COMPETITION ACT 1998

DECISION OF THE DIRECTOR GENERAL OF FAIR TRADING
No CA98/2/2001*

30 MARCH 2001

NAPP PHARMACEUTICAL HOLDINGS LIMITED AND SUBSIDIARIES (NAPP)

Relating to a finding by the Director General of Fair Trading (the Director) of an infringement of the prohibition imposed by Section 18 of the Competition Act 1998 (the Act) in respect of conduct by Napp Pharmaceutical Holdings Limited and its subsidiaries.

I INTRODUCTION

1. This decision relates to conduct by Napp Pharmaceutical Holdings Limited and its subsidiaries (together referred to as Napp) in the supply and distribution of sustained release morphine in the United Kingdom (UK).

2. The case results from a complaint. The complainant alleges that through the use of discounts of over 90% to hospitals, Napp has prevented its competitors from gaining a foothold in the market for the supply of sustained release morphine to hospitals and to pharmacies in the community.

3. An enquiry into the allegations made by the complainant was launched in July 1999 under the Competition Act 1980. Napp provided information in response to requests from the Director in September and October 1999. An investigation began under the Act following its entry into force on 1 March 2000. In May 2000 representatives of Napp attended a meeting at the Office of Fair Trading to discuss the market and the allegations made by the complainant and Napp subsequently provided additional information.

* Certain information has been excluded from this document in order to comply with the provisions of section 56 of the Competition Act 1998 (confidentiality and disclosure of information). Excisions are denoted by […]. Where possible, following such excisions, wording has been added and this has been placed in square brackets and is in italics.

4. A notice under section 26 of the Act was sent to Napp and to other companies on 7 July 2000. The Director has also received information from the Department of Health (DoH), NHS Supplies, NHS Purchasing and Supplies Agency (NHS PASA), Medicines Control Agency (MCA), the Office of Health Economics, clinicians and relevant trade and professional bodies (British Medical Association (BMA), British National Formulary (BNF), Medicare Audits).

5. On 25 August 2000, a notice was issued to Napp under the Act in accordance with rule 14 of the Director's procedural rules (the Director's rules).[1] In accordance with the Director's rules,[2] Napp was given the opportunity to submit written and oral representations on the Notice to the Director which it did on 16 October 2000 and 20 October 2000 respectively. Napp submitted further written representations on 27 October 2000. In coming to this decision, the Director has given full consideration to these representations.

6. On 2 February 2001, a supplementary notice was issued to Napp also under rule 14 of the Director's rules. Napp was given the opportunity to submit written and oral representations on the supplementary Notice which it did on 6 March 2001 and 12 March 2001 respectively. In coming to this decision, the Director has also given full consideration to these representations on the supplementary Notice.

7. On 13 March 2001, a further supplementary notice was issued to Napp. This was concerned with directions which the Director proposed to make under section 33 of the Act. These are not dealt with in this decision, although the Director has taken into account, for the purposes of this decision, written representations subsequently made by Napp on 27 March 2001 in relation to the level of penalty imposed under section 36 of the Act.

[1] The Competition Act 1998 (Director's rules) Order 2000 SI 2000 No 293.
[2] Rule 14(7) and Rule 14(8).

II THE FACTS

A THE UNDERTAKING

8. Napp is based in the UK. It comprises Napp Pharmaceutical Holdings Limited and its wholly owned subsidiaries only six of which are currently trading - Napp Pharmaceuticals Limited, Napp Pharmaceutical Group Limited, Napp Laboratories Limited, Napp Research Centre Limited, Moore Chemicals Limited and Bard Pharmaceuticals Limited. It had a UK turnover of approximately £51.2 million in 2000, of which £[...] million was derived from the sale of sustained release morphine. Napp also produces drugs for the heart and circulation, gastro-intestinal drugs and respiratory treatments.[3] It has recently launched a new pain relief product, OxyContin (sustained release oxycodone). Napp describes itself as "a research-based company" with 28% of its Cambridge-based staff being involved in research.

9. Napp was the first company to launch a sustained release morphine product (MST) in the UK in 1980. Prior to the launch of MST, only immediate release morphine products were available for the treatment of cancer pain and other severe pain. MST was a new sustained release formulation of an existing chemical entity, morphine sulphate. Napp held a UK patent on this formulation between 1980 and 1992. In addition to MST tablets, Napp produces two other sustained release morphine pain relief products: MST Suspension and MXL.[4] It also exports sustained release morphine tablets. As a contract manufacturer, Napp has no involvement in the promotion, marketing or sale of its products overseas.

[3] Zanidip (calcium channel blocker), Co-danthramer (relief for drug-induced constipation), Gastrobid Continus (relief for upper digestive track problems) and Uniphyllin Continus (theophylline) see "Science in the market place" Napp, 1998.

[4] Napp also produces several other pain relief products: Palladone (hydromorphone), Sevredol (immediate release morphine), DHC Continus (dihydrocodeine), Remedeine and Remedeine Forte (paracetamol and dihydrocodeine), Codafen Continus (controlled release ibuprofen), Felxin Continus (indomethacin).

B THE PRODUCT

(a) Morphine

10. Morphine is a strong opioid analgesic[5] used to treat moderate and severe pain (particularly in cancer patients). It is a controlled drug which is only available on prescription. The oral route is the optimal route for the administration of analgesics, including morphine.[6] There are two different types of oral morphine formulations on the market – sustained (sometimes called slow, modified or controlled) release and immediate release. Immediate release preparations provide short acting, but immediate pain relief for use primarily where the pain is unstable. Sustained release morphine extends the duration of action of a morphine preparation and is used when the pain is fairly constant. Its use reduces the number and frequency of tablets that need to be administered.

11. As at 1 March 2000 there were four suppliers of sustained release morphine in the UK:

    (i) Napp, which supplies MST and MXL;

    (ii) Boehringer Ingelheim Limited (BIL), which supplied Oramorph SR;

    (iii) Link Pharmaceuticals Limited (Link), which supplies Zomorph; and

    (iv) Sanofi-Winthrop which supplies Morcap SR.

    BIL has since stopped supplying sustained release morphine in the UK.[7]

12. Sustained release morphine is supplied in many different presentations (i.e. tablets, capsules, suspension and different pack sizes). The brands are also sold in different strengths. Napp's MST tablets are offered in seven different strengths and is the only product to offer tablets in 5mg and 15mg packs. Napp's MXL and Sanofi Winthrop's Morcap SR are the only once daily (24 hour) sustained release products.[8] The others all need to be administered twice daily.

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[5] Analgesics are painkillers. Non-opioid analgesics, such as aspirin or paracetamol, are generally use in the treatment of mild pain. Opioid analgesics have an opium base and are used in the treatment of moderate to severe pain.
[6] Napp.
[7] See paragraphs 115 and 173 to 178 below.
[8] Morcap SR may also be used as a twice daily preparation.

(b) Regulatory regime

Licensing requirements

13. Firms that want to manufacture or market sustained release morphine in the UK must be properly authorised to do so. To manufacture medicinal products in the UK, a firm must have a manufacturers licence under the Medicines Act 1968. To market such a product in the UK a firm must obtain a specific marketing authorisation for that product under the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 (SI 1994/3144). Manufacturers' licences and marketing authorisations are granted by the MCA. These provisions are subject to a number of exemptions, none of which is relevant in this case. In addition, companies wishing to import controlled drugs, such as morphine, need to obtain approval from the Home Office.

14. Where a firm has already been granted a marketing authorisation in respect of a product from the licensing authority of another member state of the European Union (EU), it can rely on the shorter "mutual recognition" procedure to obtain a UK marketing authorisation from the MCA in respect of that product. In certain cases it may be possible to rely on an even shorter "abridged" procedure. This applies where the applicant is submitting an application for a product which is essentially similar to another product which has been authorised within the EU for not less than six years and already has a marketing authorisation in the UK. For a firm to rely on the abridged procedure, it must have obtained the consent of the holder of the existing UK marketing authorisation for the MCA to cross refer to the dossier on the existing authorisation holder's product. However, after the product has been authorised for 10 years, the consent of the holder is no longer required.

15. Alternatively, a firm may be able to obtain a Product Licence for Parallel Import (PLPI). A PLPI will only be available if the product in question is in every respect the same, or whose differences have no therapeutic effect, as another product which is already the subject of a marketing authorisation for the UK. In addition, a parallel import licence is only given for an imported product that is manufactured by the same company or group of companies as that which holds the UK marketing authorisation. PLPIs are issued by the MCA.

Pharmaceutical Price Regulation Scheme (PPRS)

16. The PPRS is a voluntary scheme agreed between the Secretary of State for Health and the Association of the British Pharmaceutical Industry (ABPI). It regulates the profit that companies may make from their sales of branded prescription medicines supplied to the National Health Service (NHS). Although participation in the scheme is voluntary,

companies that do not participate in the scheme are subject to statutory regulation under sections 34 to 38 of the Health Act 1999. Napp is a member of the current PPRS.

17. The current PPRS agreement (1999-2004) has the same objectives as the agreements which preceded it. These are:

    (i) to secure the provision of safe and effective medicines for the NHS at reasonable prices;

    (ii) to promote a strong and profitable pharmaceutical industry capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines; and

    (iii) to encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in the UK and other countries.[9]

18. The PPRS sets a limit on the rate of return (measured as a percentage return on capital employed or sales) that a company can earn on its sales of branded prescription medicines to the NHS. The PPRS 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 scheme, companies are set a target rate of return on capital (ROC) of 21% with an upward margin of tolerance of 40% of the target. Companies exceeding the margin of tolerance (i.e. with an ROC over 29.4%) are required to repay any excess to the DoH.

19. Under the terms of the PPRS, companies are free to set the NHS list prices of new branded products (new clinical entities) provided profits from NHS sales overall remain within the profit limit.[10] This flexibility is designed to allow companies to price new and innovative products so as to gain a return on that innovation during a period of patent protection.[11] Once prices are set, however, the PPRS restricts any increase. Under the current PPRS, a company may only apply for a price increase if its profits fall short of 50% of an ROC target of 17% (i.e. 8.5%).

20. Periodically, the DoH has negotiated an across the board price cut on all branded medicines sold to the NHS. In the context of the current PPRS agreement a price cut of 4.5% was negotiated. Companies were permitted to lower some prices more than others provided the overall effect was that of a 4.5% price cut.

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[9] *The Pharmaceutical Price Regulation Scheme*, July 1999, p3.
[10] The price of new branded medicines may, in some cases, be subject to limited confirmation by the DoH.
[11] *Pharmaceutical Price Regulation Scheme*, Report to Parliament, May 1996, paragraph 5.2.3.

(c) Distribution and purchasing

22. There are two different distribution channels serving two different customer segments in the market: the community segment and the hospital segment. The majority (86-90%) of supply is distributed by pharmaceutical wholesalers for resale to community pharmacies (the community segment). Product supplied through this channel is intended for patients in community (or primary) care, and is prescribed by GPs. Wholesalers are usually given a standard discount of 12.5%.

23. The remaining 10-14% of supply is purchased directly from manufacturers by hospitals (the hospital segment).[12] This is intended for patients in a hospital or hospice (secondary care) and is invariably prescribed by hospital doctors or specialists.

24. The NHS PASA competitively tenders purchasing contracts on behalf of ten hospital regions in England,[13] while authorities in Yorkshire, Scotland, Northern Ireland and Wales tender their own regional contracts. Together, these fourteen contracting regions cover almost all NHS trusts in the UK.

25. Most regional contracts will be awarded to one supplier of sustained release morphine (sole contract). Occasionally, however, a contract may be awarded to more than one supplier (shared contract). Regional contracts are framework contracts only and as such do not create a binding commitment on the part of individual NHS trusts to purchase exclusively from the contracted supplier(s). Rather, an individual hospital may choose either to purchase drugs under the terms of their regional NHS PASA contract or to negotiate an individual contract, which may be on different terms. Usually, if a hospital chooses to subscribe to the NHS PASA negotiations, however, it will not negotiate individual deals with pharmaceutical companies.

(d) Prescribing practices

26. A patient may be initiated onto sustained release morphine either by a hospital or hospice specialist or by a GP in the community. Most patients initiated in hospital will require

[12] The calculation of the relative size of the hospital and community segments is based on volume sold through each channel and not value. A precise calculation is difficult owing to different measurements of unit volumes and to the fact that relative sales vary from year to year. An interval of 10-14% is based on the evidence submitted by Napp on 31 July 2000 and 19 March 2001 and on data supplied by Medicare Audits and the DoH relating to hospital volume and community volume in UK Health Authorities.

[13] Central, North West, North East, South and West (divided into South West, Wessex and Oxford), South East, and North Thames Anglia (divided into North East Thames, North West Thames and East Anglia).

continuing treatment away from the hospital for a considerable amount of time. This follow-on care is generally provided in the community by their GP and by specialist or Macmillan nurses.

27. A prescription may be written either generically or by brand name. Where a prescription is written generically either by a hospital doctor or GP, the choice of brand or manufacturer is left to the pharmacist which dispenses the product.

28. Most hospitals use formularies to determine which drugs are prescribed, and any new drugs must be added to the formulary before they are used by the hospital. Formularies are fairly limited lists of drugs drawn up using comparisons of clinical features and prices of the drugs. Before a drug is included on the list, prices will be discussed with the manufacturer. The majority of drugs listed on a formulary will be generic. However, in the case of sustained release morphine, all products have proprietary titles (branded generics) and there are no products licensed and marketed under non-proprietary titles (true generics).[14] In this case the formulary will include a limited selection of branded generics.

29. Day to day prescribing in hospitals is usually done by junior doctors who will generally follow the formulary. Although generic prescribing is generally encouraged by the DoH, hospital doctors may still be influenced by the reputation of particular brands and their familiarity with those brands when deciding what to prescribe. However, hospital pharmacists will routinely substitute another generic equivalent for a branded drug where this is covered by an inter-professional agreement at the level of the individual hospital. By contrast, if a GP prescribes a particular brand, the community pharmacists must dispense that brand.

30. In the case of sustained release products, GPs are recommended not to prescribe them generically.[15] This is because brands may have slightly different release profiles and patients familiar with one brand may become confused if switched to another. Hence, sustained release morphine is not usually prescribed generically in the community.

(e) Funding

31. The DoH is able to monitor NHS purchases in both the hospitals (through NHS PASA) and the community (through the Prescription Pricing Authority). Most NHS purchases will be

[14] Generic drugs have essentially the same compound preparation as the original branded drug and usually carry a non-proprietary name based on the compound preparation e.g. morphine sulphate. In cases where they have their own brand name, they may be referred to as "branded generics" or "me-too" products.
[15] The British Medical Journal (BMJ) suggests that it is unwise to change between preparations when using modified release products because of possible variations in release profiles and oral bioavailability. *British Medical Journal*, 30 March 1996, Vol 312, p824.

made or administered locally by purchasers working for individual NHS organisations such as Trusts and Health Authorities.[16]

32. In the case of the community, community pharmacists supply the drug specified on the prescription from the GP. Each GP practice is awarded an indicative budget for prescribing. This is awarded by a Primary Care Group (PCG) and is used as a means of ensuring that each PCG stays within its cash limit. This unified budget system means that the GP faces peer pressure not to overprescribe and is intended to encourage GPs to be price sensitive. In the case of morphine, however, GPs tend not to be price sensitive, since the proportion of a GP's total indicative budget which is spent on morphine is likely to be small.

33. Community pharmacists' NHS income is made up of two elements - an amount to reimburse them for the costs of the medicines and appliances they dispense on NHS prescription and an amount to remunerate them for the dispensing of medicines and the range of professional services they provide. The Prescription Pricing Authority (PPA) is responsible for reimbursing each prescription it receives from the pharmacist.

