IN THE COMPETITION COMMISSION

APPEAL TRIBUNALS

Case No. 1001/1/01

New Court
48 Carey Street
London WC2A 2JT

8 August 2001

Before:

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

BETWEEN:

NAPP PHARMACEUTICAL HOLDINGS LIMITED
AND SUBSIDIARIES — Appellant

and

THE DIRECTOR GENERAL OF FAIR TRADING — Respondent

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

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

Judgment on certain matters arising from a
Case Management Conference on 30 July 2001
(non-confidential version)

Background

1. This is an interim decision on certain matters that arose at a case management conference on 30 July 2001, relating to the conduct of the appeal brought before this Tribunal by Napp Pharmaceutical Holdings Limited and subsidiaries (Napp). Napp is appealing against (i) a decision by the Director General of Fair Trading (the Director) dated 30 March 2001 (the Decision) which found that Napp has abused a dominant position contrary to the Chapter II prohibition imposed by the Competition Act 1998 (the Act); and (ii) certain directions dated 4 May 2001 (the Directions) given to Napp by the Director under section 33 of the Act with a view to bringing to an end the infringement found in the Decision.

2. In the Decision, the Director found that Napp has a dominant position in the supply of sustained release morphine tablets and capsules in the United Kingdom, and that Napp has abused that dominant position, in breach of the Chapter II prohibition in that:

> "Napp has:
>
> (a) while charging high prices to customers in the community segment of the market, supplied sustained release morphine tablets and capsules to hospitals at discounts which have the object and effect of hindering competition in the market for the supply of sustained release morphine tablets and capsules in the UK. The pricing behaviour of Napp has to be considered as a whole, but the particular aspects in which, in the circumstances of the present case, its discounting behaviour is abusive under section 18 of the Act are as follows:
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> (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."
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> (See paragraphs 142 and 236 of the Decision.)

3. At paragraphs 241 to 246 of the Decision the Director found that Napp's infringements had been committed intentionally, or at the very least negligently, and ordered Napp to pay him a penalty, under section 36 of the Act, of £3.21 million.

4. By the Directions, which followed some five weeks later, the Director notably ordered Napp (i) to reduce its NHS list price for sustained release morphine tablets and capsules by 15%; and (ii) not to supply those products to hospitals or hospices within the United Kingdom at a price lower than 20% of the NHS list price. The Director thus ordered both a reduction of the price at which Napp's products are sold to the NHS for use by patients under the care of their GP in the community segment of the market, and imposed a 'floor' price for sales in the hospital segment of the market.

5. Napp's appeal, lodged on 30 May 2001, has the automatic effect of suspending the obligation to pay the penalty of £3.21 million until the determination of the appeal: section 37 of the Act. The Directions have also been suspended on terms, pending the hearing of the appeal, following a consent Order made by the President on 22 May 2001: see [2001] Comp AR 1.

6. Napp's Notice of Appeal is a substantial document, and is supported by voluminous evidence and annexes running to some 2,500 pages. In accordance with the procedure set out in the Competition Commission Appeal Tribunal Rules 2000 SI 2000 no. 261 (the Rules) and the Tribunal's own *Guide to Appeals under the Competition Act 1998* (the *Guide*), a first case management conference was held on 25 June 2001. The date for service of the defence was fixed for 11 July 2001 and the date for the hearing of the appeal was fixed for 24 September 2001. Further issues for decision relating to production of documents, witness statements, and other matters were held over to the next case management conference fixed for 30 July 2001. After an extension of time for service of the defence granted by the President on 10 July 2001, the defence was served on 16 July. The defence runs to some 59 pages and nine annexes, and is accompanied by seven witness statements and accompanying documents. The defence bundle of witness statements and documents runs to some 400 pages.

7. Instead of proceeding in an orderly manner to the case management conference fixed for 30 July, matters then took an unexpected turn. By letter of 20 July 2001 Napp, by its solicitors, wrote to the Registrar of the Tribunal contending that, in the defence, the Director "relies on

new evidence, takes a different position in respect of certain key questions of fact and adopts different reasoning in support of his findings of infringement, by comparison with the position taken in the original infringement Decision". Napp therefore gave notice of its intention to apply, at the case management conference fixed for 30 July 2001, "for the Tribunal to disallow those parts of the Defence and its supporting annexes which depart from or enlarge upon the original infringement Decision". The essence of the submission made in that letter was that the Director was seeking to support the Decision by reference to a "new case" which the Tribunal neither could nor should entertain.

8. Particulars of the respects in which the Director is said to have made a "new case" are set out in the letter of 20 July 2001 and in a subsequent letter from Napp's solicitors to the Registrar dated 24 July 2001. That letter gave notice of Napp's intention to make the following applications at the case management conference of 30 July 2001.

> "...
>
> 2. An application that the following parts of the infringement decision and the direction be set aside:
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> (a) Decision: paragraphs 142(b); 203-234; 235 third sentence; 236(b); 246; 252; 253; 258-260; 262; 263 fourth and fifth sentences; 264.
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> (b) Direction: All.
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> The basis of the application is that the Director has in his Defence abandoned those parts of the Decision wherein the Director found that prices charged by Napp in the community segment were a violation of the Chapter II prohibition simply because of their absolute level: see Defence paragraphs 16 and 17. Napp will contend that (a) those parts of the Decision which find that Napp's prices in the community were unlawful simply because of their absolute level should now be set aside and (b) the Direction should be set aside in toto because it is predicated upon the basis that Napp's prices were excessive in an absolute sense and upon the conclusion (from which the Director now resiles – see below) that Napp's prices charged to hospitals should be regulated in a manner which takes account of a follow on linkage which he now contends not to exist or (if it does exist) which he now contends it is impermissible to take into account in setting hospital prices (also contrary the Decision).
>
> 3. An application (i) that the Report of Ms Linda Prior be excluded as evidence upon this appeal and (ii) for a ruling that the Director be prevented from altering the basis of the Decision under appeal. The basis of this application is that the Director accepted in his Decision (see paras 150 et seq including in particular paragraph 160) that there was a follow-on effect between hospital and community of 15% which could serve as a crude estimate of the follow-on effect at a national level over time. The Director now pleads: (a)

that this was a "concession" which he seeks now to withdraw (Defence para 38); and (b) that the extent of the follow-on effect previously accepted is now "manifestly inaccurate" (Defence para 24(b)). Napp will contend that it is not open to the Director to seek to advance a new case on appeal and that the jurisdiction of the Tribunal is limited to determining the Appellant's challenge to the Decision, which challenge does not include a challenge to the paragraphs from which the Director now resiles.

4. An application that the witness statements of: John Michael Brownlee; John Robert Hartley; Mark Dominic Connolly; Roger Penrose; Stephen Robert Potter, be disallowed. The basis of this application is that:

(a) The evidence contained within the statements relates directly to matters which were in issue during the administrative procedure.

(b) The said evidence could have been advanced in the course of that procedure, but was not.

(c) In the circumstances, Napp has been denied significant rights of defence in that: this evidence was never included in any Rule 14 Notice, but could have been; Napp has never therefore had a chance to address this evidence prior to the stage of an appeal as it should have been entitled to; it is inappropriate and unfair that the first opportunity which a defendant to a criminal law proceedings (see Defence para 113) has to rebut material allegations of fact made against it to support a penalty should be in a reply to a defence upon an appeal.

(d) The evidence enlarges upon the factual basis of the Decision, whereas the Decision should be the end, and not the start, of the Director's adjudicatory and investigatory role.

(e) The evidence seeks to support the Director's new case as to follow-on effects, which is inconsistent with the position set out in the Decision.

(f) The statements exhibit documents which are not relied upon in the Decision. These documents are now relied upon against Napp. There is no reason why these documents could not have been put to Napp as part of a Rule 14 Notice.

5. An application in the light of paragraphs 2-4 above that in the premises the Director's case against Napp has changed to such a degree as to render it unfair and improper for the Director to defend the Decision and Direction at all and that consequently the Decision and the Direction should be annulled.

