approach of the *Commission's Guidelines* is to indicate that the penalty will be made up of a fixed 'basic amount' depending on whether the infringement is categorised as 'minor', 'serious' or 'very serious'. The basic amount is then liable to be increased by reference to whether the infringement has lasted more than a year, and then further adjusted, upwards or downwards, according to whether there are aggravating or mitigating circumstances. Where there are differences between the *Director's Guidance* and the *Commission's Guidelines*, it seems to us that the differences are probably "relevant differences" for the purposes of section 60 of the Act, so that we are not required, at present, to take account of the *Commission's Guidelines*. Neither party has suggested that we should do so. However the principle of starting with a certain amount (either a percentage figure, as under the *Director's Guidance*, or a fixed sum, as under the *Commission's Guidelines*) and then adjusting that starting figure to meet the circumstances of the case, is common to both approaches.

The issue of duration in relation to hospital pricing

504. The infringement found in the Decision is the period from 1 March 2000 to 31 March 2001. However, in the event, Napp's abusively low prices to hospitals have continued not only during that period but up to the date of this judgment in January 2002. That is because, at the stage of Napp's application for interim relief, the Director consented to an order suspending the Directions: see [2001] CompAR 1. Although Napp gave certain undertakings relating to reimbursing the Department of Health if its case on prices in the community segment should turn out to be unfounded, those undertakings did not extend to the hospital segment. As a result, Napp's infringement in the hospital segment has in fact continued, or will have continued, for a period which is, in effect, at least 21 months from 1 March 2000 to the date of the Tribunal's judgment, rather than the 13 months found in the Decision. Taking account of the period of grace allowed by the Directions for the renegotiation of contracts, the infringement in the hospital segment is close to a duration of two years.

505. By virtue of Article 3 of the Maximum Penalties Order, Napp's applicable turnover for an infringement of (say) 21 months would be £51.2 million (UK turnover for 2000) plus $^{9}/_{12}$ of £53.9 million (UK turnover for 1999), that is to say £91.6 million. On that basis the maximum penalty to which Napp would now be subject would be £9.16 million.

506. However, since the point has not been raised by the Director, nor canvassed with Napp in the course of the proceedings, we think for the purposes of the penalty we are confined to treating Napp's hospital pricing as an infringement of 13 months duration which, on the basis of the Director's calculations, means that the maximum penalty is £5.56 million. There is, however, artificiality in this approach, since Article 3 of the Maximum Penalties Order proceeds on the basis that the infringement has ended whereas, in the case of Napp's policy of discounts to hospitals, it has not yet done so.

"The gain" at Step 3

507. We sympathise with the Director's intentions in increasing the penalty, at Step 3 of his calculation, by an amount representing Napp's 'gain' during the period of the infringement, in accordance with the *Director's Guidance* (see paragraph 260 of the Decision). However, in our view that approach presents certain difficulties. In the first place, there is the practical difficulty of assessing, in any

given case, what the gain is. That difficulty is illustrated by the present case. The Director did not disclose his original calculations which, according to him, showed a gain to Napp of £2 million. Since then, in the notice of appeal and the defence, and in a flurry of calculations and counter calculations exchanged between the parties in the days before the hearing, various different hypotheses and scenarios have been put forward by both sides. The Director's final figure (still £2 million) is some 100 per cent above Napp's final figure (some £1 million). The major difference between the parties are their different assumptions as to the rate at which Napp would have lost market share in the community segment if it had not priced below cost in the hospital segment from 1 March 2000 – 7 per cent over 3 years, according to Napp, and 25 per cent over 2 years, according to the Director.

508. Whatever our views as to which assumption is more plausible, neither assumption is verifiable. Other steps in the calculations, including the effect of taxation are more or less complex. This method of calculation, so it seems to us, is more suited to the process for assessing damages in civil litigation, rather than the fixing of a deterrent penalty. The fixing of the penalty under section 36 of the Act should in our view be done by methods which are as simple as possible, and easily verifiable by the Tribunal. In this case, the calculations submitted to us do not meet either criterion. Apart from anything else, once one changes, for the purposes of the calculation, one key parameter of competitive conditions – in this case Napp's ability to exclude competitors from the hospital market – one cannot assume that all other parameters remain static.