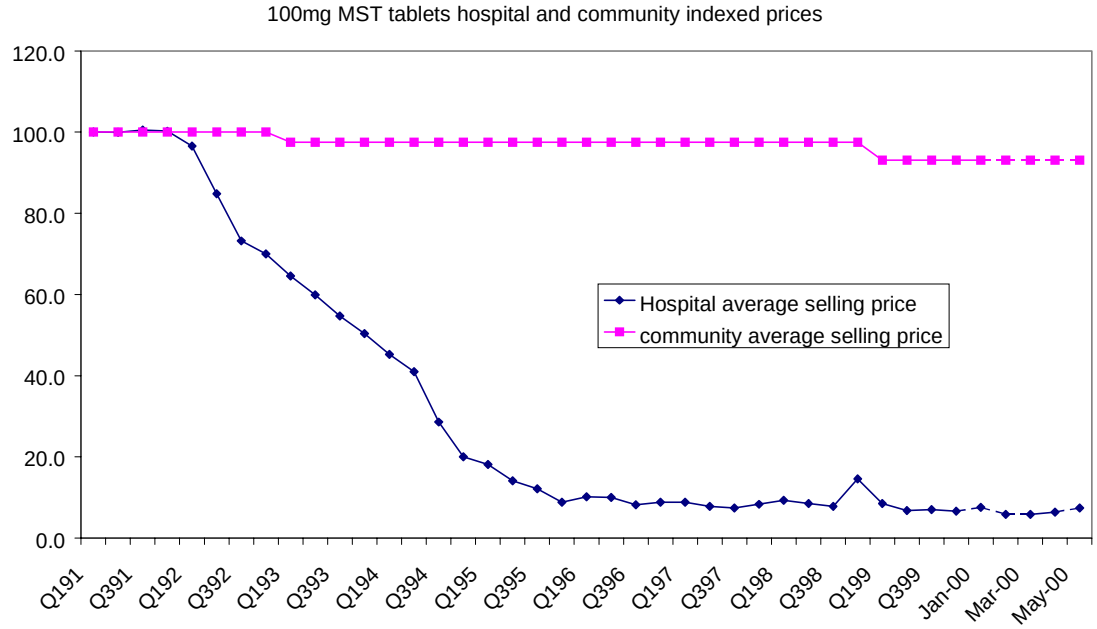
34. In the case of sustained release morphine tablets and capsules, all products have brand names and there are no products licensed and marketed as true generics. This means that the pharmacist will be reimbursed at the NHS list price of the particular brand dispensed.

C CONDUCT

35. Following expiry of the MST patent in August 1992, the price of MST tablets to the community has remained relatively stable at 12.5% discount from trade price (also stable), over the period to May 2000.[17] However, discounts to hospitals have increased dramatically over the period, following the launch by Farmitalia in October 1991 of SRM Rhotard.[18] This is reflected in Chart 1 below, which shows the widening price differential of MST 100mg as between the hospital and the community segments of the market. The picture is similar for the 10mg, 30mg and 60mg strengths of MST where the differential between the prices charged to hospitals and the prices charged to the community has also widened substantially over the last nine years.

[16] DoH website www.DoH.gov.uk/purchasing/intro.htm.
[17] The two small price reductions in 1993 and 1999 were the result of PPRS price reductions on all branded medicines sold to the NHS. The evidence on the Director's file does not extend beyond May 2000. The Director has no reason to believe that the position has altered significantly since that date, however.
[18] Supplied since 1994 until September 2000 by BIL as Oramorph SR.

Chart 1: Hospital and Community indexed prices of MST tablets (100mg) Q1 1991 = 100



Source: OFT calculation based on data from Napp
NB: figures for 2000 are given monthly, not quarterly

36. Chart 2 below compares the average hospital selling price of MST 10mg and Oramorph SR 10mg. The drop in Napp's prices to hospitals started in the first quarter of 1992 after it had lost a contract to supply MST to the Wessex NHS region in 1991 to Farmitalia. Napp failed to win the contract again in 1993 and 1995 despite offering 60% and […][*in excess of 90%*] discounts in those years, respectively.

37. Chart 2 also demonstrates that Napp's hospital prices continued to fall sharply with the introduction of Oramorph sustained release tablets in 1994. For a while the price of Oramorph SR did not fall over that period and remained above the price of MST tablets.

38. In 1995, Napp offered a […][*in excess of 90%*] discount to South East Supplies division and managed to retain that contract. Following this success, a […][*in excess of 90%*] discount was offered in all NHS tenders for MST tablets. This is reflected in Chart 2 below where the price to hospitals of MST tablets remained more or less stable from 1995 to the first quarter of 1997. Napp lost the North West Supplies contract in 1996, even though it tendered at a […][*in excess of 90%*] discount and has since offered a [...][*in excess of 90%*] discount against trade price to hospitals. This can be seen in Chart 2 below as Napp's hospital price dips again slightly in the second quarter of 1997.

39. BIL was forced, since the first quarter of 1997 until it withdrew from the market in September 2000, to sell at the same discount to hospitals as Napp.

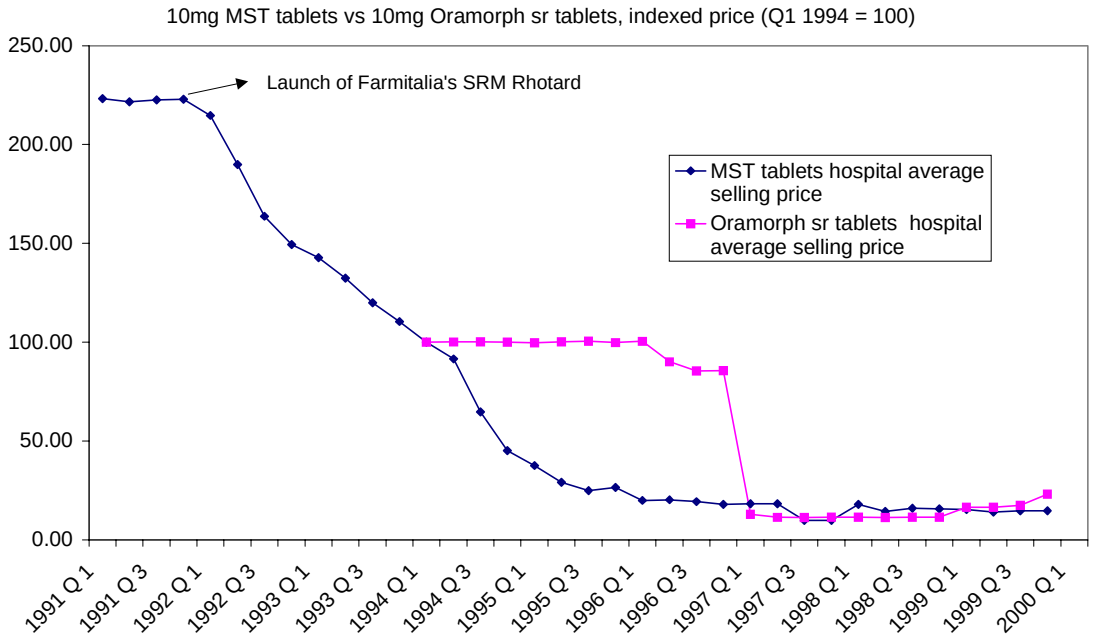
40. In current contracts that Napp holds with regional NHS PASA for the supply of sustained release morphine tablets, full discounts of [...][*the highest discount (in excess of 90%)*] are only available on four strengths of MST (10mg, 30mg, 60mg and 100mg). For 5mg, 15mg and 200mg MST tablets, Napp's discounts to hospitals are below 85%.

41. In tendering for regional hospital contracts, Napp's discount policy also distinguishes between those contracts which are tendered on the basis that a contract will be awarded to only one supplier of sustained release morphine tablets (sole contracts), and those contracts which are tendered on the basis that they may be awarded to two or more competing suppliers. As Napp states, "where we expect that a contract might be shared we only offer a […][*less than the highest discount*] discount."

42. Of the fourteen regional supply contracts, Napp reported that it held seven of these contracts on a sole basis from the beginning of March 2000. All of these contracts were of a duration of two or more years. It reported that it shared a further four contracts with BIL. The highest discount of [...][*in excess of 90%*] is available in five of the seven contracts awarded to Napp on a sole basis. For only one of the four contracts that Napp reports as shared with BIL is the highest discount available and this was the result of a mistake on the part of Napp.[19]

[19] Napp: "There are certain exceptions to this as we do not always guess correctly. For example, we believed that the all Wales contract was to be awarded exclusively and so tendered at a […] [*the highest discount*] discount, only to find that the contract was awarded on a shared basis."

Chart 2: Comparison of 10mg MST tablets and 10mg Oramorph sustained release tablets indexed hospital prices



Source: OFT calculation based on data from Napp and Boehringer Ingelheim
NB: Q1 2000 average actual selling price to hospitals for MST 10mg tablets was calculated as an average of average actual selling prices for January, February and March 2000.

III LEGAL AND ECONOMIC ASSESSMENT

43. Section 18(1) of the Act provides that any conduct on the part of one or more undertakings which amounts to the abuse of a dominant position in a market is prohibited if it may affect trade within the UK. "Dominant position" in section 18 means a dominant position in the UK or any part of it.[20]

44. Section 60(1) of the Act sets out the principle that, so far as is possible (having regard to any relevant differences between the provisions concerned), questions arising in relation to competition within the United Kingdom are dealt with in a manner which is consistent with the treatment of corresponding questions arising in European Community law in relation to competition within the Community. In particular, under Section 60(2) of the Act, the Director must act (so far as is compatible with the provisions of the Act) with a view to ensuring that there is no inconsistency with either the principles laid down by the EC Treaty and the European Court or any relevant decision of the European Court.[21] Under Section 60(3) of the Act, the Director must also have regard to any relevant decision or statement of the European Commission.

A THE RELEVANT MARKET

45. For the purposes of Community competition law the relevant market comprises a relevant product market and a relevant geographic market. These may be defined as follows: "a relevant product market comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of the products' characteristics, their prices and their intended use ... the relevant geographic market comprises the area in which the undertakings concerned are involved in the supply and demand of products or services, in which the conditions of competition are sufficiently homogeneous and which can be distinguished from neighbouring areas because the conditions of competition are appreciably different in those areas."[22]

46. The European Commission has provided guidance on how it applies this concept in practice in its Notice on market definition.[23] The Notice also describes the sorts of information that may be used to define markets. These include product characteristics, evidence of past substitution, differences in prices and price trends, and the views of customers and

[20] Section 18(3) of the Act.
[21] The European Court is defined as the Court of Justice of the European Communities and includes the Court of First Instance (section 59(1) of the Act).
[22] Commission Notice on the definition of the relevant market for the purposes of Community competition law (OJ C 372, 3.12.1997, p.5). The definitions reflect the case law of the European Court.
[23] See footnote 22 above.

competitors. Supply-side substitution may also be relevant to a definition of the relevant market where its effects are equivalent to those of demand substitution in terms of effectiveness and immediacy.

(a) The relevant product market

47. One starting point for defining the product market in the case of pharmaceutical products is the Anatomical Therapeutic Classification (ATC) system recognised and used by the World Health Organisation (WHO). The ATC allows products to be grouped by reference to their composition and therapeutic qualities. Different "levels" of the ATC group medicines together on different bases. The third level is generally thought to be the most useful level for the purposes of market definition. This allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use, and can therefore be used as a starting point for the operational market definition. This is consistent with the European Commission's analyses of pharmaceutical markets in a number of cases.[24]

48. Sustained release morphine belongs to the N2A class (narcotic analgesics) in the third level of the ATC system. This includes all presentations of sustained release morphine, immediate release morphine and non-morphine products such as hydromorphone, oxycodone, fentanyl and diamorphine. The Director considers that this is too wide for the purpose of defining the relevant market in this case, however.

49. This too is consistent with decisions of the European Commission, which recognises that the relevant market in economic terms may be wider or narrower than the ATC classification system allows.[25] In its decision in *Ciba-Geigy/Sandoz,* for example, the Commission states:

> "Medicines may be subdivided into therapeutic classes by reference to the 'Anatomical Therapeutic Classification' (ATC) which is recognised and used by the World Health

[24] *Hoffmann-la Roche/Boehringer Mannheim* (Commission Decision 98/526/EC) Case IV/M.950 OJ (1998) L234/14, [2000] 4 CMLR 735; *Ciba-Geigy/Sandoz* (Commission Decision 97/469/EC) Case IV/M.737 OJ (1997) L201/1; *Astra/Zeneca* Case IV/M.1403 OJ (1999) C335/3; *Adalat* (Commission Decision 96/478/EC) Case IV/34.279/F3 OJ (1996) L201/1; *Sanofi/Sterling Drug* Case IV/M.0072 OJ (1991) C156/0, [1993] 5 CMLR M1; *Procordia/Erbamont* Case IV/M.323 OJ (1993) C128/0, [1993] 5 CMLR 115 (IP); *Rhone Poulenc/ Cooper* OJ (1994) C113/0; *La Roche/Syntex* Case IV/M.457 OJ (1994) C278/3, [1994] 5 CMLR 27 (IP); *AHP/Cyanamid* Case IV/M.500 OJ (1994) C278/3; *Glaxo/Wellcome* Case IV/M.555 OJ (1995) C065/3, [1995] 4 CMLR 321 (IP); *Behringwerke AG/Armour Pharmaceutical Co*. Case IV/M.495 OJ (1995) C134/4 [1995] 4 CMLR 609 (IP); *Hoechst/Marion Merrell Dow* Case IV/M.587 OJ (1995) C193/5, 1995 5 CMLR 134 (IP); *Upjohn/Pharmacia* Case IV/M.631 OJ (1995) C294/9, [1995] 5 CMLR 390 (IP).

[25] *Hoffmann-la Roche/Boehringer Mannheim* (Commission Decision 98/526/EC) Case IV/M.950 OJ (1998) L234/14, [2000] 4 CMLR 735.

> Organisation. … it might be appropriate to apply a narrower market definition where the medicines in question have clearly differing indications. … The interchangeability of products depends in principle not on their physical, technical or chemical properties but on their functional substitutability as viewed by those supervising their consumption. In the case of medicines available on prescription only, therefore, these would be established medical practitioners. But the prescription practices of medical practitioners are regularly influenced by the objective scientific knowledge available to them concerning the active properties and similarities of medicines. … Factors militating against any more far-reaching market definition include different degrees of tolerance of medicines by the patient and differences in price. In the case of medicines available on prescription only, therefore, the market definition cannot be based simply on whether different medicines are prescribed for the same illness (i.e. the same indication group). The criterion is that prescription is based on fundamentally the same medical grounds. For such prescription practice, account can be taken of whether the medicines correspond to each other, for example in terms of principle, tolerance, toxicity and side effects."[26]

50. In practice, pain control by doctors in palliative care is widely approached using the WHO's three step analgesic ladder. This is summarised by the Medicines Resource Centre (MeReC) as follows:

> "The first 'step' involves the use of non-opioid analgesics e.g. paracetamol and non-steroidal anti-inflammatory drugs. If these do not control pain, one of the opioids suitable for *mild to moderate pain* is added – step 2. At step 3, opioids suitable for *severe pain* are used."
>
> "Morphine is the preferred oral opioid at step 3."[27]

51. The Welsh Medicines Resource Centre (WeMeReC) also suggests that non-opioids should be used in step one, weak opioids and non-opioids such as codeine and dihydrocodeine should be used in step two and strong opioids such as morphine or diamorphine in step three. WeMeReC adds that at step three, for the palliative care of severe pain, "Morphine is the drug of choice because of its ease of administration and titration and well understood pharmacokinetics."[28]

52. Thus the market at issue is at its widest that for strong opioids, used for the treatment and prevention of severe pain, in which morphine is the drug of first choice.[29] Further analysis shows that the relevant product market is, in fact, narrower than this.

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[26] *Ciba-Geigy/Sandoz* (Commission Decision 97/469/EC) Case IV/M.737 OJ (1997) L201/1.
[27] MeReC Bulletin (National Prescribing Centre) Vol 7 No 7 July 1996 p25.
[28] WeMeReC Bulletin Vol 5 no 6 October 1998 p 2.
[29] Napp, 'Targeting Pain Series', May 1999.

Non-morphine products

53. There is a number of non-morphine opioid analgesics available in the UK, such as fentanyl, hydromorphone, oxycodone and diamorphine.

54. These non-morphine drugs would not be considered a demand-side substitute for morphine on the basis of price alone as the decision to use non-morphine substitutes is based on patient needs and not price considerations. In its evidence to the Director, the BMA stated that, "The cost is rarely considered in terminal care pain relief". It also stated in evidence that, "Only rarely can sustained release morphine be substituted by other non morphine pharmaceuticals."