6. An application for suspension of the remainder of the timetable fixed at the case management conference on 25th June 2001 for the disposal of these Appeal proceedings, pending a resolution of the applications at 2 to 5 above.

7. An application for consequential and other directions to take account of the Tribunal's determination of the applications above."

9. Following the exchange of skeleton arguments, we heard Napp's application at the case management conference on 30 July 2001, both Napp and the Director being represented by

leading counsel. At the conclusion of the argument we gave an indication of the ruling we were inclined to make for case management purposes and adjourned the matter generally to the next case management conference, since fixed for 8 August 2001. Normally at a case management conference we would expect the above indications to suffice for the purposes of the parties and the future planning of the case, but Napp has since requested a formal decision on its application. Since this is the first case under the Act, we accede to that request by way of this interim ruling. It is convenient to set out the relevant statutory framework before proceeding to the issues and the approach we have adopted.

The statutory framework

— *The Director's Rules*

10. Before the Director takes a decision finding an infringement of the prohibitions of Chapters I or II, he must follow the procedure set out in "the Director's Rules" made pursuant to Schedule 9 of the Act and contained in the Competition Act 1998 (Director's rules) Order 2000, SI 2000 no. 293. For present purposes it is sufficient to set out Rule 14 of the Director's Rules which provides:

> "14.—(1) If the Director proposes to make a decision that the Chapter I prohibition or the Chapter II prohibition has been infringed he shall give written notice:
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> (a) ...
>
> (b) ... to each person who that Director considers is a party to the agreement, or is engaged in the conduct, as the case may be, which that Director considers has led to the infringement.
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> ...
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> (3) A written notice given under paragraph (1) or (2) above shall state the facts on which the Director relies, the matters to which he has taken objection, the action he proposes and his reasons for it.
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> ...
>
> (5) Subject to paragraph 6 below, the Director shall give each person referred to in sub-paragraph (1)(a) or (b) or paragraph (2) above, whichever is applicable, a reasonable opportunity to inspect the documents in that Director's file relating to the proposed decision.
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> (6) The Director may withhold any document:
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> (a) to the extent that it contains information which a person has stated to that Director to be, and which that Director has found to be, confidential, in the sense given to that word by sub-paragraph (1)(c) of rule 30 below;

(b) which is, in the opinion of that Director, otherwise confidential; or

(c) which is internal, in the sense given to that word by sub-paragraph (1)(f) of rule 30 below.

(7) Subject to rules 25 and 26 below, the Director shall give each person referred to in sub-paragraph (1)(a) or (b) or paragraph (2) above, whichever is applicable, written notice of the period within which that person may make written representations to him on the information referred to in paragraph (3) above.

(8) The Director shall give each person referred to in sub-paragraph (1)(a) or (b) or paragraph (2) above, whichever is applicable, a reasonable opportunity to make oral representations to him on the information referred to in paragraph (3) above."

11. In the present case the first "Rule 14 Notice" was sent to Napp on 25 August 2000, and a supplementary notice ("the second Rule 14 Notice") was served on 2 February 2001. According to the Director's letter of 2 February 2001 the second Rule 14 Notice "does not replace the original Notice but should be read with it". A further Rule 14 Notice relating to the Directions was issued on 13 March 2001. Napp replied both in writing and orally to the first two of these Notices and in writing to the third.

— *Appeals under the Act*

12. An appeal against a decision by the Director lies to this Tribunal, which has a statutory jurisdiction as defined by ss. 45(2), 46 to 48 and Schedule 8 of the Act. Under s. 46(2) "Any person in respect of whose conduct the Director has made a decision may appeal to the Competition Commission against, or with respect to, the decision". In the present case the relevant "decisions" are both the Decision finding that the Chapter II prohibition has been infringed and imposing a penalty (see s. 46(3)(b) and (g)) and the Directions (s.46(3), last sub-clause). By virtue of ss. 48(1) and 59(1) the appeal is to be determined by an appeal tribunal constituted in accordance with the provisions of Part III of Schedule 7 of the Act. The functions and powers of the appeal tribunal are determined by Schedule 8 of the Act and the Rules made under the wide powers conferred by s.48(2), (3) and (4).

13. Schedule 8, paragraph 3 of the Act provides:

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

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

(a) remit the matter to the Director,

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

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

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

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

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

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

14. Schedule 8, paragraph 9(1) provides that Rules may make provision:

"(a) as to the manner in which appeals are to be conducted ...;

(c) for requiring persons to attend to give evidence and produce documents and for authorising the administration of oaths to witnesses;

(d) as to the evidence which may be required or admitted in proceedings before the tribunal and the extent to which it should be oral or written;

(e) allowing the tribunal to fix time limits with respect to any aspect of the proceedings before it and to extend any time limit ...

(f) for enabling the tribunal to refer a matter back to the Director if it appears to the tribunal that the matter has not been adequately investigated;

(g) for enabling the tribunal ... (i) in England and Wales ... to order the disclosure between, or the production by, the parties of documents or classes of documents ...

(h) for the appointment of experts for the purposes of any proceedings before the tribunal ..."

— *The Tribunal's Rules*

15. Turning to the Tribunal's Rules, Rule 6 governs the bringing of an appeal. Pursuant to Rule 6(2), an appeal is brought by the service on the Registrar of a notice of appeal (in the Rules referred to as "the application") within two months of the relevant decision. As appears notably from Rules 6(5) and (6), as elaborated in the *Guide*, the notice of appeal is intended to be a fully pleaded document, setting out the appellant's contentions in fact and law, supported by reasoned argument and accompanied by any documents or witness statements relied. The requirement that the appellant set out a detailed argued case at the outset explains the relatively long time limit allowed for appealing. The first case management conference takes place about 4 weeks after the service of the notice of appeal (*Guide*, paragraph 7.5).

16. Pursuant to Rule 12, the defence must be served by the respondent Director within six weeks of the service of the notice of appeal, subject to the limited possibility of an extension of time: see the President's order of 10 July 2001. Broadly speaking, the defence will be designed to meet, in a reasoned manner, the points made in the application, and will be accompanied by such witness statements and documents as are relied on by the Director. Paragraph 8.2 of the *Guide* provides:

> "The form of the defence will vary with the nature of the case. In general, the Director's position in fact and law will have already been set out in the decision and the documents referred to therein, and there may be little need to elaborate on that position in the defence. If, for example, the application consists largely of arguments already dealt with in the decision, it is sufficient to make brief references to the passages in the decision which deal with the arguments advanced rather than rehearsing the contents of the decision all over again."

17. Rules 13 to 14 provide for the possibility of intervention by interested third parties, who may, depending on the circumstances, seek the tribunal's permission to lodge a statement of intervention supported by witness statements and documents. How far the tribunal will permit intervening parties to do that will depend on the nature of the case: see paragraphs 9.8 and 9.9 of the *Guide*. In the present case there are no interveners, although it is true that competitors of Napp such as Link Pharmaceuticals Limited (Link) and Boehringher Ingelheim Limited (BIL) would appear to have had a 'sufficient interest' to intervene.

18. Rules 17 and 18 provide:

> "17.—(1) The tribunal may at any time, on the request of a party or of its own motion, at the pre-hearing review or otherwise, give such directions as are provided for in paragraph (2) below or such other directions as it thinks fit to secure the just, expeditious and economical conduct of the proceedings.
>
> (2) The tribunal may give directions–
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> (a) as to the manner in which the proceedings are to be conducted, including any time limits to be observed in the conduct of the oral hearing;
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> (b) that the parties file a reply to the defence or other additional pleadings;
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> (c) for holding a pre-hearing review;
>
> (d) requiring persons to attend and give evidence or to produce documents;
>
> (e) as to the evidence which may be required or admitted in proceedings before the tribunal and the extent to which it shall be oral or written, including, where a witness statement has been submitted, whether the witness is to be called to give oral evidence;

(f) as to the submission in advance of a hearing of any witness statements or expert reports;

(g) as to the examination or cross-examination of witnesses;

(h) as to the fixing of time limits with respect to any aspect of the proceedings;

(i) as to the abridgement or extension of any time limits, whether or not expired;

(j) to enable a disputed decision to be referred back (or in Scotland, remitted) to the person by whom it was taken;

(k) for the disclosure between, or the production by, the parties of documents or classes of documents; or in the case of proceedings taking place in Scotland, for such recovery or inspection of documents as might be ordered by a sheriff;

(l) for the appointment and instruction of experts, whether by the tribunal or by the parties and the manner in which expert evidence is to be given; and

(m) for the award of costs or expenses, including any allowances payable to persons in connection with their attendance before the tribunal.