509. Secondly, we accept the Director's submission, albeit made at a very late stage, that the approach in the Decision which limits the 'gain' to the period of the infringement is extremely conservative, since in a case such as the present the consequences of the infringement for competition do not end on the date when the infringement ends. This is because, as Napp points out in its assumptions on the gain, even if the hospital pricing infringement had ended on 31 March 2001, it would still take some time for hospital contracts to be renegotiated, or hospitals to re-tender, for stocks to be run down, and for competitors to Napp to build up a sufficient 'presence' in the hospital segment. Only having established such a presence could those competitors then begin to make material gains in the community segment. Because of this "spill over" or "time lag" effect, we think it reasonable to assume that Napp's real "gain" from the infringement would have been likely to last for a considerable period after 31 March 2001.

510. Thirdly, and in our view more significantly, it seems to us that an arithmetical calculation of the 'gain' during the period of the infringement, of the kind carried out here, is likely to understate the real commercial gain from the infringing conduct, and thus risk being an ineffective penalty. In a case of predatory pricing, a significant part of the 'gain' made by the undertaking concerned is the deterrent effect it has on other undertakings which might have entered the market, or even other markets, where the dominant undertaking is active. That general effect, flowing from a general reputation for aggression, is not picked up in the calculations and is unquantifiable. Moreover the 'gain', as seen from the dominant undertaking's point of view, is not merely the market share it would otherwise have lost in some period determined arbitrarily by reference to when the Director chose to take his Decision. The real 'gain' is the long-term strategic advantage of protecting a monopoly market share and the profits that flow from that for as many years as possible. For example, Napp's calculations at Annex 26 to its skeleton argument show that Napp would have lost a minimal market share in the community segment up to the end of February 2001 if it had corrected its hospital prices on 1 March 2000, leading to a 'gain' after tax of just over £50,000. In our view it would be wholly unrealistic to fix a deterrent penalty by reference to that figure or anything resembling it, because such a figure does not reflect the real, but unquantifiable, commercial rationale behind Napp's hospital pricing policy. That rationale was to protect and preserve its monopoly revenues from the community segment, of over £10 million a year, for as long as possible.

511. For these reasons, we do not think that the calculation of a 'gain' should necessarily form the sole, or even the main, means of marking, for deterrent purposes, the seriousness of an infringement, notably in the context of Step 3 of the *Director's Guidance*, except perhaps in the clearest cases. We revert to the question of how market circumstances may develop in the future when we deal with the Directions below.

Aggravation under Step 4

512. At paragraph 262 of the Decision, the Director has increased the penalty by 10 per cent under 'Step 4' on the grounds that Napp did not alter its pricing policy, in particular after 25 August 2000, when it became "apparent to it that the Director regarded its behaviour as infringing the Chapter II prohibition". According to paragraph 2.11 of the *Director's Guidance* "continuing the infringement after the start of the investigation" is an aggravating circumstance. Although a comparable provision does not appear explicitly in the *Commission's Guidelines*, we can see that

continuing with infringing conduct after a clear warning of the illegality of the conduct in question could be an aggravating circumstance. Otherwise, the temptation might be to continue the illegal conduct for as long as possible, in the hope that the resulting commercial gain would outweigh any subsequent penalty. Nor, in our view, does such a possibility of taking account of such an aggravating circumstance necessarily contravene the "rights of the defence". The undertaking may still vigorously defend itself before the Director. The 'aggravating circumstance' is simply that continuing with conduct after an express warning of its illegality may be a worse offence than it would have been if no warning had been given.

513. On the other hand, we feel that some caution is called for on this aspect. The mere fact that the Director has commenced an investigation does not mean that an undertaking has committed an infringement, nor does the issue of a Rule 14 Notice. The threat that penalties may be increased if an undertaking does not "give in" on receipt of a Rule 14 Notice could perhaps, in some circumstances, inhibit the undertaking from defending itself or, perhaps, cause it to modify commercially defensible conduct without a finding of infringement having been made.

514. In these circumstances, we think the fact that an undertaking has continued an infringement after the start of an investigation can in many cases be sanctioned appropriately by simply taking into account the longer duration of the infringement thereby resulting. Further "aggravating circumstances" should be limited to cases where an undertaking has received a clear warning that it is engaging in a plain and obvious infringement of the Act, but has blatantly ignored that warning. Conversely, if an undertaking has, in fact, discontinued an infringement at the start of an investigation by the Director, that in our view is likely to be a mitigating factor.