55. Expert testimony submitted by Napp confirms the view that the drug prescribed would depend on the needs of a particular patient:

    (i) "Based on my expertise and experience, when a patient presents to me with chronic severe pain, I am able to select a particular product which I consider to be the best treatment in all the circumstances of the patient's case...it would be an unusual case where I was effectively indifferent as between oral sustained release morphine and another product.";

    (ii) "Where I conclude that a patient requires some general pharmaceutical treatment to reduce his chronic pain, I tend to think of prescribing tramadol, morphine or oxycodone.... There are few cases where I would consider that I could equally well prescribe oral sustained release morphine or another product: In the end, I tend to conclude that, for each patient…there is one product which is the best option.".

56. In addition, evidence from medical experts suggests that while non-morphine strong opioids could, in principle, substitute for morphine to control severe pain, they would only be used as a substitute for morphine where there was a perceived clinical problem with the patient's use of morphine. Non-morphine drugs such as fentanyl, diamorphine, hydromorphone or oxycodone are only to be used when the patient is sensitive to the side effects of morphine and cannot tolerate the drug[30] or when the drug cannot be administered orally.[31] According to the BNF and others, morphine remains the most valuable opioid

[30] Mary Allen and Ros Taylor (1999) "Issues in Pain control in palliative care", *The Pharmaceutical Journal* May 1999, Vol 262; WeMeReC Bulletin Vol 5, No 6, October 1998 p3.

[31] Hydromorphone and oxycodone are currently the only orally administered sustained release strong opioids other than morphine. Fentanyl (brand name, Durogesic) is administered subcutaneously, through an adhesive patch. Diamorphine is administerd intravenously.

analgesic for severe pain and is the opioid of choice for the oral treatment of severe pain in palliative care.[32]

57. Napp recommends Palladone SR capsules for cancer patients for whom morphine is unsuitable. However Napp's research states that "The percentage of patients with opiate responsive pain, treated by palliative care specialists, that do not receive either morphine or diamorphine is estimated to be extremely small, that is in the region of 1-2% … Morphine remains the gold standard and is used wherever and whenever possible." Thus demand side substitution of morphine and non-morphine products is unlikely.

58. Furthermore, Napp's own internal documents point to the relatively low effect that Palladone (brand name for hydromorphone), MXL and fentanyl have had on sales of MST.

59. A comparison of the community prices of various morphine and non-morphine products in 1998 and 2000 (Table 1 below) shows that the price of non-morphine products such as Durogesic (the brand name for fentanyl) and diamorphine is unlikely to constrain the price of sustained release morphine. (The reduction in prices since 1998 reflects the recent PPRS negotiations.) Diamorphine costs almost three times as much as morphine for a comparable dose and Durogesic almost twice as much.[33]

[32] BNF March 2000 section 4.7.2 "Opioid analgesics" p209; MIMS June 2000 section 4A "Analgesics and antipyretics" p133; "Guidelines for Managing Cancer Pain in Adults" Working party on clinical guidelines in palliative care, September 1994 p11; MeReC Bulletin Vol 7 No 7, July 1996 p27; WeMeReC Bulletin Vol 5, No 6, October 1998 p1; Mary Allen and Ros Taylor (1999) "Issues in Pain control in palliative care", *The Pharmaceutical Journal* May 1999, Vol 262, p620; Napp "Analgesics in Palliative Care, A Clinical Overview."

[33] The price differential is likely to reflect both differences in the costs of production and also the lower volume usage of non-oral presentations of such opioid analgesics.

Table 1: Comparison of the approximate cost to the community of morphine sulphate[34] and non-morphine products (120mg daily for 28 days or equivalent)

Product	Cost (£)	
	2000	**1998**
Normal [immediate] release morphine		
Solutions		
Oramorph oral solution	29.33	32.59
Oramorph concentrated oral solution	30.43	33.81
Oramorph unit dose vials	44.49	44.49
Tablets		
Sevredol tablets	36.15	37.86
Modified [sustained] release morphine		
Suspensions		
MST Continus suspension	105.97	110.95
Tablets/capsules		
Morcap SR capsules	30.55	31.98
MST Continus tablets	31.34	32.82
Oramorph SR tablets	25.10	25.10
Zomorph SR capsules	18.80	19.69
MXL capsules (once-daily)	31.34	32.82
Other [non-morphine]		
Subcutaneous diamorphine	N/A	89.04
Durogesic patches	57.94	57.94

Source: Supplement to WeMeReC Bulletin Vol. 5 No. 6, October 1998, updated by PPRS branch of DoH.

60. In its reply to the Director's original rule 14 notice, Napp contends that differentiated products, in particular Durogesic, compete on the basis of their therapeutic innovation and their ability to treat a particular condition rather than on the basis of price. In this respect, comparing absolute prices may not give a full indication of the degree to which two products compete. It argues in particular that the launch of Durogesic has led to a dent in the sales of MST, and that this is evidence of the competitive constraint that Durogesic represents.

61. Differentiated products may well be more suitable for the treatment of some patients. However, the question for the purposes of defining the relevant product market is whether the degree of differentiation is sufficiently small such that in a sufficiently large number of

[34]Morphine sulphate is the active ingredient in both immediate (normal) and sustained (modified) release morphine.

cases the two products will be regarded as substitutable or interchangeable. The testimony above suggests that this is not the case. Furthermore, the significant gap between the price of Durogesic and MST is a strong indication that the two products are not regarded as substitutes in a large number of cases.

62. In addition, survey evidence submitted by Napp and its competitors indicates that fentanyl (Durogesic) is used in practice only when patients are intolerant to morphine:

    (i) "This survey suggests that the Janssen product (Durogesic) is mainly being prescribed to solve specific problems (e.g. patient cannot swallow) as opposed to being used as a 1st line strong opiate";[35]

    (ii) "Durogesic is often used 2nd line (or even as a last resort)…";[36]

    (iii) "Transdermal fentanyl was seen as useful for selected patients, but too expensive for widespread use. The patches were considered valuable for patients with sensitivity or intolerable side effects to morphine; difficulties in swallowing or gut absorption; younger patients wishing to maintain a mobile lifestyle; older, confused patients for compliance";[37] and

    (iv) "The main reason cited for each respondent's most recent Durogesic initiation was side effects with MST, constipation, nausea and vomiting and sedation all being specifically mentioned." This research suggests that the top three situations in which respondents to the research have ever prescribed or recommended Durogesic are when patients have swallowing difficulties, morphine side effects or compliance/convenience issues.[38]

63. There are also many disadvantages to using fentanyl patches – lack of flexibility, difficult to titrate, difficult route of administration, and disposal.[39]

64. Neither is it clear that the launch of Durogesic has had a significant impact on MST sales. This would be inconsistent with the internal documentation of Napp cited at paragraph 58 above. In addition, MST sales have not substantially fallen since the launch of Durogesic, and any slow down in the MST sales trend since 1995 is also, at least in part, attributable to the launch of three other brands of sustained release morphine (Oramorph SR (1994), Morcap (1996) and Zomorph (1997)), and their impact on the unit sales of MST and its price in the hospital segment.

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[35] From research commissioned by Napp, May 1999.
[36] From research commissioned by Napp, May 1999.
[37] From research commissioned by one of Napp's competitors, September 1997.
[38] From research commissioned by Napp, February 1998.
[39] Napp.

65. On the supply side, morphine and non-morphine products should also not be considered to be effective substitutes. If the price of morphine products rose, it would not be possible for manufacturers of non-morphine analgesics to enter the market within a short space of time and thus constrain the price of morphine. Firms would also need to obtain an authorisation from the MCA to manufacture and market morphine products as opposed to non-morphine products.[40] This can take more than a year.

66. One competitor estimates that even when a company already produces immediate release morphine or a non-morphine based strong opioid, it could take two to three years to obtain a marketing authorisation. This would typically involve developing a sustained release formulation, as well as collating data that demonstrates bio-equivalence. This is confirmed by another competitor which stated in its evidence to the Director that it would take a considerable amount of time for a company to develop and obtain a licence even for a product that was "essentially similar" to one that had been licensed in the UK for 10 years or more.

67. Even in the case of BIL, which was able to make an "abridged" application,[41] it took 11 months to obtain a marketing authorisation for Oramorph SR in the UK. In the case of Oramorph SR, BIL was able to cross-refer to the dossiers already submitted to the MCA by Ethical Pharmaceuticals Ltd (who manufactured Oramorph SR for BIL) under the name SRM Rhotard.[42] A new entrant wishing to market a new sustained release product would not have this option and obtaining a licence from the MCA would be likely to take considerably longer.

68. Napp contends that it obtained marketing authorisation for MXL (another sustained release morphine product) in seven months. However, it is likely that Napp's existing expertise in the development and marketing of MST allowed it to process the application and answer the MCA's queries with unusual speed. For companies without prior experience in the manufacture and marketing of sustained release morphine, it is unlikely that a marketing authorisation could be obtained so rapidly. Thus the need to obtain authorisation implies that supply-side substitution from non-morphine to morphine opioids is not rapid.

69. Even if obtaining a marketing authorisation from the MCA were rapid, a firm would also need to establish a reputation for its new product. As described in paragraphs 104 to 111 below, the need for a new brand of sustained release morphine to establish a reputation constitutes a significant barrier to entry. Manufacturers of non-morphine products are, if anything, more accurately described as potential entrants rather than actual competitors.

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[40] The same would be true in the case of a supplier of immediate release morphine products which wanted to supply sustained release morphine products.
[41] See paragraph 14 above.
[42] SRM Rhotard was marketed by Farmitalia.

70. In conclusion, non-morphine products do not constrain the price of morphine products and hence should not be included in the relevant market in this case. This is because doctors tend to choose between morphine and non-morphine products on the basis of clinical need and clinical uses for the two differ. Supply-side substitution is also unlikely.

Non-oral morphine

71. For reasons similar to those discussed in relation to non-morphine products, morphine that is not administered orally is also not an effective demand side substitute for oral morphine. The European Association for Palliative Care advises that "the optimal route of administration of morphine is by mouth".[43] The oral route of administration is preferred as it is convenient, safe, reduces dependence on medical personnel and also offers pharmacokinetic advantages: when medications, particularly morphine, are given orally their duration of action is prolonged, an advantage for chronic pain. The periodical *Drugs* further states, "Indications to abandon oral morphine are relatively rare and include intractable emesis, dysphagia, obstruction of the GI tract and the comatose patient who might still require analgesia." [44] This is further supported by evidence submitted by Napp which states that "Non-invasive techniques of analgesic administration should be used where possible."[45]

72. Also, for reasons similar to those given in relation to the substitutability of morphine and non-morphine products, oral and non-oral morphine products would not be considered supply side substitutes. Firms would need to obtain a specific licence from the MCA and gain a reputation for their new product.

73. As is the case of morphine and non-morphine products, the choice between oral and non-oral morphine is based on clinical need. Non-oral morphine products do not constrain the price of oral morphine products and hence should not be included in the relevant product market in this case.

Sustained release and immediate release morphine

74. There are two types of oral morphine formulation: immediate release (for dose titration)

[43] Expert Working Group of the Association for Palliative Care (1996), "Morphine in cancer pain: modes of administration" in *British Medical Journal*, Vol 312, p 823-826.
[44] Schug, S.A., R.Dunlop, and D.Zech (1992), "Pharmacological management of cancer pain", *Drugs* vol 43, no 1, p46.
[45] Professor E. Klaschik, "Opioids -The Route of Administration" in *Opioid Evolution - Natural Selection?* Fifth Congress of the European Association of Palliative Care.

and controlled release (for maintenance treatment).

75. Immediate release morphine is primarily administered for short acting, immediate relief from pain. If there is "breakthrough pain",[46] immediate release preparations are given.[47] By contrast, sustained release morphine is administered for on-going control of stable pain. Given that they are used for such different purposes the two are unlikely to be substitutable. The BNF has stated in correspondence to the Director, that it does "not believe that sustained release morphine at present can be substituted with other morphine products."

76. One doctor has suggested that if sustained release preparations were not available, it would be possible to control pain with regular administration of immediate release morphine. Napp also argues that immediate release morphine is used for the treatment of stable pain. However, use of immediate release morphine requires more regular doses. There is a risk that the pain will return between one dose and the next. Immediate release morphine must be given every three to four hours to maintain adequate pain control. This results in interrupted sleep and inconvenience for the patient, and the potential for non-compliance and medication errors.[48] Also, in the hospital segment, it requires the presence of two registered nurses to administer the drug each time.

77. In addition, sustained release morphine offers considerable advantages over immediate release morphine for on-going control of stable pain. According to the statement of the Wessex Regional Drug Information Centre submitted by Napp: "administration of a modified-release preparation every 12 hours avoided the excessive peaks (sic) and trough serum levels associated with 4 hourly morphine. This helped provide continuous analgesia with minimum "breakthrough" pain at trough levels of morphine". Doctors say they are unwilling to substitute between the two if the pain remains stable and controlled.

78. Immediate release and sustained release morphine are used as complements rather than substitutes. Immediate release morphine is often prescribed to patients for immediate or breakthrough pain in order to establish a controlling dose followed by a sustained release preparation for on-going control of stable pain. MIMS advises that "When initiating therapy, start with an oral dose of 2.5mg to 5mg four hourly [immediate release]…Once control is established switch to a sustained-release formulation…".[49]

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[46] "Breakthrough pain" is pain which occurs just before the next usual dose of morphine is due, usually, in the case of cancer, because the cancer is progressing. The sustained release dose should be increased to prevent the pain from recurring. "Incident pain" can also require the use of immediate release morphine. This is pain associated with some activity involving movement or weight-bearing.

[47] MIMS, June 2000, p133; BNF, March 2000, p12; MeReC Bulletin, National Prescribing Centre, July 1996, Vol 7 No 7, p27; Robert Twycross (1999), *Morphine and the relief of Cancer*, 1999 p6.

[48] "Comparison of two oral morphine formulations for chronic severe pain of malignant and non-malignant origin" T. Floter, EMW Koch and the Kap-Cas study group.

[49] MIMS June 2000 p133.

79. The complementarity of immediate release and sustained release preparations is consistent with survey evidence and testimony submitted by Napp: "It was noted that 301 of the 343 patients taking modified release opioids had been prescribed at the same time an immediate acting opioid to be taken for "break-through" pain. This is a recognised good clinical practice to allow patients, if they experience pain while taking a modified release opioid, to take an immediately acting preparation to deal with pain."

80. For reasons similar to those given above, immediate release morphine and sustained release morphine are also not effective supply side substitutes. Companies wishing to market a sustained release product would need to obtain a specific licence from the MCA and gain a reputation for their new product.

81. In conclusion, immediate release products are not in the same market as sustained release products. This is consistent with the European Commission's recent finding that sustained release and immediate release analgesics belong to separate markets. The Commission stated that, "The market definition suggested by the parties regarding the existence of two different segments as well as their complementarity has been confirmed by the Commission's market investigation. Therefore, for the purposes of the present case, the immediate-release and the slow-release segments of the N2A ATC class will be considered to constitute two separate relevant markets".[50]

Sustained release morphine suspension

82. In addition to tablets, Napp also markets MST in the form of a suspension (MST Suspension). Evidence submitted by Napp indicates that this would not be used as a substitute for sustained release morphine tablets and capsules, however, unless the patient suffering from continuous severe pain was unable or unwilling to swallow tablets. In addition, the price levels in Table 1 show that MST Suspension is more than three times the price of MST tablets for a comparable dose.

83. While this evidence would indicate that MST Suspension is not a demand-side or supply-side substitute for tablets and capsules it is not sufficient to rule out that possibility. Even if it were included in the relevant product market, however, it would make no material difference to the Director's findings.

[50] *Monsanto/Pharmacia & Upjohn* Case COMP/M.1835 OJ (2000) C143/4 paragraph 30, p7.