(3) The tribunal may, in particular, of its own motion:–

(a) put questions to the parties;

(b) invite the parties to make written or oral submissions on certain aspects of the proceedings;

(c) ask the parties or third parties for information or particulars;

(d) ask for documents or any papers relating to the case to be produced;

(e) summon the parties' representatives or the parties in person to meetings or case conferences.

(4) A request by a party for directions shall be made, as far as practicable, in the application or defence, or on notice at the pre-hearing review. A request made at any other time shall be made in writing and shall be served by the Registrar on any other party who might be affected by such directions and determined by the tribunal taking into account the observations of the parties.

18.—(1) Where it appears to the tribunal that any proceedings would be facilitated by holding a pre-hearing review, taking into account the criteria set out in paragraph (3) below, the tribunal may on the request of a party or of its own motion, give directions for such a review to be held. The Registrar shall give the parties not less than fourteen days notice, or such shorter notice as the parties agree, of the time and place of the pre-hearing review.

(2) The pre-hearing review shall be in private unless the tribunal otherwise directs.

(3) The purpose of the pre-hearing review shall be–

(a) to ensure the efficient conduct of the proceedings;

(b) to determine the points on which the parties must present further argument or which call for further evidence to be produced;

(c) to clarify the forms of order sought by the parties, their arguments on fact and law and the points at issue between them;

(d) to ensure that all agreements that can be reached between the parties about the matters in issue and the conduct of the proceedings are made and recorded;

(e) to facilitate the settlement of the proceedings. ..."

19. Rules 20 and 21 provide–

"20.—(1) The tribunal may control the evidence by giving directions as to–

(a) the issues on which it requires evidence;

(b) the nature of the evidence which it requires to decide those issues; and

(c) the way in which the evidence is to be placed before the tribunal.

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

(3) The tribunal may require any witness to give evidence on oath or affirmation or if in writing by way of affidavit.

(4) The tribunal may allow a witness to give evidence through a videolink or by other means.

21.—(1) ..., the tribunal may at any time, either of its own motion or on the request of any party, issue a summons, (or in relation to proceedings taking place in Scotland, a citation), requiring any person wherever he may be in the United Kingdom to do one or both of the following–

(a) to attend as a witness before the tribunal at the time and place set out in the summons or citation; and

(b) to answer any questions or produce any documents or other material in his possession or under his control which relate to any matter in question in the proceedings."

20. As regards the above provisions paragraphs 10.1 to 10.3 of the *Guide* indicate:

"10.1 The object of the procedure following the defence and any interventions is to enable the case to proceed to a hearing as soon as possible. The Rules envisage that the tribunal may give a wide range of directions under Rule 17 and/or hold a pre-trial review under Rule 18, but the procedure adopted will depend in part on the outcome of the first case conference, and in part on the contents of the defence itself. In some cases, matters may already be sufficiently far advanced for the tribunal to proceed rapidly to the main

hearing of the case, possibly giving written directions in that regard. In other cases it will be convenient to proceed either to a further case management conference or (more formally) to the pre-trial review envisaged by Rule 18.

Further pleadings after the defence

10.2 Rule 17(2)(b) provides that the tribunal may give directions that the parties file a reply to the defence or other additional pleadings. Unlike the procedure in the CFI in cases under Articles 81 and 82, the filing of a reply and a rejoinder is not automatic. Given that a further round of written pleadings will add substantially to the duration of the case, the tribunal may be reluctant to order such further pleadings unless they are really necessary.

Directions as to evidence etc

10.3 In so far as not already dealt with at the first case conference, the second case conference and/or pre-hearing review will deal primarily with the organisation of the hearing of the case, including any remaining matters concerning witnesses, expert witnesses or disclosure of documents (see eg Rule 17(2)(d) to (g), (k) and (l), and Rules 20 to 21). If there is any question of a decision being referred back to the respondent prior to the main hearing (Rule 17(2)(j)) or of the tribunal being invited to deal with any preliminary points of law, or of a possible reference to the Court of Justice under Article 234 of the EC Treaty (see Rule 31), those matters will also be addressed. A timetable for the hearing will also be set (Rule 19)."

21. Rule 8(1)(a), read with Rule 12(6), empowers the Tribunal to strike out a notice or appeal or defence if it discloses no valid ground of appeal or defence, as the case may be. Paragraph 11.3 of the *Guide* states that "An application to the tribunal to strike out a pleading on the ground that it discloses no valid ground of appeal or defence should not be made except in the clearest cases".

22. After the various interlocutory steps have been completed the matter proceeds to the main public hearing in accordance with Rules 23 and 24, after which the Tribunal gives its decision (Rule 25).

The issues on this application

23. In very brief summary, the nub of the application as made by Napp is (i) that it appears from paragraphs 16 and 17, 84 and 86 of the defence that the Director has abandoned, or at least significantly changed, his case on the abuse as to excessive pricing set out in the Decision, with the consequence that that part of his defence should be struck out and/or that Napp should

immediately have some form of summary judgment as regards the alleged abuse of excessive pricing, with a consequent quashing of the penalty and Directions; (ii) that the Director should be refused the permission he requests in paragraph 38 of the defence to alter the stance taken by him in paragraph 150 of the Decision relating to the so-called "follow-on effect"; (iii) that most of the further witness statements adduced by the Director should be excluded; and (iv) that the Director should not be permitted to rely on evidence in electronic form as regards discounting from list price of some 12,500 other NHS products referred to in paragraph 46 of the Defence. (This last point is mentioned in Napp's solicitor's letter of 20 July but not in that of 25 July.) It is convenient to deal with each of these issues in turn.

The issue regarding the alleged abuse of excessive prices

— *Arguments of the parties*

24. Napp argues first that the Director's case on excessive prices, as advanced at paragraphs 16, 17, 84 and 86 of the defence, is fundamentally different from the case against Napp in the Decision. Paragraphs 16 and 17 of the defence read as follows:

> "16. In essence, the Director General's case is that Napp charges excessively low and/or discriminatory prices in the hospital segment and *thereby* sustains very high prices and market share in the community segment of the market. These two aspects are accordingly interlinked. Napp's pricing practices have the effect of placing significant obstacles against the successful entry of competitors, and in consequence serve to preserve its quasi-monopoly position in the community segment of the market and enable it to continue to charge prices for MST higher than could be sustained in the absence of that quasi-monopoly position (i.e. competitive prices). The NHS list price for the most popular size of MST tablets is now as much as [≫ *in excess of ten*] times the hospital price. Napp has been able to sustain a market share in excess of 95% of the total market, and also of the profitable community segment, over nine years after the first competitive entry and notwithstanding the entry of further competitive brands, without reducing its NHS list prices.
>
> 17. Accordingly, the Director General does not seek to condemn the prices in the community segment in isolation; in other words, if his case should fail as regards the exclusionary character of Napp's pricing practice in the hospital segment, he does not contend that the prices in the community segment violate the Chapter II prohibition simply because of their absolute level."

25. Paragraphs 84 and 86 of the defence read as follows:

> "84. As stated above, it is the Director General's case that Napp's conduct has had the effect of excluding competitors from the hospital segment, thereby foreclosing the essential gateway for entry to the community segment. As a result Napp has retained its quasi-monopoly position in the community segment and has been able to charge quasi-monopoly prices. In those circumstances, the charging of prices, which are higher than Napp would be able to charge in a competitive market, constitutes an abuse.
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> ...
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> 86. Similarly here, the Director General found that as a result of the exclusionary practices Napp has been able to charge prices in the community segment sheltered from effective competition. To support that finding of excessive pricing, the Director General relied on five considerations."