515. In the present case, the first Rule 14 Notice, dated 25 August 2000, alleged both excessive prices in the community segment and prices below direct costs in the hospital segment. However, that Notice proposed as a remedy that Napp should not discriminate between customers in the community and hospital segments respectively – i.e. that the prices in the two segments should be the same, except for objectively justified reasons. That position was maintained in the second Rule 14 Notice sent to Napp on 2 February 2001, although the Director indicated his willingness to make certain alternative directions. In that second Rule 14 Notice, more prominence was given to the abuse in the hospital segment, and the Director included new material outlining his response to Napp's representations made in answer to the first Rule 14 Notice. In the third Rule 14 Notice of 13 March 2001, the Director dropped the direction he had originally proposed on 25 August 2000,

and instead proposed a direction to the effect that the NHS list price of MST in the community segment should be reduced by 20 per cent, with a floor price for MST sold in hospitals of 25 per cent of the reduced community price. Following further representations by Napp, the Directions, as finally made on 4 May 2001, imposed a reduction of 15 per cent in the NHS price of MST, plus a floor price for MST sold in hospitals of 20 per cent of that reduced community price.

516. The Director's willingness to modify his case following Napp's representations reflects credit on him and shows that the administrative procedure gave Napp a genuine opportunity to argue its case. However, the fact is that it was until March 2001 an integral part of the Director's case that Napp's hospital and community prices should be the same, which contention the Director has subsequently abandoned. In view of that modification to his case which the Director made at a very late stage of the administrative procedure, we do not think it right, in the present case, to regard it as an aggravating circumstance that Napp did not change its behaviour after the start of the investigation or the first Rule 14 Notice. We propose therefore to disregard the adjustment made in paragraph 262 of the Decision and to treat this case as if the Director had imposed a penalty of £2.92 million.

Factors affecting the amount of the penalty in the present case

517. We agree with the Director that it is artificial to regard the two abuses here in question as unconnected with each other. For ease of analysis, however, we deal first separately with the gravity of Napp's pricing in the hospital and community segments respectively, including our views on Napp's arguments in mitigation (paragraphs 487 et seq above).

— *Hospital pricing: seriousness*

518. We agree with the Director that predatory pricing, even of short duration, falls into the category of a serious abuse. Although it may, at first sight, seem anomalous that the application of competition law should result in higher, rather than lower prices, the present case vividly illustrates that the reason for predatory pricing is typically to exclude or neutralise competitors with a view to maintaining market share and/or high prices in sectors that would otherwise be threatened by competition. The "benefit" that some consumers (in this case hospital purchasing authorities) receive from below-cost predatory prices is wholly outweighed by the "disbenefit", in terms of high costs and lack of choice, which flows from the monopoly (in this case in the community

segment) that the predatory pricing is designed to protect or strengthen. Unless predatory pricing, and especially pricing below average variable cost, by dominant undertakings is rigorously penalised by competition law, new competitive entry may be thwarted, with the result that consumers never receive the benefit of competitive conditions, and the lower long-run price levels, wider choice and better quality which, in general, competition brings.

519. We therefore agree with the Director's view, at paragraph 2.4 of his *Guidance* that predatory pricing by a dominant undertaking is one of the most serious infringements of the Act.

520. As far as the present case is concerned, we regard Napp's conduct in the hospital segment as a serious abuse. We accept the Director's submission that Napp "consciously and very deliberately" priced below its direct costs in order to exclude competitors from the hospital segment and thus prevent them from gaining any form of toehold from which they might enter the community segment. Price reductions were not made across the board but were targeted selectively against competitors. Napp's pricing policy was in support of the monopoly already enjoyed by a "superdominant" undertaking. To borrow Mr Mountain's phrase, Napp had the key to the only viable point of entry into the whole of the relevant market, but chose to keep that gate locked.

521. As regards the various points made by Napp in mitigation, in the Decision the Director found that Napp had intentionally eliminated competition (paragraph 236(a), last sentence), and plainly proceeded on that basis when fixing the penalty. The infringement, in our view, was not novel as *AKZO* and *Tetra Pak II* show. In any event, the present case falls squarely within the principles of *Compagnie Maritime Belge* and *Irish Sugar*.

522. Although paragraphs 4.15 to 4.17 of OFT 414 are not entirely happily worded, we do not think in the circumstances of this particular case that Napp can credibly claim to have been misled by those paragraphs into believing that its hospital pricing policy in this case was not abusive (see paragraph 288 above).