Substitutability of different brands of sustained release morphine

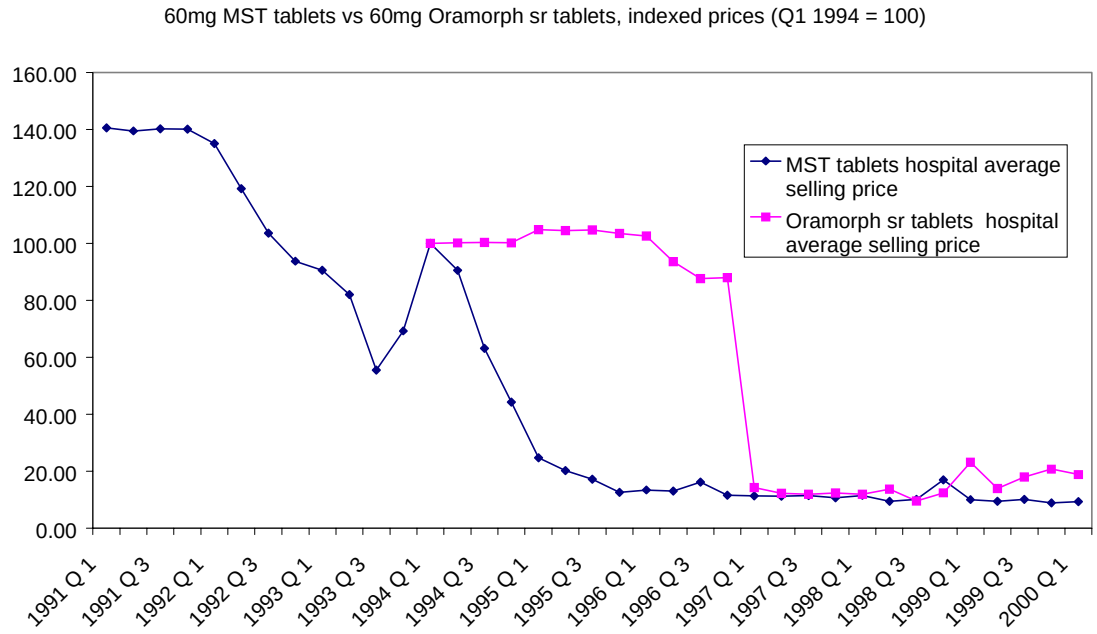
84. The Director has also considered the possibility of product markets that are narrower than sustained release morphine tablets and capsules. Although there is evidence that for some patients at least, different brands of sustained release morphine may not be directly substitutable,[51] clinicians that have been consulted have not observed any significant clinical difference between different brands of sustained release morphine in their analgesic efficacy. Hence, they should be willing to choose between brands based on price and their perception of quality, reliability and other relevant factors when initiating patients with a particular brand.

85. Invitations to tender for hospital contracts are conducted under the specification of "Morphine Sulphate Modified Release Tablets".[52] This indicates that hospitals view different brands of sustained release morphine tablets, including once daily and twice daily, as competing substitutes.

86. This is supported by pricing data for different brands of sustained release morphine tablets. Chart 3 below compares indexed prices for MST 60mg tablets with Oramorph 60mg sustained release tablets to hospitals. Price movements in the two different brands of sustained release morphine follow similar trends in the hospital segment. This data is consistent with the brands being in the same market.

[51] The different brands of sustained release morphine products release the drug at slightly different rates and come in different presentations. *WeMeReC Bulletin, Welsh Medicines Resource Centre*, October 1998, Vol 5 No 6, p2; BMA.
[52] Napp.

Chart 3: Comparison of 60mg MST tablets and 60mg Oramorph sustained release tablets, indexed hospital prices (Q1 1994 = 100)



Source: OFT calculation based on data from Napp and Boehringer Ingelheim
NB: Q1 2000 average actual selling price to hospitals for MST 60mg tablets was calculated as an average of average actual selling prices for January, February and March 2000.

87. Napp argues that, in the community segment of the market, other brands of sustained release morphine tablets or capsules provide less competition to MST than more differentiated products such as Durogesic. It states that if a GP "is satisfied with MST as being an effective sustained release morphine preparation, there is no real point in his switching to another similar preparation: it is unlikely to offer any benefits, and he has the hassle of learning about different dosage levels in which it is offered, and the potentially different absorption profile etc". In addition, the fact that the price of MST tablets is 40% higher than the price of Oramorph sustained release tablets in the community segment may indicate that the two brands only have limited substitutability in the community segment of the market.

88. The extent to which non-morphine products, such as Durogesic, may be substitutable for morphine products, including MST, has been considered above.[53] As regards the substitutability of other brands of sustained release morphine for MST, it is admittedly not possible in the case of a technically complex product such as sustained release morphine

[53] See paragraphs 53 to 70 above.

for consumers to assess readily whether two similar products are in fact substitutes. GPs, unlike hospital specialists and pharmacists, often lack the time and expertise to assess the substitutability of different products, and this leads to a degree of switching inertia. Indeed these factors contribute to Napp's market power in the community segment of the market.[54] However, there is no reason why rival brands should not be competitive substitutes for MST in the eyes of GPs, in the same way as they have already become in the hospital segment of the market.

(b) The relevant geographic market

89. In order to import and market a relevant medicinal product in the UK, a firm must obtain either a marketing authorisation or a PLPI from the MCA.[55] Obtaining a marketing authorisation is likely to take at least a year and could take two to three years.[56] Obtaining a PLPI, where this is available is also likely to take some time to obtain.[57] In addition to the licence from the MCA, imports of controlled drugs (such as morphine) need to be approved by the Home Office.

90. There are no other overseas companies with UK marketing authorisations for sustained release morphine tablets. There are also currently no PLPIs for any products containing morphine sulphate. This implies that the time needed to organise imports of sustained release morphine could be quite considerable. The market is not, therefore, wider than the UK.

91. This is consistent with decisions of the European Commission in which it has found that the markets for medicines are national and not European. In its decision in *Hoffmann-La Roche/Boehringer Mannheim*, for example, the Commission stated that:

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[54] See paragraphs107 to 108 below.
[55] See paragraphs 13 to 15 above.
[56] See paragraphs 66 to 67 above.
[57] Although one of Napp's competitors has estimated that approval for a PLPI from the MCA would take less than 6 months to obtain, the MCA has stated that "it is not possible to give a meaningful estimate of how long it takes to issue a PLPI licence." It points out that "a number of factors affecting the length of time taken to obtain a PI licence are outwith the MCA's control. For example, there is usually a need to wait for information from the regulatory authority in the member state concerned to ensure that the product to be imported has no differences, having a therapeutic effect, from the corresponding UK product. This is particularly so for a product [such as sustained release morphine] that has not been imported into the UK before. Also there are often delays in the applicant responding to requested changes in their application, to the text of their proposed labelling and to the drafting of their patient information leaflet." Although, as Napp has argued in its representations to the Director, delays on the part of the applicant will to some extent be within its control, it is clear that a number of issues need to be addressed before a PLPI can be approved and these may take some time.

"Given that prices for medicines may differ from one Member State to another since sales are influenced by the administrative procedures or purchasing policies which the national health authorities have introduced, with some countries exercising a direct or indirect influence over prices and different levels of reimbursement by social security systems for different categories of medicines, and the fact that there are far reaching differences in terms of brand and pack-size strategies and in national distribution systems, pharmaceutical markets may be regarded as national." [58]

92. The market is not narrower than the UK as national players compete for each local tender, regardless of the location in the UK.

(c) Conclusion on the relevant market

93. Based on the evidence above, the relevant market is the supply of sustained release morphine tablets and capsules in the UK.

[58] *Hoffmann-la Roche/Boehringer Mannheim* (Commission Decision 98/526/EC) Case IV/M.950 OJ (1998) L234/14, [2000] 4 C.M.L.R. 735.

B DOMINANCE

94. The European Court has defined a dominant market position as:

> "… 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, customers and ultimately of its consumers."[59]

95. In assessing whether there is dominance the Director considers whether and to what extent an undertaking will face constraints on its ability to behave independently. Those constraints might be:

(i) existing competitors, according to their strength in the market: this may be shown by market shares;

(ii) potential competitors: this may be shown by a lack of significant entry barriers and the existence of other undertakings which might easily enter the market; and

(iii) other constraints such as strong buyer power from the undertaking's customers (which may include distributors, processors and commercial users).

(a) Market shares

96. The European Court has stated that dominance can be presumed in the absence of evidence to the contrary if an undertaking has a market share persistently over 50%.[60]

97. Market share can be measured using either cash sales or volume sales, whether in packs, units (i.e. number of tablets sold) or in milligrams (mgs). Napp has a very high market share regardless of the measure used. Napp's market share is also very high regardless of whether community and hospital sales are considered separately or as a whole.

98. Table 2 shows the market shares of Napp and its competitors in unit volumes, taken from spreadsheets compiled by IMS for one of Napp's competitors. Tables 3 and 4 show Napp's share of supply to the community and hospital segments, respectively. The figures for 2000 include January to April only. BIL, the supplier of Oramorph SR, has since withdrawn from the market. There is no reason to believe that Napp's market share will have changed materially as a result. If anything it is likely to have increased.

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[59] Case 27/76 *United Brands v EC Commission* [1978] ECR 207; [1978] 1CMLR 429.
[60] Case C62/86 *AKZO Chemie BV v Commission* [1991] ECR I-3359; [1993] 5 CMLR 215.

Table 2: Market share (unit volumes) of sustained release morphine tablets/capsules 1997-2000

Hospital and Community sales (unit volumes)	1997	1998	1999	2000[1]
MST CONTINUS[2]	93.8	94.0	93.9	94.0
MXL	2.9	3.0	2.6	2.0
Napp total	96.7	97.0	96.5	96.0
ORAMORPH SR	2.5	2.3	2.1	1.8
MORCAP	0.5	0.4	0.4	0.3
ZOMORPH	0.3	0.2	1.0	1.9
TOTAL	100.00	100.00	100.00	100.00

Source: IMS data

[1] Figures for 2000 include January to April only

[2] The figures for MST Continus include sales of MST Continus Suspension. However, given that these represent less than 1% of Napp's total sales of sustained release morphine, their inclusion should not affect the figures significantly.

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[1]
MST CONTINUS[2]	92.0	91.3	91.7	91.9
MXL	4.8	5.5	4.8	4.1
Napp total	96.9	96.7	96.5	96.0
ORAMORPH SR	2.5	2.3	2.3	2.2
MORCAP	0.7	0.8	0.6	0.5
ZOMORPH	0.0	0.2	0.6	1.3
TOTAL	100.0	100.0	100.0	100.0

Source: IMS data

[1] Figures for 2000 include January to April only

[2] The figures for MST Continus include sales of MST Continus Suspension. However, given that these represent less than 1% of Napp's total sales of sustained release morphine, their inclusion should not affect the figures significantly.

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[1]
MST CONTINUS[2]	74.2	79.6	86.3	89.0
MXL	5.7	7.2	6.0	4.3
Napp total	79.9	86.8	92.3	93.3
ORAMORPH SR	20.1	13.2	7.7	4.1
MORCAP	0.0	0.0	0.0	0.2
ZOMORPH	0.0	0.0	0.0	2.4
TOTAL	100.0	100.0	100.0	100.0

Source: IMS data

[1] Figures for 2000 include January to April only

[2] The figures for MST Continus include sales of MST Continus Suspension. However, given that these represent less than 1% of Napp's total sales of sustained release morphine, their inclusion should not affect the figures significantly.

99. Table 2 shows that in 1999 Napp had a 96.5% share of the market for the supply of sustained release morphine in the UK. Tables 3 and 4 show that Napp enjoyed a 96.5% share of supply in the community segment and a 92.3% share of supply in the hospital segment, in unit volume terms in 1999. Napp held similarly high shares in the first four months of 2000. This is broadly consistent with Napp's own estimates of its market shares as well as estimates provided by its competitors. Napp estimates that "the Napp Group's share of UK supply of sustained release morphine to the community for 1997, 1998, 1999 and the first half of 2000 is approximately 96% in volume terms and approximately 97% in value terms. … An estimate of the Napp Group's percentage share of UK supply of sustained release morphine to hospitals in volume and value terms for 1997, 1998, 1999 and the first half of 2000 ranges for volume from the high 70s to the low 90s and for value sales from the high 80s to the mid 90s."

100. Napp has enjoyed and continues to enjoy persistently high market shares in the relevant market well in excess of 90%. This is regardless of the measure used to calculate it.[61] Napp's market share is also very high regardless of whether community and hospital sales are considered separately or as a whole.

(b) Barriers to entry

101. Napp held the patent for the original brand, MST, until it expired in 1992.[62] The patent represented a regulatory barrier to entry. However, despite the expiry of the patent nine years ago, Napp has continued to have a market share above 90% while maintaining prices for MST in the community segment at the same levels as before patent expiry. This is indicative of high barriers to entry in the relevant market.

Regulatory barriers to entry

102. Strong regulatory barriers to entry still exist despite the expiry of the patent, such as the need to obtain an authorisation to manufacture a particular drug in the UK and the requirement of a marketing authorisation or, in certain circumstances, a PLPI. In the case of imports, it is also necessary to obtain authorisation from the Home Office.[63]

103. These barriers need not prevent firms, if they see a profitable opportunity, from entering the UK market in time, however. Two companies, Lannacher and Nycomed, have launched

[61] See paragraphs 97 to 99 above.
[62] The MST patent expired on 4 August 1992.
[63] See paragraphs 13 to 15, and 65 to 69 above.

sustained release morphine products elsewhere in Europe.[64] It would be open to these, and other firms, to register their products with the MCA for sale in the UK if they so wished. They could either obtain a market authorisation from the MCA via the "mutual recognition" route or via the national route. The time needed to obtain approval through either route will depend to a large extent on the speed with which the applicant could respond to any queries raised by the MCA but is likely to take some time.[65] Thus, although the UK market for sustained release morphine will be easiest to enter for undertakings producing similar drugs elsewhere in Europe, it would nevertheless be likely to take a considerable amount of time.

Napp's first-mover advantage

104. Napp has a strong and persistent first-mover advantage. This results from the fact that MST was the first brand of sustained release morphine and enjoyed a period of patent protection from 1980 to 1992. As Napp puts it: "MST has long been recognised as the gold standard for the treatment of severe intractable pain … Practitioners respect and remember Napp as being an innovator whose MST product enabled practitioners to take a new approach to the treatment of cancer pain … MST's reputation became particularly firmly rooted in practitioners' minds … MST became synonymous with the treatment of chronic severe pain … GPs are familiar with MST. It is their first choice of oral sustained release morphine." This is a barrier to entry to the community segment, but significantly less so to the hospital segment where purchases are price sensitive.[66]

105. Napp's first mover advantage is accentuated by particular features of demand in the community segment of the market.

106. Firstly, community practitioners are strongly influenced by the reputation of product. As Napp has stated, the "market for strong opioids is an extreme example of this, since it is a market where physicians are extremely wary of possible side-effects and lack of efficacy, they do not have many cancer patients for a year, and the status of controlled drugs that the strong opioids have make doctors all the more risk-averse." Since Napp has 96% of the market, its reputation is very strong. This is a barrier to entry to the community segment, but significantly less so to the hospital segment where specialists are able to assess the relative efficacy of different brands.

107. Secondly, GPs are often reluctant to experiment with new products that they have not directly experienced. Napp has stated: "The tendency [for GPs] to be conservative and to avoid experimenting with different brands is all the stronger in respect to sustained release

[64] Napp
[65] See paragraphs 65 to 70 above.
[66] See Charts 1 and 2 above.

morphine than is normal in pharmaceutical markets … GPs are reluctant to change from using a drug they know and find to be satisfactory. The fact that MST is used to treat the more severe cases of pain and/or terminally ill patients, as well as the fact that pain relief is a complex area of medicine, mean that practitioners are even less likely to switch from an established brand to a new product without good reason." Again this is a barrier to entry to the community segment, but significantly less so to the hospital segment where dedicated specialists can assess the substitutability of brands and purchasers are price sensitive.

108. Finally, GPs are not strongly price sensitive. The fact that the amount of money spent by an individual GP on morphine is relatively low means that GPs are not strongly motivated by considerations of price. This is confirmed by the BMA which has stated that "cost is rarely considered in terminal care pain relief". Survey evidence supplied by one of Napp's competitors also shows that price plays only a small part in a GP's choice of sustained release morphine brand. This is a barrier to entry to the community segment of the market but not in the hospital segment of the market where purchasers are price sensitive.