26. According to Napp, it emerges from those passages that the Director does not attack the absolute levels of Napp's prices in the community sector as a separate, self-standing abuse in itself: he attacks those prices only to the extent that they have been maintained at an excessive level *as a result of* Napp's alleged exclusionary pricing practices in the hospital sector. In other words, the excess prices in the community sector are an abuse *only* because of the exclusionary practices in the hospital sector, and not an autonomous abuse arising irrespective of the legality or otherwise of Napp's pricing to hospitals.

27. Napp then seeks to demonstrate, by a detailed analysis of, notably, paragraphs 142(a) and (b), 203-234, 235, 236(a) and (b), 141-246, 251-252, 259-260, 262 and 263, that that was not the case made by the Director in the Decision. According to Napp, in the Decision the Director was, in fact, criticising the absolute level of Napp's prices in the community sector, as a separate self-standing abuse which was not wholly dependent on the alleged abuse in the hospital sector. According to Napp, the Decision alleged two abuses: (a) predatory and discriminatory pricing in the hospital sector, one result of which was to enable Napp to maintain higher prices in the community sector; and (b) excessive prices in the community. Napp has been fined for both abuses, and the Directions are based on the existence of two abuses. However, so Napp argues, if the allegedly excessive prices in the community sector are *now* regarded as excessive only as a result of the abuse in the hospital sector, Napp has been effectively fined twice for the same consequences.

28. Napp further argues that if the excessive pricing in the community sector is now regarded as an abuse only because of the pricing practices in the hospital sector, it becomes necessary to

consider a new issue, namely what effect Napp's pricing practices in the hospital sector had on Napp's ability to maintain its prices in the community in the period between 1 March 2000 when the Act came into force and 30 March 2001, when the Decision was taken. According to Napp, even if it had ceased its pricing practices in the hospital sector on 1 March 2000, it is very unlikely that any resulting progress by its competitors in the hospital sector in the period of just over a year from 1 March 2000 would have had a significant impact on Napp's prices in the community sector up to the date when the Decision was taken. Moreover, Napp argues that the Decision proceeded on the basis that Napp's pricing policy in the hospital sector had the effect of foreclosing only *a part* of the total market, and not the whole of it (see paragraphs 150, 160 and 165 to 167 of the Decision). According to Napp, the Director's new case presupposes that the effect of Napp's pricing policy to hospitals was to foreclose the whole of the community sector, and that that was the only factor enabling Napp to maintain its price levels in that sector. Neither proposition is to be found in the Decision. Thirdly, Napp points out that the Director's calculation of the 'excess' profit which Napp has alleged to have made (see paragraphs 259 to 260 of the Decision) was not predicated on the difference between what Napp's prices were and what they would have been in the period March 2000 to March 2001 if the hospital pricing practices had not occurred, but on the difference in absolute levels between what they were and what the Director considered a reasonable price ought to have been.

29. As a result of those considerations, says Napp, the Director must be taken to have abandoned the case on excessive pricing as made in the Decision, and Napp should not have to deal with it any further in this appeal. The Decision and the Directions should to that extent be set aside, or at the least remitted back.

30. The Director submits that there is no statutory basis for Napp's application, and that in any event it is not a matter for striking out. The Director denies that he has abandoned the finding of excess pricing. His case as set out in the defence is that Napp's pricing policy in the hospital segment had the effect of foreclosing effective entry to the community segment; that in consequence Napp has been able to – and has in fact – charged prices in excess of the competitive price in the community segment; and that accordingly the charging of those excessive prices is an abuse.

31. According to the Director, the position set out in the defence is wholly consistent with the Decision. The only difference is that while in the Decision the Director left open the possibility that the ability to charge excessive prices in the community segment might be attributable to other (unspecified) factors *in addition to* the exclusionary pricing in the hospital segment, by the defence the Director makes clear that no other factors are relied on. The Director refers to the conclusion on excessive pricing in the Decision, paragraph 232:

> "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."

He also refers to paragraph 238, to paragraph 236(a), where it is stated that "the pricing behaviour of Napp has to be considered as a whole, ...", and to a similar statement in the letter of 4 May 2001 accompanying the Direction (at page 2).

32. In oral argument, counsel for the Director referred us to the first Rule 14 Notice which, it was submitted, still represented the Director's case. The Director maintains that prices are higher than would be expected in a competitive market, as demonstrated at paragraphs 203 to 234 of the Decision, but acknowledges that other factors, such as the lack of price sensitivity among GPs, contribute to the lack of competitive pressure on prices in the community sector. The reason for paragraphs 16 and 17 of the defence is to make clear that the Director is not seeking to be a price regulator. It is only if one of the factors which enables the charging of excessive prices in the community sector is itself anti-competitive conduct that those prices are to be characterised as abusive. The Director emphasises, finally, that there is no question of fining twice for the same conduct. Here there are two interlinked abuses, exclusionary pricing practices in the hospital sector and excess prices in the community sector. Napp has been fined for both of these, in circumstances where the pricing policies of Napp have to be viewed as a whole, as both the Decision and the Directions make clear.

— *Our preliminary view at this stage of the proceedings*

33. An appeal to this Tribunal against a decision finding an infringement of the prohibitions of Chapter I or Chapter II of the Act relates to the infringement as found in the decision as taken by the Director. Such a decision reflects, or should reflect, the Director's definitive view as regards the nature of the infringement alleged. Self-evidently, the precise nature of the alleged

infringement has important legal consequences. Any penalty must be "in respect of the infringement" (section 36(1) and (2)). A penalty may not be imposed unless the Director is satisfied that "the infringement" has been committed intentionally or negligently (section 36(3)). Any directions must be such directions as the Director considers appropriate for bringing "the infringement" to an end (section 32(1) and section 33(1)). In addition the definition of the infringement carries possible civil consequences, having regard to section 58 of the Act.

34. In these circumstances, the precise nature of the infringement found should be made clear in the decision. If an appeal is lodged, the nature of the infringement should require no further gloss or explanation in the Director's defence. However bona fide or well intentioned, any gloss or explanation in the defence regarding the nature of the infringement which does not closely reflect the wording of the decision under appeal risks giving rise to confusion as to what it was the Director intended to decide, and to allegations on behalf of an appellant that the Director has changed his stance.

35. Without burdening this interim decision with a detailed textual analysis of the Decision, it seems to us at the moment that the Decision alleges two separate and self-standing abuses in respect of (a) discounts to hospitals and (b) excessive prices in the community: see notably paragraph 142 which refers to these two abuses under the headings (a) and (b); paragraphs 144 to 202, where the first abuse is dealt with under the heading "(a) discounts to hospitals"; paragraphs 203 to 234, where the second abuse is dealt with under the heading "(b) excessive prices"; the "Conclusion" in paragraph 236, which also refers to the two abuses under the headings (a) and (b) in the same terms as paragraph 146; the discrete references to the two abuses to be found in paragraph 235; paragraphs 241 to 246 where 'intentional or negligent' is dealt with under the separate headings "discounts to hospitals" and "excessive prices"; and the methodology for calculating the fine, notably paragraphs 251 to 252 and paragraphs 259 to 263. The same conclusion is supported by the content and structure of the Directions.

36. As to the relationship between the two abuses, the Director sets out his analysis of the abuse on excessive prices at paragraph 203 of the Decision in these terms:

> "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."

37. It is not there stated that it is a necessary ingredient of the abuse on excess pricing that the absence of "effective competitive pressure" on Napp's prices in the community sector should be due to some exclusionary conduct on the part of Napp. It is enough, on the formulation in paragraph 203, that the absence of competitive pressure should result from other factors such as regulatory barriers, Napp's first mover advantage, lack of price sensitivity among GPs and so on.