523. Although it is true that the Director's case has not been wholly consistent as to what narrow "follow-on effect" he did or did not accept, we regard that as a side issue which does not affect the fundamental point that Napp's pricing policy was intended to, and in our judgment did, substantially hinder competition in the relevant market. As to the extent of foreclosure, we have already indicated our view that the whole of the relevant market was indirectly, or potentially,

affected by Napp's conduct: paragraphs 281 to 283 above. Nonetheless, we are prepared to make some slight allowance, by way of mitigation, to take account of the fact that OFT 414 is not drafted quite as clearly as it could have been, and the fact that the Director's case on follow-on effect and foreclosure has not been expressed entirely consistently.

524. We do not think that the Director's investigation in this case was unreasonably delayed, or that Napp can seriously claim that it did not know what to do to avoid infringing the Chapter II prohibition by its hospital pricing policy.

525. We reject Napp's argument that the effect of its hospital pricing policy on consumers was not great. On the contrary, we regard it as a serious feature of the present case that the product concerned is a pharmaceutical product for the treatment of patients in severe pain. Napp's conduct has, in practice, tended to limit the choice of prescribing doctors and in some cases to deny their seriously ill patients alternative oral sustained release morphine products (e.g. capsules). Napp has also made it more difficult for its competitors to bring new products to market. In so far as Napp's hospital pricing policy has tended to protect Napp's market share in the community segment and prevent market entry of cheaper products, it is the taxpayer who has suffered – in some cases paying on average a price over 1400 per cent higher depending on whether the product is dispensed by a retail pharmacist or in a hospital (see paragraph 420 above).

526. We agree with Napp that the exit of BIL should not be taken into account as such in fixing any penalty, but that matter is not mentioned by the Director as one of the factors that he has specifically taken into account. We do not take it specifically into account either, but do note that Napp's market shares in fact increased during the period of the infringement. The fact that price cutting was originally initiated by Farmitalia/BIL, and that hospital buyers allegedly 'encouraged' Napp (as to which we make no finding) are not in our view relevant to the abuse as committed during the period of infringement, especially in view of the case law cited at paragraphs 207 et seq above. The fact that we have not upheld paragraph 236(a)(i) of the Decision in our view merits only a nominal reduction in the penalty, since that point has hardly figured in the proceedings.

527. We add that we do not see Napp's alleged "co-operation" with the Director as going in any way beyond the normal, and thus not a mitigating factor. Napp has made no attempt to modify its conduct. We note that it is apparent from the documents disclosed to the Tribunal that there was material known to Napp which threw light on Napp's original motives in pursuing its hospital

pricing policy about which Napp chose, whether rightly or wrongly, to remain silent in the course of the administrative procedure and the early stages of this appeal. We see no mitigation there.

528. In the result, we have identified only slight mitigating factors in respect of Napp's serious abuse in the hospital segment.

— *Community pricing: seriousness*

529. As we have already held, we think that Napp ought to have known that it was charging prices in the community segment likely to be judged excessive. As will be seen, we do not regard the Directions as ungenerous towards Napp, in assuming as they do that the excessive pricing can be mitigated by a reduction of 15 per cent of the NHS List Price.

530. In this instance the issue of the duration of the abuse (1 March 2000 to 31 March 2001) does not arise in the same way as in regard to Napp's hospital pricing, since the period from 29 May 2001 is covered by Napp's undertaking to the Department of Health, given at the stage of interim relief, to reimburse the Department if this appeal should fail.

531. We take the view that the abuse of excessive pricing in the circumstances of this case is a serious matter. The size of Napp's margins, coupled with the extent of the differentials when the same product is sold in different segments of the same market, seem to us to be exceptional. For the reasons we have given, we do not think that Napp had any "legitimate expectation" that it would not be penalised if it remained within the limits on ROC under the PPRS, nor do we accept Napp's suggestion that Department of Health officials do not agree with the Director's case: see, on both points, Mr Brownlee's evidence.

532. Nor do we accept Napp's argument (paragraph 488 above) that the way the Director puts the matter in the defence virtually eliminates any penalty as far as the abuse of excessive pricing in the community segment is concerned. That abuse remains a separate abuse to which the Director was entitled to have regard in fixing the penalty: see paragraphs 428 to 442 above. We also entirely reject the suggestion, also made by Napp at paragraph 488 above, that the penalty should be in some way reduced "pro rata" on the basis of the volumes sold in the community and hospital segments respectively.