109. In order to overcome Napp's first-mover advantage, new brands therefore need to establish a reputation for efficacy in the eyes of community practitioners. However, such a reputation is difficult to establish as it depends to a large degree on GPs having had direct experience of a brand and GPs are reluctant to experiment with new brands.

110. Brand promotion to GPs may help overcome some of these barriers to entry. However, promotion is likely to entail high sunk costs. As Napp has stated: "Late entrants offering products of similar quality ("me-too" brands) generally fail to gain large market shares, even after expensive advertising campaigns." In addition: "Late entrants need to spend substantially more than early entrants to achieve market recognition." Moreover, promotional expenditure cannot ensure that GP's gain direct experience of the brand.

111. In this respect, hospital sales play a central role in facilitating entry. Firstly, sales of a brand to a hospital lead to follow-on prescriptions[67] of that brand by GPs in the community.[68] Follow-on prescriptions mean that, unlike in the case of promotion, GPs gain valuable first-hand experience of administering that brand to a patient.

112. Secondly, when a hospital specialist recommends to a GP that a patient be prescribed a particular brand, this serves as an independent endorsement of that brand's efficacy. An entrant can thereby benefit from the reputation effects described in paragraph 106 above.

[67] References in this 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 a 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.
[68] See paragraphs 149 to 155 below.

113. Napp also points to the centrality of hospital sales in establishing the reputation of a brand of sustained release morphine in the community segment. It has stated that if "we were to lose all hospital supply contracts, we would lose the status of the MST brand in secondary care." Napp has also argued that BIL's withdrawal from the market resulted from a failure to "recognise the full benefits of winning hospital contracts, in the form of linked community sales."

Strategic barriers to entry

114. Barriers to entry via sales to hospitals should be considerably lower than those via sales to the community because hospitals are price sensitive in their purchasing. Napp describes the position with regard to oral sustained release morphine: "Hospital doctors generally accept intra-molecular substitution – that is, they are willing to use any brand of a single molecular product to treat their patients. This allows hospital-purchasing committees to grant contracts for the supply of oral sustained release morphine to a single manufacturer – usually the one who offers the lowest price." More generally, the effect of price sensitivity in the hospital segment is seen in the fall in prices to hospitals since 1992 (see Chart 1 above).

115. However, the pricing behaviour of Napp in the hospital segment of the market has created a strategic barrier to entry via hospital sales.[69] Through a policy of heavy discounting targeted at competitors, Napp has acquired a reputation for being an aggressive competitor in the hospital segment of the market. BIL exited the market in September 2000. In a letter to the Director, it stated "When BIL launched sustained release tablets in 1994, Napp adopted an aggressive policy, cutting its price, we believe, to 10% of list price for hospital contracts in many instances. In 1996, not having had a great deal of success in the hospital market, BIL adopted a policy of offering increasing levels of discounts to hospitals in order to win hospital contracts. However, we believe that almost without exception whenever BIL did this, Napp subsequently offered to match our price and persuaded the customer to continue to take their product. In view of this campaign by Napp, BIL has decided that it can not (sic) operate profitably in the sustained release opioid sector."

116. Further support for this is taken from the following statement of intent by another of Napp's competitors, Link: " (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."

[69] See paragraphs 145 to 159 below.

117. Napp has argued that these statements are assertions and as such cannot be relied upon. They have argued that BIL's decision to withdraw from the relevant market was part of an international strategic review which led to the sale of Boehringer Ingelheim's opioid business across Europe and not, as BIL's Director asserts, a consequence of Napp's pricing conduct. Napp has also argued that recent growth in Zomorph sales belies Link's assertion that it is being bullied out of the market. Finally, Napp has argued that a number of companies plan to enter the relevant market in the near future and hence have not been deterred by Napp's conduct.

118. Napp's arguments are assessed at paragraphs 169 to 180 below. In summary, however, the Director considers the statements of Napp's competitors coupled with the facts of Napp's pricing conduct can be relied upon to establish Napp's reputation for aggressive pricing in the relevant market.

(c) Buyer power

119. The NHS funds almost all sustained release morphine sales in the UK. However, it does not exercise a significant degree of central control in deciding which drugs are purchased. While the DoH has recently taken steps to achieve some central control of prescribing decisions through the National Institute of Clinical Excellence, it is unlikely that this body will make judgements as to the relative cost-effectiveness of different brands of the same chemical entity. Rather, prescribing decisions for the vast bulk of NHS products, including sustained release morphine, are taken at the level of individual GPs in the community, or at the level of the hospital.[70]

120. A degree of buyer power may exist in the hospital segment of the market when hospital purchasing decisions are co-ordinated across NHS regions.[71] Often, however, the degree of coordination achieved is limited by the discretion exercised by individual hospitals under regional framework contracts. Moreover, given that total hospital sales account for only 10 - 14% of the market, even regionally coordinated hospital purchasing would be unlikely, by itself, to reduce substantially the 96% share of supply held by Napp.

121. In the community segment, the NHS has recently introduced a new system of "unified budgets" operated by Primary Health Care Groups.[72] These were established in April 1999. One objective was to improve the co-ordination and price sensitivity of drug purchasing among GPs, and as between the local community and NHS hospital trusts. However, sustained release morphine represents a small fraction of NHS pharmaceutical budgets[73]

[70] Napp.
[71] Napp.
[72] See paragraph 32 above.
[73] Approximately 0.2% of the UK NHS overall budget for branded medicines.

and it is unlikely that there is a strong incentive to exercise buyer power. Moreover, there is no indication that these policy changes have had an effect on the market share of MST or the price of MST in the community segment over the past two years.

(d) Pharmaceutical Price Regulation Scheme (PPRS)

122. Napp has contended that the PPRS acts as the primary constraint on its pricing of MST in the following ways:

    (i) by setting limits on the level of return it can achieve on its overall sales to the NHS, the PPRS effectively constrains Napp's autonomy to set prices and maximise profits;

    (ii) the DoH has a degree of control over the price of new pharmaceutical products sold to the NHS;

    (iii) companies are only permitted to raise the price of a product with the consent of the DoH;

    (iv) the DoH has periodically required an across the board percentage decrease in the price of all pharmaceutical products sold to the NHS; and

    (v) the DoH applies strict expenditure allowances in the calculation of allowable profits and when assessing proposed price increases.

123. In the face of these regulatory constraints, Napp has argued that it cannot be considered to hold a dominant position.

124. In assessing Napp's argument, it is necessary to consider whether the PPRS prevents Napp from having the power to behave to an appreciable extent independently of its competitors and customers on the relevant market.

125. Firstly, the PPRS does not seek to control margins or prices for individual products. It is one of the stated aims of the PPRS to promote a strong and profitable pharmaceutical industry capable of sustained research and development.[74] To this end, companies are free to set the prices of new, innovative branded products sold to the NHS provided the company remains within PPRS limits on the overall rate of return on NHS sales. This flexibility is designed to provide a significant incentive for the early introduction of innovative medicines by allowing companies the flexibility to earn high margins on individual products.[75]

[74] *Pharmaceutical Price Regulation Scheme, July 1999*, paragraph 1.1.2.
[75] *Pharmaceutical Price Regulation Scheme, Report to Parliament, May 1996*, paragraph 5.2.3.

126. Secondly, the PPRS allows member companies to increase the price of individual pharmaceutical products through price modulation. The PPRS only applies limits on a company's rate of return across all the products it sells to the NHS, not on individual products. Thus, for a member company, such as Napp, that sells a range of branded medicines to the NHS, there is scope to change the relative prices of those products (price modulation) providing that overall rates of return on NHS sales stay within the PPRS limits and the effect of the modulation is cost neutral to the NHS. Under the terms of the current PPRS agreement, companies are permitted to increase the list price of individual products by 20% over the term of the agreement provided the overall effect of the price modulation is cost neutral.

127. Thirdly, in allowing flexibility in the prices and margins of individual products, the PPRS does not distinguish between new products that enjoy patent protection and older, patent-expired products for which generic competition is possible. The list price of MST was established in 1980 when the product first came within the scope of the then PPRS. At that time, MST was the first and only sustained release morphine product sold to the NHS and enjoyed a degree of patent protection which lasted until 1992. However, since patent expiry and the introduction of lower priced products, Napp has not been required to lower the list price of MST under the PPRS in response to competition. Rather, the two price reductions have been the result of across-the-board price cuts that the DoH has applied to the products of all PPRS companies and have been limited to 2.5% and 4.5% respectively.

128. Napp has argued that a system of price and profit regulation that applies across the portfolio of a company's sales has considerable advantages in relation to the pharmaceutical sector. It further argues that by focusing on the regulation of individual product prices, the Director has mis-characterised the nature of PPRS control.

129. It is accepted that the PPRS has considerable advantages as a system of portfolio pharmaceutical price and profit regulation in the UK. Nevertheless for the purposes of deciding whether Napp holds a dominant position in the relevant product market it is clearly appropriate to focus on the constraints that the PPRS imposes on the prices and margins of individual products in that market.

130. Fourthly, in order to provide further incentives for innovation, the limits on the rates of return which a company can earn on its overall sales to the NHS under the PPRS are not restrictive. The target for return on capital is subject to a margin of tolerance above which companies must repay profits to the DoH. Under the current PPRS (October 1999 - 2004) the target rate of return is 21% within an upward margin of tolerance of 140%.This makes an overall maximum rate of return of 29.4% before a company must repay profits to the NHS. Under the previous scheme, in the four years 1995 to 1998 profit repayments

averaged 2.8% of total profit across all PPRS companies.[76] Neither under this nor under the previous PPRS agreement has Napp been obliged to repay profits to the DoH.

131. Napp points out that, for the purposes of the PPRS, profits are calculated after disallowing certain expenditures and assets and argues that this results in an over-estimation of the ROCE. It also argues that by classifying research and development costs as expenses rather than as assets, accounting practice tends to overestimate the rates of return in the pharmaceutical sector. For these reasons, it has argued that its actual ROCE as recorded by its statutory accounts is much lower than that recorded by the PPRS.

132. Any system of rate of return regulation such as the PPRS creates strong incentives for companies to inflate their expenditures and assets. For this reason, it would be surprising if the PPRS did not place restrictions on the costs and assets that can be claimed by member companies. Furthermore, it is not clear that PPRS expenditure limits are necessarily restrictive. In particular, research and development is, on average, limited to 20% of sales revenue under the PPRS which is higher than the worldwide average expenditure on research and development of pharmaceutical manufacturers of 15.2% of sales.[77]

133. Finally, the PPRS has neither the object nor effect of preventing Napp from conducting itself in ways that may restrict or prevent competition in the market for sustained release morphine through, for example, heavy discounting to the hospital segment of the market.

134. More generally, Napp has argued that the DoH possesses a high degree of discretionary regulatory authority over pharmaceutical companies which, along with its control of the pharmaceutical budget and its knowledge of company cost structures, allows it to exercise indirect control over many aspects of company behaviour.

135. Section 33 of the Health Act 1999 does provide the Secretary of State with statutory reserve powers to control the prices of pharmaceutical products. However, it is noted that these powers would be unlikely to apply to Napp so long as it is a member of the PPRS and it complies with the terms of the PPRS agreement.[78] They are intended to be used only when a company does not agree to, or does not comply with, the terms of a voluntary agreement such as the PPRS.[79] Indeed, the need for reserve statutory powers has been expressly linked to the failure of the PPRS to impose an effective constraint on some member companies in the past. Furthermore, the practical scope for the Secretary of State

[76] *Pharmaceutical Price Regulation Scheme*, Third Report to Parliament, December 1999, Table 2, p 10. This percentage is likely to decrease under the current PPRS scheme due to the higher margin of tolerance.
[77] Pharmaceutical Price Regulation Scheme, Report to Parliament, May 1996, paragraph 2.7.
[78] Napp.
[79] Statements by Baroness Hayman, Lords Hansard text for 18 March 1999 (990318-10), Column 858 and 859.

to exercise his discretionary powers under the Health Act 1999 is likely to be limited by the need to maintain agreement with the ABPI. Any action by the Secretary of State that is seen to circumvent the terms of the PPRS would risk undermining that agreement and would invite legal challenge. As such the Secretary of State's powers under section 33 of the Health Act 1999 do not prevent Napp from holding a dominant position on the relevant market.

Conclusion on the PPRS

136. The PPRS does not prevent Napp from holding a dominant position on the market for sustained release morphine in the UK.

137. This is consistent with decisions of the European Commission in which the Commission has assessed whether mergers between pharmaceutical companies would strengthen a dominant position in the individual markets of EU member states. In a number of these cases, the Commission has found that mergers would strengthen dominance on EU national markets including the UK, despite the acknowledged existence of price or profit regulation in all EU countries.[80]

(e) Conclusion on dominance

138. The presumption of dominance created by Napp's very high market share is reinforced by the existence of high barriers to entry: regulation, first mover advantage, high sunk promotional costs, and strategic barriers to entry arising from Napp's pricing strategy in the hospital segment. Neither limited buyer power in the hospital segment of the market nor the operation of the PPRS provide significant evidence to the contrary. Napp therefore holds a dominant position in the supply of sustained release morphine tablets and capsules in the UK.

[80] e.g. Case No IV/MN.1403 - *Astra/Zeneca*, OJ C335/3; Case IV/M.1846 *Glaxo Wellcome/SmithKline Beecham*, OJ C170/6.

C ABUSE OF DOMINANCE

139. Section 18(2) of the Act provides that conduct may in particular constitute 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.

140. This list is illustrative only and not exhaustive. The European Court has held that 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 ... has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition."[81]

141. The European Court has also held that an undertaking in a dominant position "has a special responsibility not to allow its conduct to impair genuine undistorted competition".[82] Furthermore, the European Court has held that "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 a weakened competitive situation."[83] The Director considers that this special responsibility will be particularly strong where an undertaking is a monopolist or near-monopolist.

[81] Case 85/76 *Hoffmann-La Roche & Co. AG v Commission*, [1979] 3 CMLR 211, para 91.
[82] Case 322/81 *Nederlandsche Baden-Industrie Michelin NV v Commission*, [1983] ECR 3461 (*Michelin*), paragraph 57.
[83] Case C-333/94 P *Tetra Pak v Commission*, [1996] ECR I 5951 (*Tetra Pak II*), paragraph 24.

142. 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.

143. 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.

(a) Discounts to hospitals

144. Discounts will be an abuse if they serve to strengthen a dominant position in such a way that the degree of dominance reached substantially fetters competition.[84] In *Irish Sugar*, the European Commission found that a policy of selective low pricing to potential customers of a competitor "infringes the principle set out in Michelin v. Commission that a company in a dominant position has a special responsibility not to diminish further the degree of competition remaining on the market."[85]

[84] Case 6/72 *Europemballage and Continental Can v Commission* [1973] ECR 215, para 26.
[85] Commission Decision (14/5/97) *Irish Sugar plc* (OJ L258/1), para 123.

Object and effect of hindering competition

Hospital segment

145. Napp supplies hospitals at a discount of up to [...][*in excess of 90%*] off the NHS list prices for sustained release morphine tablets. Conversely, NHS list prices paid in the community segment are up to […][*in excess of ten*] times higher than the discounted hospital price. By supplying at these discounts only in the hospital segment, Napp has targeted discounts specifically at new competitors and hindered competition in the hospital segment of the market.

146. Since the arrival of competition in 1992, Napp can be seen to have consistently matched or undercut the prices of competitors in the hospital segment.[86] Table 5 below shows the average hospital price for MST tablets from March to May 2000. In the case of 10mg, 30mg, 60mg and 100mg MST tablets, the NHS list prices was discounted by [...][*in excess of 90%*] on average in sales to hospitals. The average discount on MST tablets to hospitals meant that, except on 15mg and 200mg tablets, UK hospital sales of tablets were below total delivered cost over this period.[87]

147. Table 5 also compares prices with direct costs, where direct costs have been defined as materials and direct labour.[88] Only in the case of 5mg, 15mg and 200mg tablets, where Napp didn't face competition from an equivalent strength BIL product, was the average hospital price above direct cost; in the case of the other four tablet strengths, price was below direct cost. As examined in paragraph 188 below, supplying at prices below average variable cost (AVC) give rise to the presumption of predatory intent and may itself be an abuse.