38. In paragraphs 204 to 230, the Director then goes on to establish that Napp's prices in the community sector are excessive, on the basis that (i) Napp's prices are substantially higher than its competitors; (ii) Napp's community prices have not fallen over time; (iii) Napp's prices in the community sector and for export are extremely high compared with those in the hospital sector; (iv) Napp's gross profit margins are substantially higher on its community sales of sustained release morphine than on its total NHS sales; (v) Napp's gross profit margin is substantially higher than that of its nearest competitor.

39. The Director's conclusion is set out at paragraphs 231 to 234 is as follows:

> "*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."

40. Those paragraphs do not, at first sight, support the proposition that Napp's excessive community prices are abusive only because of the exclusionary effect of Napp's pricing practices in the hospital sector, nor the proposition that the excessive level of Napp's prices in the community sector arises solely because of Napp's practices in the hospital sector. The nearest the Decision comes to such a contention is the last sentence of paragraph 232, where the Director states "This [absence of competition from successful new entry] is due, *at least in part*, (our emphasis) to Napp's exclusionary pricing practices in the hospital segment". However, this sentence does not say what part, nor even that a preponderant part, of Napp's ability to maintain its excessive prices in the community sector is due to its practices in the hospital sector.

41. Similarly the expression "The pricing behaviour of Napp has to be considered as a whole", which appears in the context of Napp's alleged abuse in the hospital sector in paragraphs 142(a) and 236(a) of the Decision is not further elaborated upon and is not linked, at least explicitly, to the abuse on excessive pricing which is dealt with separately in paragraphs 142(b) and 236(b).

42. It is true that in the context of his analysis of the first abuse, discounts to hospitals, the Director considers that that abuse has effects not only in the hospital sector (paragraphs 145 to 159) but also in the community sector (paragraphs 160 to 180). In particular, he accepts as a 'crude estimate' that there is a follow-on effect of 15% between hospital and community sales at a national level over time (paragraphs 150 and 160) but considers that 15% is the lower limit of the foreclosure of the community sector because of the so-called "reputation effect" (paragraph 165). As far as we can see, the Director nowhere in the Decision clearly quantifies the foreclosure effect in the community sector of the "reputation effect". However, at paragraph 167, the Director refers to "40% of the relevant market" (i.e. hospital and community sales combined) as being a substantial foreclosure effect. Since on his case 24-27% of the relevant market is foreclosed by hospital sales and the "follow-on effect" combined, at least one inference from this passage is that, in the Director's view, the "reputation effect" forecloses the equivalent of some 13 to 16% of the relevant market. While the Director will no doubt put us

right if, in our as yet incomplete study of the Decision, we have drawn an incorrect inference, it does seem to us, at the moment, that the Decision as taken does not allege, at least in clear and explicit terms, that the "reputation effect" of hospital sales is such as to foreclose the whole, or even the preponderant part, of the community sector.

43. As regards the reference made in argument on behalf of the Director to the first Rule 14 Notice, and Napp's reply thereto, it seems to us, at first sight, that the case on foreclosure as put to Napp in the second Rule 14 Notice represents a substantial development from the case as put in the first Rule 14 Notice. Moreover, it is the case as put in the second Rule 14 Notice that appears to be reflected in the Decision. In any event, our primary duty is to decide the appeal by reference to what is said in the Decision and not what is said in a Rule 14 Notice.

44. We do not therefore find ourselves able, at least at this preliminary stage, fully to accept the Director's submission that the case on the excess pricing abuse now made in paragraphs 16, 17, 84 and 86 of the defence is exactly the same as the case made on that issue in the Decision, albeit that any change seems to be to Napp's advantage.

45. It does not, however, seem to us that the Director can be said to have abandoned the totality of his allegations as regards excessive pricing. All the detailed comparisons to show excess prices set out in paragraphs 203 to 229 of the Decision are maintained and are not factually contested by Napp. The Director continues to maintain both abuses. On the basis of the defence, so long as the abuse on hospital pricing is maintained so too is the abuse on excess prices in the community sector.

46. The most that can be said at this stage is that the Director's case on excess pricing *may* have shifted, perhaps to an important extent.

47. That in our view is not a matter for striking out the defence pursuant to Rule 8(1). Even if that rule could apply to parts of the defence, it cannot be said that the Director's defence on excess pricing discloses *no* valid defence within the meaning of that Rule. The striking out power contained in that Rule is a reserve power to deal with a wholly exceptional case. Similarly, our duty under the Act is to determine the appeal on the merits. This is not a case where we could conceivably 'set aside' the decision at this stage of the matter, depriving the Director of a full

hearing, especially since we have not yet fully absorbed the voluminous documents placed before us. It would in any event not be a correct exercise of our discretion to reach, at this stage, a final disposal on a part only of the contested decision. For the same reasons, we do not consider it appropriate, at this stage of the proceedings, to refer the matter back to the Director.

48. We observe moreover that *if* the Director's case has shifted, that would appear to be a development favourable to Napp, in that, at least potentially, it gives Napp further arguments, of the kind advanced to us by Napp on 30 July, with which to attack the findings on excess pricing and the associated penalty and Directions, even if the Director's case on hospital pricing should succeed. On the other hand, if that latter case should fail, then Napp has the chance to invoke the Director's concession as to the excess pricing case.

49. In these circumstances, we think the better course is to give Napp a further brief opportunity to set out in writing its reply to the defence on this issue and to seek such consequential directions as are appropriate. We can then evaluate the arguments in more detail in a structured way in the context of the full hearing. Any prejudice to Napp can be met by an order for costs, if appropriate.

50. We add finally, as a cautionary note, that if we found that Napp has correctly interpreted the Decision, and if, as Napp submits, our jurisdiction is to determine the appeal by reference to the Decision, it is arguable that we should simply proceed on the basis that Napp faces two self-standing abuses, as Napp alleges the Decision to have found, ignoring any purported gloss in the defence. In that event, Napp would be back where it started. That point, among others, may have to be further explored in due course.

The issue on paragraph 38 of the defence

51. In paragraph 38 of the defence, the Director sought permission to "withdraw" the phrase in paragraph 150 of the Decision to the effect that the Director accepted that "Napp's figure of 15% may serve as a crude estimate of [the follow-on effect between hospital and community sales] at a national level over time". The 'follow-on' effect refers to the further sales of sustained release morphine in the community sector which may occur once a patient who has been initiated onto the product in hospital returns to the community and is prescribed the same product by his GP. The defence indicates that the Director now has doubts about the validity of

the Internet Survey on which he says the figure of 15% was based, which doubts are supported by a witness statement by Linda Prior which the Director wished to adduce. Napp strongly opposed this admitted change in the Director's position at this stage of the proceedings. It emerged in argument that the figure of 15% was considered by the Director in the Decision to be supported not merely by the Internet Survey but also by other evidence: see paragraph 160, and to form the basis of further arguments by the Director e.g. at paragraphs 165 to 167 of the Decision. All those passages, including paragraph 150, represent the way the case was put against Napp in the second Rule 14 Notice. At the end of his submissions counsel for the Director abandoned his request to withdraw paragraph 150 of the Decision, and with it paragraph 38 of the defence and the witness statement of Linda Prior.

52. We would have had great difficulty – even if we have power to do so – in permitting the Director to withdraw paragraph 150 of the Decision in view of the significance of the figure of 15% for the Decision as a whole (e.g. paragraphs 160 to 167) and the contents of the Rule 14 Notice, but we do not have to make a ruling in view of the Director's withdrawal of his request. This somewhat perplexing course of events did however lead Napp to argue in its closing submissions (i) that it was unsatisfactory that the Director should be defending before the tribunal a case which, according to the original version of the defence, he no longer believes in; and (ii) that certain other passages in the defence linked to the now withdrawn paragraph 38 should be withdrawn or disregarded as well.

53. In our view those points are probably best set out in writing in a further short written reply to be served by Napp and explored in more detail at the final hearing. We do not propose to make a further interlocutory ruling at this stage.