533. On the other hand, we see some mitigation in Napp's favour. First, it was not until the adoption of the Directions that Napp finally knew the Director's position as to the amount of reduction required to mitigate the "excess". Secondly, the existence of the PPRS, while not in our view sufficient to prevent Napp's infringement from being at least negligent, is in our view some mitigation. Although in our view Napp should have realised that the PPRS afforded no defence, it may not have been easy for Napp to come to terms with the fact that, as from 1 March 2000, the Chapter II prohibition imposes restraints on unfairly high prices charged by dominant undertakings, in addition to the constraints under the PPRS which, of course, applies to dominant and non-dominant firms alike. It is also true that the way the Director has characterised the abuse of excessive pricing before the Tribunal, linking it more explicitly to the abuse on hospital discounting, has to some extent "muddied the waters" as to the circumstances in which he (the Director) might consider the PPRS to be a defence to a charge of abuse of excessive pricing on pharmaceutical products. In addition there has been no decided case at Community level upholding an abuse of excessive pricing in circumstances comparable to the present case, and the principles upon which a price is to be judged "unfairly high" for the purposes of the Chapter II prohibition have not been considered in any previous decision of the Director or the Tribunal.

534. In all those circumstances, serious though the abuse of excessive pricing is, we think that the overall penalty imposed on Napp should take account of the mitigating factors we have identified.

The Tribunal's assessment of the penalty

535. This is the first occasion on which the Tribunal has considered the amount of a penalty under the Act. We propose to adopt a "broad brush" approach. Each case will depend on its own circumstances.

536. In this case the Director considered an appropriate penalty to be some £3.2 million. Omitting the "aggravating circumstance" that we are minded to exclude (paragraph 516 above) the Director's figure is £2.92 million.

537. We begin by taking the case as a whole. This is a serious case of predatory and selective pricing, lasting for thirteen months up to the date of the Decision, committed by a "superdominant" undertaking in one segment of the market (the hospital segment) and tending to protect high prices and margins in another segment of the market where that undertaking is also a virtual monopolist

(the community segment). In addition, Napp's prices in the community segment have been maintained well above the competitive level. If the objectives of the Act are to be achieved such conduct calls, in our judgment, for severe penalties. In those circumstances, absent any significant mitigating factors, we do not think that a penalty of £3 million, as a global figure, is outside the range of penalties that could reasonably be imposed, in a case such as the present, having regard to the permitted maximum of £5.56 million.

538. However, in view of the mitigating factors we have mentioned in paragraph 533 above, and to a slight extent those mentioned at paragraph 523 above, we have come to the conclusion that the overall penalty in this case should be fixed at the sum of £2.2 million.

539. If, as a "cross-check", we were to apply the methodology of the *Director's Guidance*, the same result would be reached by taking the Director's starting percentage under Step 1, applying to that percentage a multiplier of slightly over three to reach £2.92 million under Step 3, and then reducing that figure by some 25 per cent for mitigating factors under Step 4. That in our view would equally have been a reasonable approach.

540. For the reasons already indicated, in paragraphs 507 et seq above, we do not use the calculations of gain presented to us as the basis for our decision. However, we are satisfied that Napp's calculations of the gain do not adequately capture the full commercial advantage of the policy it has followed, for the reasons already given.

541. We consider that a penalty of £2.2 million is the lowest amount that can reasonably be arrived at to penalise Napp's conduct and to send an appropriate signal to the business community of the seriousness of infringements of the Competition Act 1998.

Interest on the penalty

542. Under Rule 27 of the Tribunal's Rules, if it confirms or varies any penalty the Tribunal may, in addition, add interest on the penalty from the date no earlier than the date on which the application was made, in this case 29 May 2001. We attach importance to this provision, since under section 37 of the Act the mere fact of making an appeal effectively postpones the obligation to pay until the appeal is determined.

543. We see no reason not to exercise this power in the present case. Subject to any observations by the parties, it seems to us that interest should be payable at a commercial rate on the penalty we have fixed from 30 June 2001 until payment by Napp or judgment under section 37. We will hear argument on the appropriate commercial rate of interest.