[86] See paragraphs 35 to 42 and Chart 1 above.
[87] On the evidence supplied to the Director, total delivered cost is taken to be a close, but conservative, approximation to average cost in this case.
[88] On the evidence supplied to the Director, direct cost is taken to be a close, but conservative, approximation to average variable cost in this case.

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	[...]	4.30	[...]
10mg	[...]	7.17	[...]
15mg	[...]	12.57	[...]
30mg	[...]	17.22	[...]
60mg	[...]	33.58	[...]
100mg	[...]	53.16	[...]
200mg	[...]	106.34	[...]

Source: Napp, 31 July 2000, OFT calculation.

148. Napp has argued that large discounts to hospitals do not have the effect of hindering competition in the hospital segment of the relevant market. It has argued that it remains open to competitors to match Napp's discounted hospital prices, even at below cost, due to the compensating margins earned on follow-on sales in the community segment. It has also argued that there is no asymmetry between Napp and its competitors in bidding for hospital contracts. Indeed, Napp contends that competitors could give away their products to hospitals and still make an overall profit from the follow-on effect.

149. From the results of its internet survey of GPs, Napp has estimated that 15% 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 then calculates that 1 unit sold to hospitals will result in 1.35 "follow-on" units of the same brand sold to the community. In addition, Napp has described this follow-on effect as "mechanistic".

150. While the Director accepts that there is a follow-on effect between hospital and community sales and while Napp's figure of 15% may serve as a crude estimate of this effect at a national level over time, the Director does not accept Napp's argument.

151. Firstly, to the extent that Napp can recover losses on below cost sales to hospitals, this depends on the very large margins that Napp can earn on sales in the community segment.[89] These margins result from the 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. In this respect, Napp's argument is circular.

[89] See paragraphs 203 to 230 below.

152. Secondly, the Director does not consider that the follow-on effect is mechanistic. GP responses to the internet survey are heterogenous and show no clear pattern of prescribing practices. In addition, whilst the ratio of hospital to community sales does indeed lie between 1:9 and 1.4:8.6 as a national average, the ratio of hospital to community prescriptions for individual patients, and as between different contracting regions, is likely to vary considerably.

153. The unpredictability of both the magnitude and timing of the follow-on effect is also demonstrated by other evidence submitted by Napp. As Napp states: "There is no simple correlation between hospital contracts and community sales". This is confirmed by evidence from Napp showing the variability of the hospital-community linkage in areas where Zomorph has achieved significant hospital sales. It is also demonstrated by the variable effect that hospital contracts held by BIL have had on sales of Oramorph SR in the community.[90]

154. In addition, the unpredictability of the follow-on effect is confirmed by data showing the monthly hospital sales and community prescriptions of each brand of sustained release morphine in Health Authorities in England and Wales between November 1997 and October 1999. While these show a link between hospital sales and community prescriptions of a brand at a national level over time, a comparison of the hospital sales and community prescriptions of a brand across regions shows no simple or mechanistic correlation.

155. Given the unpredictability of the follow-on effect, the Director does not accept that a new entrant can rely on being able to recover losses made on a hospital contract by generating higher sales in the community segment. This makes the prospect of below-cost pricing to hospitals considerably less attractive for entrants than Napp would suggest. It follows that, the Director does not consider that competitors could give their product away to hospitals and rely on recovering losses through the follow-on effect.

156. Thirdly, contrary to Napp's arguments that there is no asymmetry between Napp and its rivals in tendering for hospital contracts, Napp has significant advantages which result from its position of dominance on the relevant market.

157. Napp has significantly higher community prices than its rivals which make its follow-on sales more profitable.[91] This means that Napp will always be in a position to bid lower than its rivals. More generally, the desire of an incumbent firm to protect its monopoly will be greater than the desire of an entrant to become a duopolist: competition erodes profit to the benefit of consumers. Given the history of aggressive price cutting by Napp in the hospital segment, rivals will have no doubt as to the lengths that Napp will go to protect its position as a near-monopolist.

[90] Napp.
[91] See paragraphs 207 to 212 below.

158. In addition, unlike its rivals, MST has a well-established reputation in, and a very large share of the relevant market overall. As a result, hospitals incur switching costs in moving away from MST owing to the latter's dominant use and familiarity in the community segment.[92] It also means that the follow-on effect may be more "mechanistic" in relation to MST, whose reputation is already well-established, than in relation to its rivals. By contrast, new entrants may need to incur significant additional costs on promotion in order to gain the full benefits of the follow-on effect. As Napp has stated of Oramorph's performance, hospital sales alone do "not seem to be able to lift community sales if not combined with other complementary marketing tools (such as direct promotion to nurses and GPs)."

159. The success of Napp's discount policy to hospitals is illustrated by the fact that Napp has increased its share of the hospital segment of the market from 80% in 1997 to 93% in 2000.[93] This is not normal. Evidence adduced by Napp shows that, following the entry of generic competition, the market shares of pioneer brands reduce much more significantly in the hospital segment of the market than in the pharmacy or community segment.[94]

Community segment

160. As argued in paragraph 150 above, the figure of 15% may be taken as a crude estimate of the follow-on effect from hospital to community sales as a national average over time. This figure gains support from the additional survey and sales evidence adduced by Napp in its reply to the Director's original rule 14 notice. It is also supported by a comparison of the hospital sales and community prescriptions data at a national level over time.[95] Such a figure nevertheless means that Napp's discounting policy impairs, if not excludes, competition in 24 - 27% of the relevant market (the hospital segment which is 10-14% of the relevant market,[96] plus 15% of the community segment which is 86-90% of the market).

161. Napp has argued that the community segment of the market is not foreclosed by any actions on Napp's part in the hospital segment. As noted in paragraph 149 above, Napp estimates that 15% of community sales have their outcomes determined by the brand chosen in the hospital through the follow-on effect. It contends that this leaves 85% of the

[92] Napp.
[93] See table 4 above.
[94] Caves R, and M, Hurwitz (1988), "Persuasion or Information? Promotion and the Shares of Brand Name and Generic Pharmaceuticals", *Journal of Law and Economics*, Vol.31, pages 299-320.
[95] See paragraph 154 above.
[96] See paragraphs 22 to 23 above.

community segment open to competition from competing products through strategies such as direct promotion to community GPs and nurses.

162. However, the hospital segment is a key strategic entry point for new competitors in the relevant market. Firstly, as noted in paragraphs 114 to 118 above, barriers to entry should, in principle, be considerably lower in the hospital segment of the market. Secondly, as noted in paragraphs 111 to 113 above, hospital sales are central to establishing the reputation of a new product brand of sustained release morphine in the community segment of the market.

163. Hospital sales serve to establish the reputation of a brand (the reputation effect) in two ways. Firstly, the prescribing decisions of hospital specialists can establish the credibility of a product brand in the minds of GPs. Secondly, through the follow-on effect, GPs acquire first hand knowledge of a product and its efficacy.

164. The existence of a reputation effect from hospital sales of a brand of sustained release morphine to community prescriptions of that brand is confirmed by the following evidence:

(i) Research at the University of Keele has demonstrated that, for all pharmaceutical products, some 76% of prescriptions in primary care are influenced to some degree by prescriptions in secondary care.[97]

(ii) One competitor which gave evidence to the Director, commented that "As a general rule, pharmaceutical companies are interested to have their products available in hospitals in order to improve the opportunity for them to be prescribed in the community once a patient leaves hospital care. Hospital doctors are often opinion leaders and are consulted by general practitioners about prescribing practices".

(iii) Marketing research commissioned by one of Napp's competitors for its sustained release morphine product suggests that Macmillan nurses, hospice directors and hospital doctors are "very influential in terms of … affecting GP prescribing behaviour". It concludes, "since hospitals have a strong influence over GP prescribing a greater presence in hospitals should be a key focus".

(iv) Napp's own survey evidence points to the existence of a significant reputation effect. In its qualitative survey of 40 GPs, over 30% responded that hospital specialists have a significant degree of influence on their prescribing of sustained release morphine tablets. In addition, over 40% of GPs responding to Napp's internet survey stated that the reason they had not prescribed other brands of sustained release morphine was due to a lack of knowledge concerning those products.

[97] B Strickland-Hodge (1988), "Role of the hospital consultant in general practice prescribing", *Journal of the Royal Society of Medicine*, April 1988, p207.

(v) Expert testimony relied on by Napp also points to the importance of hospitals for establishing the reputation of new products. One witness states, "As a generality, I would say that prescribing practices in hospitals do have an influence on GPs."[98] Napp's evidence also highlights the influence of clinical nurse specialists on GPs prescribing of sustained release morphine. This indicates a further reputational link from hospitals to the community segment.

(vi) In a letter to the Director in September 1999, Napp stated that if "we were to lose all hospital supply contracts, we would lose the status of the MST brand in secondary care".

165. In view of the importance of the reputation effect of hospital prescriptions, but also the difficulties in quantifying it, the Director also accepts Napp's conclusion "that the measured 'follow-on linkages' would constitute a lower bound on the overall hospital-community linkages".

166. Thus, even if it is accepted that only approximately 15% of community sales are determined by hospital prescriptions through the follow-on effect, this means that Napp's discount policy impairs competition in at least 24-27% of the relevant market overall. However, 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.

167. The Director does not, therefore, accept Napp's argument that its policy of heavy discounting to hospitals does not have a significant foreclosure effect in the relevant market. This is consistent with the decision of the European Commission in *Van den Bergh* in which it found that conduct affecting 40% of the relevant market had a "very substantial" foreclosure effect.[99]

168. Finally, the Director also relies on the statement of BIL cited at paragraph 115 above to support his conclusion that Napp's discount policy has had an effect on competition in the relevant market. Indeed, together with the statement of Link Pharmaceuticals cited at paragraph 116 above, there is a risk that Napp's discount policy will have the effect of eliminating competition altogether. Through its conduct Napp has acquired a reputation as an aggressive competitor in the relevant market. This undermines the ability and incentive of existing competition to remain in the market. Furthermore, it sends a signal to potential

[98] Napp, Witness Statement of Professor Geoffrey Hanks
[99] Case Nos IV/34.073, IV/34.395 and IV/35.436, *Van den Bergh Foods Limited*, OJ L246, paragraph 265.

competitors that if they seek to enter the market in the future, they can expect Napp to compete aggressively, at prices below direct costs.

169. In its representations, Napp has argued that the Director has failed to recognise the true explanation of why its competitors have enjoyed limited success in the relevant market. It has argued in particular that:

(i) In pharmaceutical markets, late entrants offering brands that are essentially the same as the pioneer brand ("me-too" brands) generally fail to gain a significant market share. Markets characterised by competition from "me-too" brands also exhibit a high frequency of entry and exit;

(ii) BIL's exit from the relevant market was part of a strategic review of its product portfolio internationally and was paralleled by the sale of BIL's opioid businesses in other countries;

(iii) BIL's exit resulted from its failure to understand the dynamics of the relevant market. In particular, BIL "did not recognise the full benefits of winning hospital contracts, in the form of linked community sales."[100] In addition BIL and other rivals have failed to promote their brands sufficiently;

(iv) Link's assertion that it is being bullied out the market is contradicted by the recent sales growth of Zomorph and its success in winning certain hospital contracts; and

(v) Indications of possible new entry in the future undermine the view that Napp's conduct has deterred competition or made access to the relevant market more difficult.

170. In relation to (i), it is acknowledged at paragraphs 114 to 118 above that barriers to entry into the relevant market are high. However, Napp's pricing conduct has hindered competition in the relevant market and raised barriers further.

171. Napp has supplied evidence of low competitor penetration in two other UK pharmaceutical markets characterised by competition between branded generics. The same markets are used by Napp to demonstrate a high frequency of entry and exit among later brands. The Director does not consider that reliable general conclusions on the nature of competition can be drawn from the evidence of these two markets. Like MST, the pioneer brands in both of these markets have maintained an exceptionally high share of hospital sales. This is unusual[101] and suggests that, contrary to Napp's representations, these markets are

[100] Napp
[101] See paragraph 159 above.

atypical. Also, the Director does not have, and Napp has not supplied corresponding pricing data for these markets by which to judge the strength of competition. [102]

172. The Director's view that it is not normal for pioneer brands to retain such a high market share following patent expiry receives support from a recent OECD report submitted by Napp in its evidence to the Director. The report provides strong evidence that pioneer brands have lost considerable market share to generic competitors in the UK and elsewhere.[103]

173. In relation to (ii), Napp has submitted minutes from two meetings held between Mundipharm, an associate company of Napp, and Boehringer Ingelheim[104] on 11 June 1999 and 13 July 1999. These show that, with the exception of the UK and Ireland, Boehringer Ingelheim was actively considering the divestment of its Oramorph range in Europe.

174. While the decision of BIL to divest Oramorph SR in the UK may have been influenced by a strategic review of Boehringer Ingelheim's opioid business internationally, it would seem from the two minutes that the decision as regards the UK, and the factors influencing that decision were quite separate from those relating to Boehringer Ingelheim's non-UK business. Moreover, it is to be noted from the minutes that the strategic review concerned the entire Oramorph range (including immediate release products) in Europe but excluding UK and Ireland. In the UK, BIL decided only to withdraw Oramorph SR.

175. In addition, the Director has received two statements from BIL, made by its Chairman and Managing Director respectively, which indicate that low prices in the hospital segment were a strong factor in BIL's decision to withdraw from the relevant market. The Director does not consider that there are strong reasons to doubt these statements, particularly since both statements were made in connection with an investigation under the Act.[105] They are also consistent with an earlier statement made to the Director by BIL's Chairman in connection with the Office's initial enquiries into Napp's conduct.[106]

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[102] The accuracy of the market share data is also open to doubt. The data does not include sales that have been recorded generically and there is no reason to believe such sales would be spread evenly among the brands.

[103] S. Jacobzone (2000), *Pharmaceutical Policies in OECD Countries*, Labour Market and Social Policy - Occasional Papers No.40, (OECD, Paris), section 2.4.1, p21 - 23.

[104] The European Head Office is based at Ingelheim in Germany.

[105] Knowingly or recklessly providing information which is false or misleading in a material particular in connection with the exercise by the Director of his functions under Part I of the Act is a criminal offence under section 44 of the Act.

[106] These were made under the Competition Act 1980 and will have been subject to provisions similar to those in section 44 of the Act in relation to the furnishing of false or misleading information (section 93B of the Fair Trading Act 1973).

176. In relation to (iii), the argument that BIL did not recognise the full benefits of winning hospital contracts is inconsistent with BIL's statement cited at paragraph 115 above. In addition, the fact that BIL tried to compete with Napp on the basis of large discounts in the hospital sector would indicate that it was well aware of the benefits of hospital sales.

177. In relation to promotional expenditure, the Director does not accept that Napp's competitors failed to market or promote their products adequately to the community segment. This is supported by IMS data showing that in 1996, 1997 and 1998, promotional expenditure on Morcap (Sanofi-Winthrop) was considerably above Napp's expenditure on MST.[107] In addition, the ratio of promotional expenditure to sales for Morcap and Zomorph was considerably above that for MST from 1998 to June 2000.

178. Moreover, it is not evident that promotional expenditure alone will be sustain successful entry. Napp has argued that "late entrants offering products of similar quality ('me-too' brands) generally fail to gain large market shares, even after expensive advertising campaigns." Equally, Napp represented to the Director that the status of the MST brand in the community depends on making hospital sales.[108] Given the centrality of hospital sales for establishing the reputation of a product in the community, competitors may not be willing to commit additional promotional expenditure without the prospect of securing a presence in the hospital segment of the market. This would be consistent with the evidence of Napp and BIL to the effect that BIL significantly reduced its promotional expenditure in 1997/98 having failed to make any progress in the market, and concentrated instead on trying to win hospital sales.

179. In relation to (iv), it is clear that there has been recent growth in the sales of Zomorph starting from a low base in 1999. However, it is also clear from financial information on the Director's file that Zomorph has not been earning an overall profit for Link due to the high promotional expenditure required. It may also be expected that Zomorph has picked up some sales left by BIL's withdrawal from the market in September 2000.