Witness statements

— *Arguments of the parties*

54. Napp objects to the production by the Director of witness statements by Mr Hartley, Head of Sales and Marketing at Link, an active competitor of Napp, Mr Connolly, Marketing Director of the Prescription Medicine Division for BIL, a competitor of Napp which withdrew from the market in 2000, Mr Penrose, NHS and Development Manager for BIL, Mr Potter, Director of

Pharmacy for the University Hospital Birmingham NHS Trust, and (although this is not entirely clear) Stephen Blake, solicitor, of the Legal Division of the Office of Fair Trading.

55. Napp's grounds of objection are, first, that, pursuant to the structure of the Act and the rights of defence, it is not open to the Director to adduce new evidence on appeal. The Decision should be definitive and not merely "a stage on the way" to the case being advanced on appeal. Alternatively, any discretion to admit new evidence, should be exercised very sparingly, otherwise the rights of the defence at the administrative stage and Rule 14 of the Director's Rules will not have been respected. As regards the specific evidence in question, Napp criticises notably the fact that, in the Decision, the Director relies on the evidence of Mr Mountain of Link and Dr Heil of BIL whereas now he relies on Mr Hartley of Link and Mr Connolly and Mr Penrose of BIL. There is no reason why the evidence of the new witnesses or the documents they produce should not have been available in the administrative procedure. In addition, parts of Mr Hartley's evidence and Mr Penrose's evidence appear to support a new case on 'follow-on effect'. Napp also criticises the detail of the evidence on various points.

56. On the question of principle, the Director submits that an application to the Tribunal sets in motion the judicial stage under the 1998 Act whereas the Director took an administrative decision. The Director submits that he should not be expected or required to obtain full witness statements on all relevant matters before taking his decision. When that decision is challenged, then on specific matters that are material to the appeal, it is right and appropriate that the Director should be entitled to obtain such statements and, if required by the Tribunal, whether at the request of the applicant or of its own motion, make those witnesses available for cross-examination. See also the Tribunal Rules, rule 20(2) ["whether or not the evidence was available to the respondent when the disputed decision was taken"]. According to the Director, the applicant has made assertions of fact in its application and adduced further evidence in support of the appeal, including new factual matters in reports. The Director would be gravely handicapped in the appeal process if he was not entitled to adduce evidence in response.

57. Moreover, Napp specifically criticises the Director for relying on material which "has no evidential value or carries insufficient evidential weight or which Napp has not been able to test by cross-examination": (Notice of Appeal, paragraph 5.61(v)). At paragraph 5.70(iii) of the Notice of Appeal Napp complains that the Director has "taken at face value" statements from

BIL and Link about the effect on them of Napp's conduct "without testing whether their assessment of the situation (even assuming it to be honestly described) is correct".

58. As regards Mr Hartley's evidence, in the Decision the Director held that a new entrant cannot rely on a mechanistic follow-on effect to recover from loss-making sales (paragraph 155) and relied on statements from Link that it was under threat of being driven out of the market (eg at paragraph 116). In the Notice of Appeal, paragraphs 3.63-3.64 and 5.39(iii)-(iv), Napp asserts that Link believes in a follow-on effect, contending that all firms compete on the basis of a "packaged" opportunity, with community sales factored into hospital prices. Napp also contends that Link is making "steady progress" in the market and criticises the Director for ignoring the growth in Link's sales since May 2000, referring to the information in the Nera report of 29 May 2001 (p. 2450 of Bundle A/IV), see the Notice of Appeal paragraphs 3.76-3.77. At paragraph 5.70(iii), Napp contends that the Director should not have taken "at face value" Link's statements about the effect on it of Napp's conduct (with the suggestion that Link may not even have described its views honestly).

59. According to the Director, it is only correct and appropriate to adduce evidence from Link rebutting those points developed in the Notice of Appeal. That is the scope of Mr Hartley's statement, save that he also expresses Link's own criticism of the Direction. Link, like BIL, could clearly have sought to intervene in the proceedings: see Rule 14. Had permission to intervene been granted, Link (and BIL) would have been entitled to adduce facts and arguments before the Tribunal. It should not make a material difference that they have furnished witness statements to the Director to be placed before the Tribunal as opposed to themselves seeking to intervene and furnish witness statements to be placed before the Tribunal.

60. As regards to Mr Connolly, the reason why BIL withdrew Oramorph SR in the United Kingdom in 2000 is one of the issues in the case in so far as it goes to the exclusionary effect of Napp's conduct. In the Decision, the Director expressly rejected Napp's suggested explanations and accepted statements from BIL's Chairman and Managing Director indicating that low prices in the hospital segment were "a strong factor" in BIL's decision to withdraw: paragraph 175. In its Notice of Appeal, Napp submits that "the documents on which the Director relies are of no evidential value or weight": Annex 1, paragraph 53, and paragraph 5.70(iii). Napp maintains that BIL's exit is unrelated to Napp's conduct: paragraph 5.52(i). It is appropriate that the

Director should adduce a witness statement dealing with these matters. Mr Connolly also answers the claim at paragraph 15 of Mr Brogden's 2nd witness statement of 25 May 2001 that Amarin is preparing to launch a SRM product in the United Kingdom: see also Notice of Appeal, paragraph 3.79.

61. As regards Mr Penrose, in the Decision, in rejecting the argument of a "follow-on effect", the Director relied, inter alia, on the fact that BIL did not benefit from a direct follow-on effect in the community of its hospital sales: paragraph 153. In response, Napp makes a sustained attack on BIL's marketing efforts and skill, effectively accusing them of incompetence: see the Notice of Appeal, paragraph 3.65(ii), relying on Mr Brogden's second witness statement, paragraphs 21-22, and Mr Steed's witness statement. Napp also contends that BIL, like Link, believed in a direct follow-on effect and priced on that basis: Notice of Appeal, 5.39(iii) and Annex 1, paragraph 23(vi). Mr Penrose rebuts these allegations.

62. Mr Penrose also deals, at paragraphs 60-65 of his statement, with a new matter raised by Napp in the paper, *Evidence of Other Therapeutic Markets*, served in support of the appeal, namely the effect of the entry of Sevredol (sold by Napp) on the market share of Oramorph solution.

63. As regards Mr Potter, the Director held that Napp had consistently "matched or undercut the prices of competitors in the hospital segment": paragraph 146. In its appeal, Napp contends "that it has not undercut Boehringer Ingelheim's prices": Notice of Appeal, Annex 1, paragraph 39. However, the Director's finding is not restricted to BIL. The statement of Mr Potter demonstrates the manner in which undercutting is engaged in by Napp against Link.

— *Our preliminary view at this stage of the proceedings*

64. We take the view, first, that it is impossible to deduce from the Act and the Rules that there is an absolute bar on the admission of new evidence before this Tribunal, whether submitted by the appellant or the respondent. Schedule 8, paragraph 9(1) of the Act envisages that the Tribunal's Rules will provide for the giving of evidence, the hearing of witnesses, the production of documents, the appointment of experts and so on: see sub-paragraphs (c), (d), (g) and (h). Those provisions are implemented notably by Rule 17(2) (d), (e), (f), (g), (k) and (l) and by Rule 20 (control of evidence by the tribunal) and Rule 21 (summoning of witnesses). Contrary to one of Napp's submissions, these powers seem to us to derive from s.48(2) to (4) and paragraph 9 of

Schedule 8, and not from the power to make 'incidental' provision to be found in s.71 of the Act.

65. The Act and the Rules imply that the procedure before the Tribunal should be evidence based, in course of a determination "on the merits". It follows that the question of what evidence is presented on the appeal, and how that evidence is to be handled, is a matter for the discretion of the tribunal: see notably Rule 20. Such discretion is of course to be exercised judicially, but it is not in doubt that there is a discretion. Moreover Rule 20(2) makes it absolutely clear that as regards the Director the discretion may be exercised "whether or not the evidence was available to the respondent when the disputed decision was taken".