X — THE DIRECTIONS

The letter of 4 May 2001

544. The purpose of the Directions is to require Napp to bring the infringements to an end (paragraph 1), to reduce its NHS List Price by 15 per cent, and to sell to hospitals at a minimum price no lower than 20 per cent of that reduced NHS price (paragraph 2). A period of grace is allowed for the renegotiation of existing contracts (paragraphs 3 and 4). Various ancillary powers are included (paragraphs 5, 6 and 8).

545. The Director considers that such directions are necessary to bring to an end the infringements found in the Decision. In the letter of 4 May 2001 the Director states:

> "At paragraph 236 of the Decision two elements of Napp's conduct were found to infringe the Chapter II prohibition. First, Napp was found to have charged excessive prices to customers in the community segment of the market for the supply of sustained release morphine tablets and capsules in the United Kingdom (the relevant market). Second, Napp was found to have supplied sustained release morphine tablets to the hospital segment of the relevant market at discounts which have the object and effect of hindering competition in the relevant market.
>
> The Director considers that these two elements of Napp's pricing conduct are inter-related and must be considered as a whole in formulating directions which are appropriate to bring the infringement to an end. First, Napp's ability to sustain high prices in the community depends in large part on the effect of Napp's discounting behaviour to hospitals in hindering competition in the relevant market. Second, the fact that Napp's prices in the community segment of the relevant market are significantly above those of its rivals contributes to Napp's asymetrical advantage in bidding for hospital contracts."

546. As regards the reduction in Napp's NHS list price, the Director continues:

> "The Director considers that an immediate reduction in the NHS list price is appropriate in order to mitigate Napp's excessive prices in the community segment of the relevant market in the short to medium term. This reduction, coupled with a corresponding reduction in the ex-factory price of MST tablets sold to the community, will also reduce Napp's ability to cross-subsidise discounts in the hospital segment of the relevant market.

In the longer term, the Director considers that the best way to prevent Napp from pricing excessively is to maintain incentives, and to create opportunities, for competition to develop throughout the relevant market.

The Director considers that the appropriate level of reduction in the NHS list price would be fifteen per cent. This will significantly reduce the price of MST tablets to the community segment of the relevant market, while nevertheless allowing for a gap between the price of MST tablets and that of Napp's competitors, thus maintaining incentives for competition to develop. This is consistent with Napp's representations that a reasonable price premium on MST tablets should be allowed to reflect their current higher brand value relative to that of rival products."

547. As regards the restriction on discounting the price of MST tablets to hospitals, the Director states:

"Paragraph 2(d) of the directions provides that the price of each strength of MST tablet sold to hospitals in the UK shall not be less than twenty per cent of the NHS list price for that product strength of MST. The Director considers that this direction is appropriate in order to prevent Napp from restricting competition by supplying hospitals at excessively low prices.

The figure of twenty per cent represents the ratio between Napp's average cost of supplying MST tablets to hospitals and the average NHS list price for those products arrived at following the fifteen per cent reduction required by the direction at paragraph 2(a). The calculation of Napp's average cost of supplying MST tablets to hospitals for this purpose is based on the total delivered cost to Napp of supplying MST to hospitals in the UK over the period of March to May 2000. The calculation of Napp's average NHS list price, to which the fifteen per cent reduction is then applied, is based on the volumes of MST tablets supplied to hospitals in the UK over the same period.

The direction at paragraph 2(d) does not impose on Napp an absolute prohibition on supplying hospitals at prices below the average cost. In order to do so, however, Napp would need to reduce further its NHS list price for the product thus limiting its ability to cross-subsidise discounts in the hospital segment and so, by weakening the asymmetry between Napp's position and that of its competitors, increasing the opportunities for competition to develop.

In its representations, Napp has argued that in order to compete for hospital contracts it would have to reduce the list price of MST tablets to unnecessarily low levels. First, the Director does not consider that discounts to hospitals will remain at their current level following implementation of the direction. Second, MST tablets will maintain non-price advantages in competing for hospital contracts owing to Napp's position of dominance on the relevant market."