180. In relation to (v), Napp has supplied information on two sustained release morphine preparations that it believes are currently undergoing trials in the UK. The Director is not in a position to confirm or deny this information. However, he considers that a decision to trial a new product is likely to be influenced by competitive conditions on many different national markets and not just the UK. It is also possible that entry plans have been influenced by an awareness of the Director's investigation particularly in the context of BIL's withdrawal from the market and the re-negotiation of its licence terms. He does not therefore consider that this evidence undermines his view that Napp's conduct has deterred competition in the relevant market.

[107] Napp.
[108] See paragraph 164(vi) above.

Targeting

181. The effect of Napp's policy of discounting to hospitals is further reinforced by the way in which its discounts have been selectively targeted at competition. Not only has Napp selectively supplied the hospital segment at discounts which have consistently matched or undercut those of its competitors,[109] thus weakening the principal, and probably the only means of competition open to competitors, but Napp has further refined its policy by targeting its discounts at competition in a number of other ways.

182. Firstly, Napp only supplies hospitals at the highest level of discount on those strengths of tablet where it has faced a direct BIL rival. In regional hospital contracts that Napp reports as holding with the NHS PASA, MST is only supplied at the highest level of discount [...][*in excess of 90%*] on those strengths where Napp has faced a rival BIL product at a similar strength (10mg, 30mg, 60mg and 100mg). For those strengths of MST where Napp has not faced a rival BIL product (5mg, 15mg and 200mg), Napp supplies hospitals at a discount of, […] [*less than 85%*].

183. Secondly, Napp supplies at higher levels of discount to those hospitals where it expected to be awarded a sole regional contract.[110] As Napp states, "where we expect that a contract might be shared we only offer a […] [*less than the highest discount*] discount".

184. The importance to Napp of preventing a competitor from winning the sole framework contract for a region is illustrated by the experience of BIL in 1997 and 1998 during which time BIL held sole contracts for Oramorph SR in the North West region and the Oxford region. Medicare hospital sales data[111] for these years show Oramorph SR achieving a share of hospital sales of between 70% and 90% in the counties and cities covered by these regions. This contrasts with a national share of hospital sales of between 15 and 20% over the same period and indicates that the award of a sole contract can have a significant impact on a competitor's sales to hospitals in a particular region. Where a competitor shares a contract with Napp, on the other hand, the impact is minimal.[112]

185. Of the fourteen regional supply contracts, Napp reported that it held seven of these contracts on a sole basis at the beginning of March 2000. All of these contracts were of a duration of two or more years. A further four contracts were shared with BIL.[113] The

[109] See paragraphs 35 to 39 above.
[110] See paragraphs 41 to 42 above.
[111] Medicare Audits Data.
[112] BIL.
[113] Of the remaining three regional contracts, Yorkshire was not awarded as a regional contract, BIL held the Oxford contract, and the North West expired as a sole Napp contract shortly before 1 March 2000.

highest discount of [...][*in excess of 90%*] is available in five of the seven contracts awarded to Napp where Napp holds the only contract. For only one of the four contracts that Napp reports as shared with BIL is the highest discount available (Wales). Moreover, this was the result of a mistake on the part of Napp.[114]

186. In its representations, Napp argued that higher discounts for sole contracts are justified by the cost saving that results from not having to promote MST to the hospitals covered by the contract. The Director has not seen figures for promotion costs that would justify this difference. Moreover, given that sole contracts do not carry any guarantee of exclusivity it is not clear that Napp would be relieved from promotional expenditure in relation to sole contracts.

187. By offering heavy discounts to hospitals and by targeting these discounts selectively at competitors, Napp has hindered competition in the hospital segment of the market.

Elimination of competition

188. The European Court has held that 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 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."[115]

189. On those strengths of MST where it faces a rival BIL product at equivalent strength (i.e.10mg, 30mg, 60mg and 100mg), Napp's prices to hospitals are below direct costs, where direct costs are defined, consistently with Napp's accounting system, as materials and direct labour.[116]

190. The Director considers that direct costs may serve as a proxy for AVC in this case. In particular, labour costs should, in this case, be included in the definition of AVC since over the term of a hospital contract of two years (during which Napp's prices can be expected to remain constant) labour is an avoidable cost. Nevertheless, although direct costs may serve as a proxy for AVC, the Director also considers that direct cost is in fact an underestimate

[114] See paragraph 42 above.
[115] Case C-62/86, *Akzo Chemie BV v. Commission of the European Communities*, [1993] 5 CMLR 215, paragraph 71.
[116] See paragraph 181 to 182 above.

of AVC since a proportion of production overheads and distribution costs will also be variable over this period.

191. In addition, the Director notes that the hospital prices quoted in table 5 above are the average of hospital prices from March to May 2000, and that in many cases MST has been supplied to hospitals at prices considerably below these averages. For example, Napp offers [...][*in excess of 90%*] discounts off trade price where it holds a sole regional contract (see paragraph 42 above) meaning that the hospital prices for 10mg, 30mg, 60mg and 100mg are £[...], £[...], £[...] and £[...] respectively. In these cases, Napp's hospital prices are between […] [*in excess than 30%*] and […] [*less than 50%*] lower than direct costs. The Director also notes that these prices are significantly below the raw material cost.

192. In its representations, Napp argued that there is an objective justification for pricing below AVC in the hospital segment owing to the compensating margins can earn through follow-on sales in the community segment.[117] Indeed, Napp has argued that it and its competitors could give away their products to hospitals and still make an incremental profit through follow-on sales. Hence it has argued that prices below AVC in the hospital segment cannot signal an intent to eliminate a competitor since it is rational for Napp and its competitors to anticipate follow-on sales in bidding for hospital contracts. The Director does not accept this argument.

193. Firstly, as argued in paragraphs 152 to 155 above, the magnitude and timing of the follow-on effect is unpredictable. As a result, Napp and its competitors cannot guarantee recovering losses in the hospital segment through follow-on sales in the community segment.

194. Secondly, Napp has not argued that price cuts to hospitals have grown the overall market for sustained release morphine. Furthermore, given Napp's very high market share and established reputation in the relevant market, it is unlikely that additional hospital sales of MST will have a significant direct effect in terms of additional GP prescriptions. Accordingly, any sales that Napp achieves in the community as a result of retaining a hospital contract will serve primarily to defend its near monopoly position in the community sector rather than grow its sales or share. Napp cannot therefore justify a policy of loss-leading, except insofar 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.

195. Thirdly, Napp's justification for pricing below AVC is circular. That Napp can earn high compensating margins in the community segment, where prices are up to […][*in excess of ten times*] times higher than hospital prices, is because its discount policy in the hospital segment has hindered competition in the community segment. The prices of sustained

[117] See paragraphs 148 to 149 above.

release morphine in the community have not been subjected to competition. 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. 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. Likewise, the expectation of earning excessive margins on future sales cannot be a justification for current loss-making sales.

196. The targeting of higher discounts specifically at actual or anticipated competition in the hospital segment of the market (paragraphs 181 to 187 above) is further evidence of an intent on Napp's part to eliminate competition in the relevant market.

Methods different from those which condition normal competition

197. Napp has argued that heavy and selective discounts to hospitals inevitably result from the necessity to meet competition in the 'winner-takes-all' hospital tendering process. It has also argued that aggressive discounts were initiated by Farmitalia and then BIL to which Napp responded.

198. While pharmaceuticals are sometimes sold at substantial discounts to hospitals, it is not normal that list prices are discounted by [...][*in excess of 90%*] in tendering for hospital contracts.[118] Napp also supplied information on the average hospital prices of three other products it supplies to hospitals (MST suspensions, Palladone SR and Oxycontin). The highest hospital discount available on any of these products is [...] for MST suspension 60mg. It is also noteworthy, that the discount of [...][*in excess of 90%*] on MST is only available on those dosages where Napp faced a BIL rival product at equivalent strength. Napp's discount policy on MST is therefore different from behaviour which conditions normal competition.

199. Indeed, the level of price discrimination as between the hospital and community segments is exceptional. NHS list prices are over […] [*in excess of 10*] times higher than average hospital prices, and in the case of sole contracts this ratio will as high as [...][*in excess of 10 times*].[119]

200. It is also clear from the correspondence attached to Napp's representations in response to the Director's supplementary rule 14 notice that Napp knew of the prices being offered to certain customers and sought to respond with lower prices aimed directly at those customers. This is consistent Napp's statement that in "late 1994, while preparing a bid for the South East Supplies division, we became aware of the level of discount being offered by BIL and realised that unless we offered a comparable discount, we would lose that

[118] Napp, Witness statement of Howard Tebby
[119] See paragraphs 145 to 147 above.

contract as well. We were forced to react by offering a discount of […] [*in excess of 90%*] in that tender and managed to retain the contract from 1st January 1995. This level of discount came to be expected by the NHS and rapidly became the norm."

201. In view of his conclusion that the purpose of Napp's pricing policy was to eliminate competition, the Director does not accept that Napp can effectively argue that it merely entered into a price war started by a competitor or even responded to the expectation of its customers and that its conduct was therefore not abusive. This is consistent with the decision of the Court of First Instance in *Compagnie Maritime Belge*,[120] recently upheld by the European Court of Justice.[121]

202. Finally, even if Napp's pricing policy was as a result of a price war started by BIL or a response to the expectations of hospital trusts, the Director considers that Napp's response to competition in the hospital segment has been both unreasonable and disproportionate.[122] Firstly, Napp has sought not only to meet competition but, by offering higher discounts, to counter it. Secondly, Napp supplies at a higher level of discount to those hospitals where it faces direct competition for the award of a sole regional contract.[123] Thirdly, Napp has targeted higher discounts on those strengths of product where MST faces a rival BIL product at equivalent strength.

[120] Cases T 24-26, 28/93, *Compagnie Maritime Belge and others v EC Commission*, [1996], ECR II 1201, paragraph 148.
[121] Case C 359-356/96P, *Compagnie Maritime Belge v EC Commission*, [2000] 4 CMLR 1076.
[122] Cases T 24-26, 28/93 paragraph 148. See footnote 123 above.
[123] See paragraphs 189 to 191 above.

(b) Excessive prices

203. The prices charged by Napp for MST in the community are excessive. 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.

204. Showing that Napp's prices are above the competitive level can be done in both of two ways. First, the European Court in *United Brands* held that excessive prices could be demonstrated by assessing "whether the difference between costs actually incurred and the price actually charged is excessive".[124] 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.

205. The second approach is to establish what the competitive price of MST is likely to be and then compare this with the actual price. Of course, it is not possible to say with certainty what the competitive price might be when it cannot be directly observed, but 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 to see whether those prices would enable Napp to earn a reasonable profit.

206. In its representations, Napp has argued that particular comparisons are invalid for reasons given below. It is always possible to criticise comparisons as being inappropriate. However the Director has not sought to rely on a single comparison, but has made a range of comparisons that all point to the conclusion that Napp's community prices of MST are excessive. The range of evidence, all of which is consistent, reinforces the conclusion of excessive prices.

Comparison of the prices for MST tablets with those of Napp's competitors

207. Napp's prices of sustained release morphine tablets and capsules to the community are considerably higher than those of its competitors.[125] Table 6 below shows Napp's actual prices and those of its next highest priced competitor, together with the percentage by

[124] Case 27/ 76 *United Brands v Commission* [1978] ECR 207, [1978] 1 CMLR 429.
[125] The Director has also taken into account, for the purpose of this section, the prices charged by BIL before it withdrew from the market.

which Napp's prices exceed those of that competitor.[126] Napp's prices to the community are between 33% and 67% higher than those of its competitors, and typically around 40% higher. Napp's actual prices to the community are thus considerably in excess of those of its competitors.

Table 6: Twice-daily sustained release morphine tablets/capsules, Community net prices, 2000

Twice-a-day sustained release morphine tablets, Community Net Prices, 2000							
£ per 60 pack	5mg	10mg	15mg	30mg	60mg	100mg	200mg
Napp: MST	3.76	6.27	11.00	15.07	29.38	46.52	93.05
Next most expensive competitor	-	4.73	-	10.66	20.54	32.63	55.82
% by which Napp more expensive than next most expensive		33%		41%	43%	43%	67%

Source: Napp and its competitors, OFT calculation
5mg and 15mg MST tablets have no competing products at equivalent strengths

208. Napp has argued that because it was the innovator it is entitled to charge higher prices to reflect the research and development and marketing expenditures in bringing MST to market. It is also to be expected that Napp's prices would be higher than competitors to reflect its brand value.

209. In relation to the recovery of research and development costs and the costs of bringing an innovative product to market, the Director accepts that these need to be recovered through higher prices. This is the role of the patent protection period. It allows the product a period of exclusivity in which the manufacturer can charge prices well above the

[126] Only twice daily tablets/capsules are included in the table. Contrary to Napp's argument, the Director does not consider it valid to include in the price comparison products that may be used as either a once-daily or a twice daily preparation. These products have a different release profile to MST and may, as a result, be administered less frequently or with less immediate release morphine. It is also difficult to compare these products with the dosage levels of MST.

competitive level. A manufacturer with an innovative product cannot demand or expect prices to remain at excessively high levels indefinitely, however.

210. In this regard, the Director notes the opinion of the OECD that reforms of "pharmaceutical policies need to foster efficiency and preserve equity. This can be realised through increased market pressure to obtain competitive prices for non-patented drugs while allowing higher prices for those still on patent."[127]

211. The Director recognises that in competitive markets branded products are often priced at a premium to other products. It is notable that in the hospital segment Napp is unable to sustain a premium price since, in effect, MST has lost its brand value. 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% over competitors. The Director accepts that even with effective price competition Napp may be able to achieve a premium over competitors' prices, but he does not accept that the premium would be as high as 40%.

212. More importantly, Napp has sustained this price premium while maintaining a 96% share of the relevant market. While firms originating a new pharmaceutical product may retain high prices following patent expiry,[128] it is not a feature of normal competition for the premium priced pioneer product to retain such a large share of sales volume.[129]

Comparison of prices for MST tablets over time

213. Unlike its prices to hospitals, Napp's prices of MST tablets to the community have not responded to the entry of rival products over the 1990s. Whereas Napp's hospital prices have fallen by over 90% since the introduction of Napp's first competitor in 1991 (Farmitalia), community prices have remained unchanged over a 10 year period except for the small reductions required by the PPRS. This is demonstrated by Chart 1 above. Napp has sustained its community prices while maintaining an exceptionally high share of the relevant market. This indicates that Napp's community prices, unlike hospital prices, have not been subject to competitive pressure.

214. Prior to the expiry of its patent in 1992, it is reasonable to infer that the price of MST was set above competitive levels. This can be inferred from the fact that Napp was the only supplier of sustained release morphine in the UK and that barriers to entry facing potential competitors were considerably higher while MST was afforded a degree of patent

[127] *Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goods* (OECD, 2000) p4.
[128] *Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goods* (OECD, 2000).
[129] See paragraph 172 above.

protection.

215. Napp argues that MST enjoyed only a formulation patent and not a patent over the chemical entity, morphine sulphate. Hence, they argue that the strength of patent protection from competition was limited. However, it is notable that it took eleven years from the launch of MST in the UK until the entry of the first competitor in 1991, almost at the same time as patent expiry in 1992. Moreover, in the five years following patent expiry, three new companies entered the market. This would indicate that the period of patent protection enjoyed by Napp did constitute a barrier to entry and afforded Napp a significant degree of protection from competition.

216. Napp also argues that competition has taken place on non-price terms in particular in the amount of marketing spend. From IMS data supplied by Napp, it is clear that Napp's promotional expenditure increased between 1991 and 1994 at the time when MST lost patent protection. However, since then Napp's promotional expenditure has declined considerably. In 1998, Napp spent less in absolute terms promoting MST than either Link or Sanofi-Winthrop spent promoting their rival products. As a proportion of sales, Napp's competitors are spending much more on promotion.