66. That gives rise to two quite distinct issues. The first issue is how the discretion to admit new evidence should be exercised? The second issue is at what stage of the proceedings it should it be exercised? It seems to us that a definitive answer to these questions is likely to depend on a fuller analysis of the role and function of this Tribunal under the Act than we have been able to undertake at the moment without the benefit of full argument in a case as yet only at a preparatory stage. It does not seem to us appropriate finally to decide such an issue of principle in the context of an early case management conference.

67. It seems to us that the only matter we have to decide at this stage, in the exercise of our case management powers under Rule 17, is (i) whether we should at this stage exclude altogether from the case the further witness statements submitted by the Director; and (ii) if not, what consequential case management directions should be given. We do not have to decide now whether and to what extent this evidence will be taken into account, or even be relevant to, our final decision. Those are issues which can only be determined in the context of the final hearing.

68. In addressing Napp's argument that the new evidence should in principle be excluded altogether, even at this stage, we do not, at first sight, find analogies with other jurisdictions particularly helpful.

69. As far as analogies drawn by Napp with criminal procedure are concerned, the Director concedes, in our view rightly (see Case C-235/92P *Montecatini v Commission* [1999] ECR I-

4575, points 175 and 176), that these proceedings are 'criminal' for the purposes of Article 6(1) of the European Convention on Human Rights and Fundamental Freedoms (ECHR). However, it does not follow that an analogy can usefully be drawn with the procedure traditionally followed in a criminal trial in the Crown Court or on appeal to the Court of Appeal (Criminal Division). The administrative procedure before the Director is manifestly not a trial in that sense and does not follow either the criminal rules of evidence or criminal procedure.

70. As the Court of Appeal has recently indicated in *Han & Yau and ors v Commissioners of Customs and Excise* (3 July 2001), the fact that certain proceedings may be classified as 'criminal' for the purposes of the ECHR gives the defendant the protection of Article 6, and in particular the right to "a fair and public hearing within a reasonable time by an independent and impartial tribunal established by law" (Article 6(1)), to the presumption of innocence (Article 6(2)) and to the minimum rights envisaged by Article 6(3) including the right "to examine or have examined witnesses against him and to obtain the attendance and examination of witnesses on his behalf under the same conditions as witnesses against him" Article 6(3)(d). But it by no means follows from the conclusion that Article 6 applies that civil penalty proceedings are, for domestic purposes, to be regarded as criminal and therefore subject to the procedures that apply to the investigation of crime and the conduct of criminal proceedings as defined by English law (see Potter LJ at paragraph 84 and Mance LJ at paragraph 88 of that judgment).

71. Similarly, we do not find the analogy of the approach of the Court of Appeal (Civil Division) to new evidence as exemplified in *Ladd v Marshall* [1954] 1 WLR 1489 directly in point. Here there has been no 'trial' as there has been in civil proceedings, there has merely been an administrative procedure. The procedure before the Court of Appeal, although strictly speaking a 'rehearing'; does not bear any real resemblance to the procedure before this Tribunal as envisaged by the Act and the Rules, which is more akin to that of a court of first instance. Similarly, the practice of the Administrative Court in judicial review proceedings is not directly analogous, since these proceedings are not judicial review but a full determination of the merits. The Court of First Instance of the European Communities (CFI), upon which the Tribunal is broadly modelled, is perhaps a little closer, but the jurisdiction of this Tribunal is couched in wider terms than that of the CFI under Articles 229 and 230 (ex 172 and 173) of the EC Treaty. Moreover, the fact-finding procedures of the CFI are rooted in the inquisitorial civil law

tradition and rarely involve witness statements of the kind in issue here. We do not find that analogy directly helpful either.

72. We start then from first principles but we do so only in a provisional way because the matter has not been fully argued and we have not been taken to any authorities. Under the structure of the Act what we have is an administrative procedure before the Director, followed by a full judicial determination of the merits of the Director's decision, with the tribunal being vested, notably, with the power to take any decision the Director could have taken (Schedule 8, paragraph 3(2)(e) of the Act).

73. As regards the administrative stage, under Rule 14 of the Director's Rules, the Director must put to the defendant "the matters to which he has taken objection, the action he proposes and the reasons for it", provide an opportunity for the defendant to inspect documents in the Director's file, and give the defendant the opportunity to make written and oral representations. We accept that under the case law of the CFI the European Commission's obligation to put to the defendant the essential facts on which he relies is a fundamental part of the rights of the defence, breach of which can result in the annulment of the decision: see e.g. Cases T-25/93 etc *Cimenteries CBR and others v Commission* (the Cement case) [2000] ECR II-491, paragraphs 106 and 476. While of course strongly persuasive, the judgments of the CFI are however influenced by the formal concepts of French administrative law, and by the nature of the jurisdiction exercised by that Court under Article 230 of the EC Treaty. Moreover, not every breach of the right to be heard in the administrative procedure will necessarily lead to annulment of the decision, see e.g. Case 85/76 *Hoffman La Roche v Commission* [1979] ECR 461, points 15 to 17; and the Cement case, at points 241 and 247.

74. We add that the fact that the administrative procedure before the Director may not itself comply with the requirements of Article 6(1) of the ECHR, does not constitute a breach of the Convention, provided that the Director is subject to subsequent control by a judicial body that has full jurisdiction and does comply with Article 6(1): *Albert and Le Compte v Belgium* 5 EHRR 533, and the decision of the House of Lords of 9 May 2001 in *Alconbury Developments Ltd and others* [2001] UKHL 23. As we see it, the Act looks to the judicial stage of the process before this Tribunal to satisfy the requirements of Article 6 of the ECHR.

75. As regards the judicial stage, we have already set out the provisions of the Act and the Rules which provide that the appeal is a full appeal on the merits, conducted by reference to witnesses and documents, under the discretionary control of the Tribunal. The ample nature of that appeal seems to us to equate to that under consideration in *Lloyd v McMahon* [1987] 2 WLR 821 where the House of Lords indicated that a court enjoying such a jurisdiction could in certain circumstances legitimately correct unfairness which may have occurred in the administrative procedure below without necessarily quashing the decision concerned: see Lord Bridge at pp 884F to 885C and Lord Templeman at p.891 E-G.

76. In that connection we note that the appellant is not limited to placing before this Tribunal the evidence he has placed before the Director but may expand, enlarge upon or indeed abandon that evidence and present a new case. Since there is no right to test the evidence of witnesses before the Director, it is at this judicial stage of the proceedings that the applicant may apply to test by cross-examination the evidence of all relevant witnesses against him.

77. We doubt, however, whether exactly the same liberal approach to the submission of new evidence can be applied to the Director. In our view the exercise of the discretion to allow new evidence by the Director at the appeal stage should take strongly into account the principle the Director should normally be prepared to defend the decision on the basis of the material before him when he took that decision. It is particularly important that the Director's decision should not be seen as something that can be elaborated on, embroidered or adapted at will once the matter reaches the Tribunal. It is a final administrative act, with important legal consequences, which in principle fixes the Director's position. In our view further investigations after the decision of primary facts, in an attempt to strengthen by better evidence a decision already taken, should not in general be countenanced.

78. Were it otherwise, the important procedural safeguards envisaged by Rule 14 of the Director's Rules would be much diminished or even circumvented altogether. There would be a risk that appellants could be faced with a "moving target". The Tribunal itself would be in difficulties if, instead of determining the appeal essentially by reference to the merits of the decision in the light of the material relied on by the Director at the time, the Tribunal was effectively adjudicating on a "bolstered" version of the decision. The Director himself concedes that he cannot 'make a new case' before the Tribunal.

79. For these reasons our provisional conclusion is that there should be a presumption against permitting the Director to submit new evidence that could properly have been made available during the administrative procedure.

80. On the other hand, there may well be cases where the Tribunal is persuaded not to apply the presumption we have indicated. As stated in the *Guide*, the procedures of this Tribunal are designed to deal with cases justly, in close harmony with the overriding objective in civil litigation under Rule 1.1 of the Civil Procedure Rules. That includes, so far as practicable, ensuring that the parties are on an equal footing, saving expense, dealing with the case in ways which are proportionate, proceeding expeditiously, and allotting to the case an appropriate share of the court's resources. Those considerations may militate against permitting new evidence by the Director, but in some circumstances considerations of fairness may point in the other direction. An obvious example is where a party makes a new allegation or produces a new expert's report which the Director seeks to counter.