Arguments of the parties

548. According to Napp (i) the Directions go beyond the powers in section 33 of the Act in prohibiting Napp from setting its prices otherwise than in accordance with the Directions without the Director's consent, even in circumstances where Napp's prices were compatible with the Chapter II prohibition; (ii) the Directions unnecessarily replicate obligations imposed on Napp by the Chapter

II prohibition or the Act itself; (iii) paragraph 6 of the Directions gives the Director power to obtain information to which he is not entitled under the Act; (iv) paragraph 2(d) of the Directions wrongly extends to private hospitals and hospices; (v) there is no basis for requiring Napp to renegotiate its hospital contracts in order to bring to an end any supposed infringement; (vi) there is no basis for concluding that a reduction of at least 15 per cent in the current NHS list price of MST is necessary in order to end Napp's supposed infringement; (vii) there is no basis for concluding that it is appropriate to prohibit Napp from discounting its prices to hospitals to a level which falls below 20 per cent of the NHS list price in order to end Napp's supposed infringement; (viii) by publishing the floor price in full the Director is distorting competition, since its rivals will know at precisely what level to undercut Napp, making up any losses from follow-on linkages, while Napp is prevented from acting likewise.

549. In its skeleton argument Napp further submitted (i) since the Director no longer maintains that the abuse of excessive pricing is a stand-alone abuse, the remedy should focus on the hospital segment and not make a link between the community and hospital prices; (ii) Mr Hartley of Link opposes any reduction in Napp's community prices; (iii) the figure of 15 per cent is "plucked out of the air"; (iv) in so far as the Directions make transparent Napp's floor price, this distorts the tendering process in the hospital segment.

550. The Director submits that the Directions are properly made under the powers in section 33 of the Act and relies on the reasons given in the letter of 4 May 2001. The reduction of 15 per cent is a considered figure, designed to enable Napp to command a brand premium while reducing its excessive pricing. Since the abuse is a distinct infringement, any argument arising out of the wording of the defence is misplaced. As to Mr Hartley, under section 33 of the Act the Director must concentrate on directions "appropriate to bring the abuse to an end". The remaining price gap between Napp and its competitors should be sufficient for competition to develop. As to transparency, the Director considers that Napp will not suffer a significant competitive disadvantage because it will continue to have non-price advantages and competitors will have to overcome hospital switching costs.

551. Finally, as to the fact that paragraph 2(d) of the Directions permits Napp to sell below direct costs provided it also reduces its NHS prices proportionately, the Director considered that this was the least restrictive solution designed to remove Napp's ability to profit from its predatory behaviour by maintaining high prices in the community segment.

552. Mr Hartley of Link believes that if Napp's excessive discounting to hospitals is ended, this will enable Link to compete effectively and win hospital business. Once that is achieved, it is neither necessary nor appropriate to regulate the community price. If Napp is ordered to reduce its community price, Mr Hartley is concerned that it will reduce the competitive advantage that Link has fought hard to establish.

Findings

553. As to the various formal arguments put forward by Napp, section 33 of the Act empowers the Director to give "such directions as he considers appropriate to bring the infringement to an end". In our judgment it is within the Director's powers under that section to adopt the Directions in the form in which he has done so. The requirement not to set prices otherwise than in accordance with the Directions without the Director's consent (paragraph 2 of the Directions) is reasonably ancillary to the Director's purpose in putting an end to the infringements as is, in our judgment, the Director's power to require the information set out in paragraph 6 of the Directions. The requirement in paragraph 1 of the Directions to cease the infringements in question, and refrain from conduct of the same or equivalent effect, is a measure supplementary to the Chapter II prohibition and similar to orders made in decisions of the European Commission. Any doubt as to the scope of that obligation would fall to be resolved if and when the Director came to enforce the Directions before the court under section 34. The fact that the Directions extend to private hospitals and hospices does not seem to us to be open to objection.

554. On the substance of the Directions, it seems to us that the requirement to reduce the NHS List Price of MST by 15 per cent is at this stage the minimum necessary to mitigate the abuse of excessive pricing while at the same time allowing the development of competitive conditions. While we note the point made by Mr Hartley of Link, we think that the Director's duty, in the public interest, is to deal with the infringement. That must prevail over Link's private commercial interests. There will still remain a substantial difference between Napp's reduced NHS list price and Link's NHS list price, which Link can exploit in the market place. The figure of 15 per cent reduces the previous gap between Napp and its competitors, while allowing Napp some brand premium and according sufficient room to manoeuvre to Napp's competitors to allow competition to develop.