Comparison of the prices of Napp sustained release morphine tablets charged to hospitals and the community and for export

217. Napp's prices to the community are considerably higher than the prices it charges to hospitals and for export. Napp's NHS list price can be up to […][*in excess of 10*] times the prices at which MST is supplied to hospitals. On average, the wholesale community price for MST[130] is over […][*in excess of 10*] times higher than the average hospital prices for MST on 10mg, 30mg, 60mg, 100mg from March to May 2000. This is shown in Table 7 below, which provides a comparison of Napp's prices over the period March to May 2000.[131]

[130] The wholesale price is the NHS list price minus a standard 12.5% discount to distributors.

[131] Hospital prices are those given by Napp as based on 'Rebate Requests'. Community prices are at NHS base price less 12.5%. Export sales prices are as supplied by Napp.

Table 7: Napp's prices of sustained release morphine tablets, March to May 2000

£ per pack of 60	Strength	UK – hospitals	NHS prices less 12.5% wholesale discount	Export
UK sales of MST Tablets and Export sales of most expensive SR Tablets in packs of 60	5mg	[...]	3.76	[...]
	10mg	[...]	6.27	[...]
	15mg	[...]	11.00	[...]
	30mg	[...]	15.07	[...]
	60mg	[...]	29.38	[...]
	100mg	[...]	46.52	[...]
	200mg	[...]	93.05	[...]

Source: Napp, 31 July 2000.

218. The price differentials vary with tablet strength. Napp's price to the community of 5mg tablets is [...][*above 70%*] higher than its price to hospitals. For 10mg, 30mg, 60mg and 100mg tablets, on the other hand, its price to the community is over 1000% higher than that to hospitals. A similar pattern emerges when comparing the prices to the community with the export prices. The differential on 5mg tablets is [...][*below 5%*] but for higher strength tablets the differential is between […] [*in excess of 100%*] and […] [*less than 700%*].

219. The considerably lower prices in the hospital segment and in export markets result from the fact that MST faces price competition in these sectors whereas it does not face such competition in the community segment of the UK market. The varying differential arises because prices to the community increase with tablet strength, whereas this is not strictly the case for sales to hospitals or for export. In both of these latter cases, 10mg tablets are cheapest and 30mg and 60mg (and in the case of hospital sales 100mg tablets) are cheaper than 15mg tablets.

220. Napp is the only UK distributor of 5mg and 15mg tablets. This suggests that Napp sets low hospital prices where it faces direct competition but higher prices where there is no directly competing product. In the case of sales to the community, on the other hand, there is no evidence of the prices for different strengths of tablets responding to the different levels of competition which Napp faces.[132]

221. The difference between Napp's prices to the UK community and its prices for export is also very large. On some strengths, community prices are over […] [*between four and seven*]

[132] This is further evidence that Napp's community prices are unconstrained by competition.

times greater than export prices. Although this alone is not conclusive of excessive prices, provided export prices are profitable, the size of the differentials is sufficiently large to suggest that Napp's profits on sales to the UK community are supra-normal. An analysis of Napp's profitability on community sales is shown below.[133]

222. Napp has pointed out that, unlike domestic prices, export prices of MST do not reflect marketing and promotion costs. It also argues that export sales are made under contract and therefore entail lower risks than community sales. However, in the period March to May 2000, Napp's sales of MST to the UK community were (net of discounts) £[...] million. At export prices, the value of these sales would have been £0.7 million. Over a full year, it can be estimated that Napp earns an additional £[...][*in excess of £5 million*] from selling MST to the community at community prices, rather than at export prices. According to IMS data supplied by Napp, the highest amount it has spent in promoting MST in one year is £0.49 million in 1994. In addition, the Director does not accept that the lower export price can be accounted for by the lower risk entailed in contract manufacturing.

Comparisons of Napp's profitability on sales to hospitals and the community

223. 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. Table 8 below shows Napp's gross profit margins comparing profits made from MST with profits made on Napp's sales excluding MST.[134]

[133] The fact that Napp's prices to the UK community do not vary also indicates that its prices to that segment of the market are unconstrained by competition.
[134] Calculations are based on PPRS data covering 1996 to 1998 and Napp's management accounts for sales and cost of goods sold for 1997 and 1998.

Table 8: Napp's gross profit margins (% of revenue)[135]

Year ended 31 December…	1996	1997	1998	1999	2000 (March to May)
MST Community	n/a	[...]	[...]	n/a	[...]
MST Hospital	n/a	[...]	[...]	n/a	[...]
Total MST	n/a	[...]	[...]	n/a	[...]
NHS – Home[1]	[...]	[...]	[...]	n/a	n/a
NHS other than MST	n/a	[...]	[...]	n/a	n/a

[1] NHS Home refers to NHS sales, separate from export sales of prescription medicines and all other sales.
Source: Napp, 22 May 2000, based on IMS data and OFT calculations

224. Although figures are not available for every period, and the results for MST and NHS – Home are unlikely to be strictly comparable, the pattern is clear. MST community sales achieve a gross margin of around [...][*in excess of 80%*]. Napp's total NHS sales earn a margin of around […] [*between 40% and 60%*], meaning that NHS sales other than MST earn a margin of around […] [*between 30% and 50%*]. Even accepting the estimates involved in this calculation, the difference between the margin earned by MST sales to the community and all other NHS sales is very large. It is the difference between a gross profit margin of [...][*in excess of 80%*] and one of around […] [*between 30% and 50%*].

225. Napp argues 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

[135] Although the figures are not strictly comparable, the differences between the results for MST and other NHS sales are so large that any distortion in the comparison would need to be considerable to alter the conclusion. The MST figures are derived from IMS data whilst the PPRS returns can be assumed to use Napp's internal accounting data. The bases of preparation may also differ. MST gross margin includes distribution costs while it is excluded from the PPRS figures. This means the MST gross margin is lower than it would be if prepared in the same way as the PPRS figures. Against that, the DoH may make adjustments to the costs included in the PPRS returns and the direction of these adjustments is likely to increase the NHS – Home gross margin, although the adjustment is unlikely to be by much. The figure for NHS other than MST is a calculation to exclude MST from the NHS – Home figure. The fact that the two sets of figures come from different sources is less likely to lead to a lack of comparability at the gross margin level than with other profitability measures. The reason for this is that gross margin relies only on turnover and the cost of goods sold. The scope for adopting allocation methods that lead to significantly different results is much less at this level than if all other operating expenses were included. In addition, the main difference between IMS and Napp's own accounting results seems to be one of timing.

products, or to subsidise those products that are less successful. As noted in paragraph 209 above, 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 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.

226. Napp also achieves a much higher gross profit margin on its sales to the community than do any of its three competitors.[136] Napp makes a gross margin of [...][*in excess of 80%*] on its sales of MST to the community. This compares with a gross profit margin of [...][*less than 70%*] for Napp's next most profitable competitor. This does not take account of the fact that Napp manufactures MST tablets while its competitors contract out the manufacture, however. In addition, Napp's higher margin may result in part from more efficient production.

227. The comparison therefore needs to allow for the profit margin that Napp might be expected to earn on the manufacture of MST and any efficiencies in Napp's manufacturing process relative to its competitors. In order to do this, Napp's gross profit margin has been calculated using the average costs of its next most profitable competitor. Table 9 below shows Napp's average gross profit margin for March to May 2000 from community sales when using the costs of its next most profitable competitor. This enables one to take account of the manufacturing margin to calculate Napp's average gross profit margin on distribution. Since the competitor in question buys the finished tablets from a contract manufacturer, its cost reflects the cost plus profit margin involved in manufacture.

[136] The Director has also taken into account for the purpose of this section the gross profit margin achieved by BIL before it withdrew from the market.

Table 9: Napp gross profit margin for March to May 2000 from community sales when using the costs of its next most profitable competitor

Napp's average selling price[137]	£15.47
Napp's next most profitable competitor's average cost of goods sold[138]	£3.01
Average gross margin	80.5%

Source: Napp, Napp's next most profitable competitor, OFT calculations

228. Napp earns higher gross profit margins on its sales of MST to the community than any of its competitors, including BIL before it withdrew from the market, earn on their competing products. Part of this is owing to Napp's manufacturing margin, but even taking that into account, Napp's prices imply much higher margins – 80% compared to [...][*less than 70%*] for the next most profitable competitor. That Napp has sustained these higher margins without stimulating successful new entry is due, at least in part, to its exclusionary pricing practices in the hospital segment of the market.

229. Napp's prices to the community are over 40% higher than those of its next most profitable competitor. Even taking account of cost differences, Napp earns a gross profit margin some […] [*in excess of ten*] percentage points higher. Even with much lower sales volumes, Napp's next most profitable competitor is still able to earn profits at a much lower community price and margin.[139] This further supports the conclusion that Napp's prices to the community are excessive due to the fact that they are not subject to normal competitive constraints.

[137] The price is Napp's average net price to the community over those tablets where its next most profitable competitor also sells tablets of the same strength. The weights used are Napp's sales volume to the community.
[138] The cost of sales uses the costs per tablet strength of the next most profitable competitor and applies Napp's sales volumes to the community to get the average cost of sales. This ensures a comparison of the sales price and cost of sales of tablets of the same strength.
[139] On the assumption that the competitor has a normal level of promotional expenditure.

PPRS

230. Napp argues that the PPRS prevents Napp from charging excessive prices. The restrictions imposed on Napp by the PPRS are assessed in paragraphs 122 to 137 above. It is not considered that these restrictions prevent Napp from charging excessive prices on MST. In particular, it is noted that the PPRS is a portfolio constraint and does not seek to ensure that the prices of individual products are not set at excessive levels.

Conclusion

231. Napp earns a gross profit margin on its sales of MST to the community segment of 80% - at least [...][*in excess of ten*] percentage points higher than the margin earned by its next most profitable rival when cost differences are allowed for. On other products that Napp sells to the NHS, it earns an average margin of […] [*between 30% and 50%*]. The difference between the costs that Napp incurs on MST and the price it charges for MST in the community is therefore excessive. Finally, the community price of MST is 40% higher than Napp's highest priced rival.

232. Unlike prices in the hospital segment where MST has been subject to competition, the price of MST in the community segment has not fallen since the expiry of Napp's patent in 1992. Instead, 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.

233. Taking account of the fact that MST 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. Also, Napp has said in evidence to the Director that given the time MST has been on the market, the advertising costs are relatively low. There seems little or no justification for such high margins.

234. Napp is charging excessive prices to the community segment.

D EFFECT ON TRADE WITHIN THE UNITED KINGDOM

235. Napp's discount policy restricts competition in the market for sustained release morphine tablets and capsules in the UK and therefore alters the structure of competition in the UK. Discounts also have a potential effect on the pattern of pharmaceutical trade in the UK. High prices to the community segment of the relevant market have an impact on NHS expenditure on other pharmaceutical products and healthcare services and therefore also alter the pattern of trade in the UK.

E CONCLUSION

236. 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.

237. 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 and thereby infringed the Chapter II prohibition imposed by section 18 of the Act.

IV ENFORCEMENT

A PENALTIES

238. Section 36 of the Act 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. No penalty fixed by the Director may exceed 10% of the turnover of the undertaking determined in accordance with the provisions specified in the Competition Act 1998 (Determination of Turnover for Penalties) Order 2000.[140]

239. Napp does not benefit from limited immunity from penalties for conduct of minor significance under section 40 of the Act since its applicable turnover in each of the years ending 31 December 1999 and 31 December 2000 exceeded £50 million.[141]

240. The Director may impose a penalty on an undertaking only if he is satisfied that the infringement has been committed intentionally or negligently by the undertaking.[142] Undertakings cannot rely on the newness of the regime as a reason against a finding of intention or negligence.

(a) Intentional or negligent

Discounts to hospitals

241. The Director is satisfied that the infringement in relation to discounts to hospitals has been committed intentionally or, at the very least, negligently.

242. Napp was aware during the period of the infringement of the strong position it held and continues to hold in the market for sustained release morphine tablets and capsules in the UK, in terms of its very high market share, the reputation of its brand and the high barriers to entry facing rivals.

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[140] Section 36(8) of the Act and SI 2000/309.
[141] Section 40 and The Competition Act 1998 (Small Agreements and Conduct of Minor Significance) Regulations (SI 2000/262).
[142] Section 36(3) of the Act.

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[143] 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 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.

245. The Director takes the view that Napp's infringement in respect of its excessive discounting to the hospital segment of the market for sustained relief morphine tablets and capsules was, for the purposes of section 36 of the Act, intentional or, at the very least, negligent.

Excessive prices to the community

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 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.

(b) Method of calculation

247. The Director has published Guidance as to the Appropriate Amount of a Penalty ("Guidance on Penalties")[144] as required by section 38(1) of the Act. The Director must

[143] On the evidence supplied to the Director, direct cost is taken to be a close, but conservative, approximation to average variable cost in this case.
[144] OFT 423, March 2000

have regard to the Guidance on Penalties when setting the amount of a penalty.[145] The Guidance on Penalties sets out a five-step approach that the Director will follow to calculate the amount of a penalty.

Step 1 - starting point

248. The starting point for determining the level of penalty 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.

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 £[...]. 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 [...][*in excess of 80%*] compared to average NHS margins of around […]

[145] Section 38(8)

[*between 30% and 50%*]. 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.

Step 2 – adjustment for duration

255. The starting point may be increased to take into account the duration of the infringement.

256. The infringement has lasted from 1 March 2000 until the date of this decision. This is a little more than one year. The Director has discretion to increase the starting point accordingly, but has decided not to do so in the present case as the period of infringement is only a little more than a year. The Director has also taken into account the fact that Napp has persisted with the infringement since March 2000 to the date of this decision under steps 3 and 4 below.

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.

Step 4 – adjustment for further aggravating and mitigating factors

261. The basic amount of the financial penalty, adjusted as appropriate at steps 2 and 3, may be increased where there are aggravating factors, or decreased where there are mitigating factors.

262. Napp has not altered its pricing policy since it became apparent to it that the Director regarded its behaviour as infringing the Chapter II prohibition and, in particular, since 25 August 2000 when it received the first notice from the Director under rule 14 of the Director's rules. The Director considers this to be an aggravating factor and that, in consequence, an increase of 10% of the penalty is appropriate. In making this adjustment, the Director has taken into account the fact that the estimate of Napp's gain from the infringements during that period has been included in the adjustment at Step 3.

263. Napp has represented to the Director that there are a number of factors which should be taken into account in mitigation in this case. The Director has given careful consideration to Napp's representations but has concluded that there are no mitigating factors in this case. In particular, there is a well established body of European Community case law on excessively low pricing and exclusionary conduct and the Director does not therefore consider that the infringement is novel. It is also well established that excessive pricing can be an abuse. Neither does the Director consider that pressure from buyers to reduce prices can be a mitigating factor. Finally, the Director does not consider that Napp's membership of the PPRS, or the provisions of the Health Act 1999, would warrant a belief on Napp's part that the Act did not apply to its pricing conduct.

264. Following Step 4 the amount of the penalty is therefore adjusted to £3.21m.

Step 5 – adjustment to prevent maximum penalty being exceeded and to avoid double

jeopardy

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.[146] The UK turnover of Napp Pharmaceutical Holdings Limited in 2000 amounted to £51.2 and in 1999 to £53.9m. [147] 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.

(c) Requirement to pay a penalty

266. The Director requires Napp to pay him a penalty of £3.21m in respect of the infringements set out in paragraph 236 and 237 above. The penalty must be paid before 30 June 2001.

267. If Napp fails to pay the penalty before the date specified above, and has not brought an appeal against the imposition or amount of the penalty within the time allowed or such an appeal has been made and determined, the Director can commence proceedings to recover the required amount as a civil debt due to him.

B DIRECTIONS

268. Section 33 of the Act provides that if the Director has made a decision that conduct infringes the Chapter II prohibition, he may give to such person or persons as he considers appropriate such directions as he considers appropriate to bring the infringement to an end.

269. Once he has considered the representations made to him by Napp in reply to the supplementary rule 14 notice dated 13 March 2001, the Director proposes to give Napp directions that he considers appropriate to bring the infringement to an end. This is without prejudice to Napp's obligation under the Act not to engage in conduct which infringes the prohibition under section 18 of the Act.

[146] SI 2000 No. 309
[147] Napp.

John Vickers
Director General of Fair Trading