81. One factor that may well be relevant in this connection is the fairness of the appeal process itself. In accordance with the Act, the first occasion on which the Decision first receives full public judicial scrutiny is in this Tribunal. An appellant will often have submitted voluminous pleadings, witness statements, and documents unconstrained by the evidence presented to the Director. The Director, at the administrative stage, may not always be able to foresee (although of course he should endeavour to do so) from what direction or in what strength an attack might come at the appeal stage. A situation whereby the appellant could always have a "free run" before the Tribunal, but the Director was always confined to the material used in the administrative procedure could lead to a significant lack of balance and fairness in the appeal process.

82. Another possibly relevant consideration is the situation of adversely affected third parties such as competitors (here BIL and Link). Such competitors may choose formally to intervene, or they may have their point of view put by means of material presented by the Director. We are not persuaded that it matters very much which route is followed; we simply indicate that what is fair as regards closely involved third parties may also be relevant to the exercise of the Tribunal's discretion to admit further evidence.

83. In the present case we consider that there are factors which tend to rebut the presumption we have just indicated and lead us, in the exercise of our discretion, not to exclude from the tribunal's file at this stage the witness statements of Mr Hartley of Link and Mr Penrose of BIL. In these proceedings, the Director's pricing case, fully canvassed in the administrative procedure and the Decision, is that Napp has engaged in below cost, selective and discriminatory discounting in the hospital sector. The thrust of the evidence of Messrs Hartley and Penrose is not directed to that pricing case, but to rebutting the defence put forward by Napp that its actions are legitimate because Napp profits from 'follow-on' sales in the community sector, a possibility equally open to its competitors. So we are dealing here with rebuttal evidence.

84. In addition, as regards Mr Hartley there are at least five additional factors. (1) Napp itself relies on the evidence of Mr Mountain of Link at paragraphs 3.63 to 3.64 and 5.39(iv) and (v) of the Notice of Appeal. We have already indicated to the parties that Mr Mountain should be available as a witness if so required by Napp. In those circumstances it seems only fair that Mr Hartley's statement should also be available on the points at issue, which relate notably to the follow-on effect and Link being "bullied" out of the market. (2) Napp makes various assertions in its Notice of Appeal about Link's recent progress in the market, which are taken into account in one of Napp's expert's reports prepared subsequently to the Decision (see 3.76 and 3.77 of the Notice of Appeal). Mr Hartley's evidence goes also to those assertions. (3) At 5.70 (iii) of the Notice of Appeal Napp implies that the statements made by Link to the Director should not be taken at face value, and Mr Hartley's evidence is relevant to that allegation. (4) Link is one of Napp's few active competitors and its evidence to the Director has been attacked by Napp before this tribunal, where the proceedings are in public. An appellant who publicly impugns the actions of a competitor before this Tribunal must expect that competitor to be given a chance to reply. (5) In at least one crucial respect, Mr Hartley's evidence is favourable to Napp, namely where he criticises the reduction of 15% imposed by the Directions.

85. Balancing these factors against Napp's basic argument that Mr Hartley's statement and its annexes should have been made available earlier, we do not think that we should exclude Mr Hartley's evidence at this stage. Further arguments as to the relevance or weight of Mr Hartley's evidence, or indeed whether the Tribunal should pay any attention to it at all, are best reserved to the final hearing.

86. As regards Mr Penrose, much of his evidence is of a historical nature relating to a period prior to the entry into force of the Act. BIL withdrew from the market in 2000 and as far as we can see – provisionally – the background to that decision and BIL's policy in the mid 1990s may not be among the most essential issues which we have to resolve. However, we would not wish at this stage to pre-judge that question. Napp has made allegations, in this public forum, regarding BIL's alleged incompetence, (paragraph 3.65 (ii) of the Notice of Appeal) and made assertions about how BIL in fact priced its products (paragraph 5.39 (iii) of the Notice of Appeal). On at least one issue pleaded by Napp, the question of who started the price cutting in the 1990s (paragraphs 3.67 to 3.71 of the Notice of Appeal), Mr Penrose's statement may be of some help to Napp. On one (side) issue, the impact of Sevredol, Mr Penrose deals with a new matter raised by Napp. Moreover, it would seem illogical to exclude BIL's evidence while admitting Link's evidence. In these circumstances we think the balance comes down against excluding Mr Penrose's evidence at this stage.

87. In deciding not to exclude the evidence of Mr Hartley and Mr Penrose we arrive at the situation where the evidence of three of the main protagonists, namely Napp and its competitors Link and BIL will be available to the Tribunal by way of witness statements, thus putting those parties on an equal footing and enabling the Tribunal to form a balanced view. It also ensues that Napp, who complains strongly about its inability to cross-examine its competitors during the administrative procedure, now has the opportunity to do so, if it wishes.

88. We add for completeness that we are not yet persuaded that the evidence of Mr Hartley or Mr Penrose moves outside the parameters of the findings in the Decision. But if Napp wishes to contend otherwise, or to persuade us that for whatever reason it would be wrong to take this evidence into account in our final decision, the time to do so is at the final hearing.

89. Mr Connolly's evidence goes to one issue, whether BIL's decision to leave the market in 2000 was affected by Napp's activities. In the Decision the Director says it was, in reliance on a statement by Dr Heil, and Mr Connolly supports that. We are not clear why it is Mr Connolly rather than Dr Heil who is being tendered as a witness. This evidence is also rather more difficult to describe as rebuttal evidence because the effect on BIL of Napp's activities forms part of the Director's primary contentions. So Mr Connolly's evidence is borderline. Our decision, out of caution, is not to exclude it at this stage but to keep the issue under review.

90. Mr Potter's evidence appears to us to be of a somewhat peripheral character, and to fall within the presumption against the Director indicated above. We therefore exclude it.

91. No real objection was taken against Mr Brownlee's evidence. It did not appear to us that strong objection was taken to Mr Blake's evidence, which relates mainly to allegations made by Napp about potential new entrants to the market. This evidence updates the Tribunal on that issue and we would not think it right to exclude this evidence at this stage. Again we reserve for later decision how far we are in fact prepared to take this evidence into account.

The electronic data referred to in paragraph 46 of the Defence

92. Napp objects to the late production by the Director in paragraph 46 of the defence of information he has obtained from the NHS Supplies Authority of some 12,500 instances of discounting of other products against NHS list prices. We for our part will not, without notice, take this information or paragraph 46 of the defence into account against Napp, since we do not know the circumstances of these numerous other products or whether their list prices represent a valid bench mark. We suggest that one issue in this case is not whether discounts off list prices represents "normal competition" but whether prolonged discounted sales below cost represent normal competition, which is a different matter. Napp, however, now has this data and may advance to us such arguments as they wish. Issues regarding the rights of the defence are once again reserved to our final decision.

Conclusion

93. We therefore make an Order as follows:

(i) Napp's application to strike out or set aside the defence, the Decision, or any parts thereof, or to have the Decision remitted to the Director, is refused.

(ii) We will consider an application by Napp to serve a reply.

(iii) We note the withdrawal by the Director of paragraph 38 of the defence and the witness statement of Linda Prior. Any consequential issues arising will be decided following submissions at the final hearing.

(iv) The witness statement of Mr Potter is excluded from the Tribunal's file.

(v) The witness statements of Messrs Hartley, Connolly and Penrose are not excluded from the Tribunal's file, all issues as to whether the Tribunal should in fact place reliance on those statements being reserved for decision after submissions at the final hearing.

(vi) Mr Mountain of Link should (if so desired by Napp) be made available as a witness.

(vii) The Tribunal will not without notice rely as against Napp on the matters referred to in paragraph 46 of the defence.

The costs are reserved.

SIR CHRISTOPHER BELLAMY QC
MR BARRY COLGATE
PROFESSOR PETER GRINYER