555. Nor do we think there is anything in the emphasis placed, in the Director's defence, as to the relationship between Napp's hospital prices and its community prices, which in any way removes

or lessens the need for the requirement to reduce by 15 per cent the list price of MST. That requirement is necessary in order to remedy the distinct infringement of excess pricing found in the Decision. As at the date of the Directions, 4 May 2001, Napp's community prices were unfairly high, as we have found.

556. Indeed, in view of the exceptionally high margins and exceptional differentials enjoyed by Napp in the community segment, coupled with Napp's strong position in the hospital segment, our concern is not whether the reduction of 15 per cent in the NHS List Price of MST ordered by the Director is too much, but rather whether that reduction is really sufficient to reduce the price of MST to the competitive level.

557. As regards the floor price for sales of MST to hospitals, and given notably the fact that Napp is a superdominant undertaking, we think it is within the Director's powers, in the light of *Compagnie Maritime Belge,* to set the floor price at the level the Director has chosen, in order to eliminate the abuse in the hospital segment.

558. As to paragraph 2(d) of the Directions, as drafted it permits Napp to price below average total costs to hospitals if, at the same time, it makes a proportionate reduction in its NHS List Price. It is true that that possibility may be somewhat academic because the chances of Napp reducing its list price in that way may not be very great. Nonetheless the possibility is there. Our concern about paragraph 2(d) is, first, that the law, as expressed in *AKZO*, *Tetra Pak II*, and *Compagnie Maritime Belge* would not permit Napp to sell to hospitals at prices below either average total or average variable costs, even if it did at the same time reduce its NHS List Price. Secondly, we think there is some risk that Napp could use paragraph 2(d) to reduce its prices to hospitals below cost, thus once again blocking competitive entry. Accordingly we invite the Director to keep this aspect of the Directions under review.

559. As to transparency, it is true that the Director could simply have required Napp to set its prices no lower than some appropriate level of costs, subject to a system of verification. We see advantages, from the point of view of certainty and administrative convenience, in the form the Director has chosen. For the reasons he gives, and those we have given earlier in this judgment (paragraphs 342 to 349) we consider that Napp is not placed at a significant disadvantage or in an unreasonable position.

560. More generally, we are concerned, in the light of the evidence we have heard, as to whether the Directions, viewed as a whole will, in practice, be sufficient to encourage competitive conditions in the market for oral sustained release morphine in the United Kingdom, in view of Napp's strong position and reputation in both the community and hospital segments. We leave it, however, to the Director to carry out periodic reviews to ascertain whether or not the Directions are having the desired effect: see paragraph 8 of the Directions.

561. Finally, we remind the parties that the renegotiation of the hospital contracts is to be carried out as quickly as possible in accordance with paragraphs 2 to 5 of the undertaking given by Napp set out in the President's order dated 22 May 2001.

562. There will be liberty to apply in respect of any matter arising out of the Directions.

XI — ORDERS MADE

563. On those grounds, the Tribunal hereby unanimously decides to confirm, in its result, and on the merits, the Director's Decision dated 30 March 2001 that Napp has committed the infringements of the Chapter II prohibition set out at paragraph 236 of that Decision, with the minor exception of paragraph 236(a)(i). As to the Director's reasoning, we have not felt it necessary to deal with every argument set out in the Decision. Where we have not referred to particular matters it is because we have not found it necessary to do so for the purposes of this judgment. Nonetheless we confirm, in substance, the essential features of the Director's reasoning. To the extent that we rely on other facts or matters, or express our finding in terms which differ from the Director, we take so far as necessary our own decision that Napp has infringed the Chapter II prohibition, pursuant to our powers in Schedule 8, paragraph 3(2) of the Act.

564. We vary the penalty and fix the amount of the penalty to be paid by Napp to the Director at £2.2 million. Interest will be payable on the penalty at a rate to be determined after hearing the parties, for the period from 30 June 2001 to the date of payment of the penalty, subject to any further observations by the parties on whether that is the relevant period. We confirm the Directions. Paragraph 1 of the President's interim order of 22 May 2001 ceases to have effect.

565. We have not yet heard submissions on costs. Our provisional view is that the proper order is for both sides to pay their own costs, including the costs of all interlocutory proceedings, but we will hear argument on any applications for costs, if made.

566. Subject to the foregoing, Napp's appeal is dismissed.

Christopher Bellamy Barry Colgate Peter Grinyer

Delivered in open court 15 January 2002

Charles Dhanowa

Registrar