IN THE COMPETITION COMMISSION APPEAL TRIBUNAL

Case No. 1000/1/1/01(IR)

Tuesday, 22nd May 2001

Before:
SIR CHRISTOPHER BELLAMY QC
(The President)

B E T W E E N:

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 JON TURNER (instructed by the Director General of Fair Trading) appeared for the Respondent.

J U D G M E N T
(As approved)

THE PRESIDENT:

1. This is an application made on 11th May 2001, pursuant to rule 32 of the Competition Commission Appeal Tribunal Rules 2000 ("the Rules"), by Napp Pharmaceuticals Limited and its subsidiaries ("Napp"). Napp seek an order suspending certain directions dated 4th May 2001 ("the Directions") given to Napp by the Director General of Fair Trading ("the Director") under section 33 of the Competition Act 1998 ("the Act"), pending the determination of an appeal to this tribunal, the Competition Commission Appeal Tribunal ("the Tribunal") which Napp intends to introduce, under section 46(2) of the Act, both against the Directions and against Decision number CA98/2/2001 ("the Decision") taken against Napp by the Director on 30th March 2001.

2. In the event, the application is being disposed of by consent. Since, however, this is the first application to come before the Tribunal under the Act, it is convenient to set out in this judgment the background circumstances and the procedure that has been followed, in order to give guidance on the points that have arisen, and to explain the Tribunal's approach to the agreed order now proposed. Needless to say, nothing in this judgment prejudges any issue that may arise on the substantive appeal.

The Decision

3. In the Decision, which forms the basis of the Directions, the Director found that Napp had infringed the prohibition of an abuse of a dominant position imposed by section 18(1) of the Act and referred to as the Chapter II prohibition. In broad terms, 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 (a) giving unduly low and/or selective discounts on the supply of sustained release morphine tablets and capsules to hospitals, with the object and effect of preventing or hindering competitors from gaining contracts in the hospital segment of the market; while (b) at the same time maintaining excessively high prices for the same products supplied for use by patients under the care of their GP in the community segment of the market.

4. According to the Decision, which is a public document and thus unnecessary to describe at any length, morphine is a strong opioid analgesic used to treat moderate and severe pain, particularly in cancer patients. Sustained release morphine extends the duration of action of a morphine preparation and is used when the pain is constant. In 1980 Napp, a pharmaceutical company based in Cambridge, launched the first sustained release morphine product to appear on the market under the name MST Continus ("MST"). According to Napp, the advantage of MST is that the active ingredient is released gradually over a 12 hour period so as to achieve a continuous and uniform level of analgesia. Napp states that it is a mark of the success of MST that, even some 20 years after its launch, it remains "the gold standard for the treatment of severe chronic pain".

5. From 1980 to 1991 MST was the only orally administered sustained release morphine product on the market in the United Kingdom. In 1991 Farmitalia launched a rival brand of oral sustained release morphine tablets and later assigned its rights to Boehringer Ingelheim Limited ("BIL"), who re-launched the product under the name Oramorph SR in 1994. BIL withdraw Oramorph SR from the market in September 2000. There are currently two other brands of oral sustained release morphine on the market, Morcap SR launched in 1996 supplied by Sanofi-Winthrop, and Zomorph launched in 1997 and supplied by Link Pharmaceuticals Limited.

6. It is common ground that about 86 to 90 per cent of the supply of oral sustained release morphine is to the community segment of the market, i.e. to patients under the care of their GP. The remaining 10 to 14 per cent of the supply is purchased directly from manufacturers by

hospitals where it is prescribed to patients by hospital doctors or specialists. The NHS Purchasing and Supplies Agency ("NHS PASA") purchases by competitive tender on behalf of 10 hospital regions, but it appears that there is a separate contract for each region. Other regions seek tenders directly without using the NHS PASA. The regional contracts are framework contracts, which mean that an individual hospital might choose to negotiate an individual contract on different terms, possibly with another supplier.

7. In the community segment of the market Napp's NHS list price for MST has remained the same since its launch, subject to periodic reductions negotiated by the pharmaceutical industry as a whole in the context of the voluntary scheme of price regulation agreed between the industry and the Department of Health known as the Pharmaceutical Price Regulation Scheme ("PPRS"). Napp's market share for the supply of sustained release morphine tablets or capsules in the community sector is and has remained for many years in excess of 90 per cent.

8. In the hospital sector the purchasing agencies and authorities are more price sensitive. According to the Decision, after the launch of Farmitalia in 1991, discounts to hospitals increased dramatically and have continued to do so. Since the mid 1990s Napp has offered discounts off the NHS list price in excess of 90 per cent on hospital tenders on four strengths of MST tablets. According to the Decision, the discounts offered may sometimes be higher if the contract is to be on a sole supplier basis rather than shared with another supplier. Napp's market share in the hospital segment is also in excess of 90 per cent.

9. In the Decision the Director finds that Napp has a dominant position in the market for sustained release morphine tablets and capsules in the United Kingdom. As regards dominance, the Director relies on Napp's market shares which have been in excess of 90 per cent, and certain barriers to entry identified by the Director. He does not consider that the buying power of the NHS or the particular features of the PPRS prevent Napp from holding that dominant position.

10. As regards sales to hospitals, the Director considers that Napp has abused its dominant position by (i) selectively supplying MST tablets and capsules to customers in the hospital segment at lower prices than to customers in the community segment; (ii) targeting competitors in (a) supplying at higher discounts to hospitals where it faced or anticipated competition, or (b) supplying at higher discounts on those strengths of MST tablets and capsules where it faced competition; and (iii) supplying MST tablets and capsules to hospitals at excessively low prices, in some cases below total delivered cost, and in other cases below direct costs.

11. As regards excessive prices in the community segment, the Director considers that a price is excessive and an abuse for the purposes of section 18 of the Act 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. To show that Napp's prices in the community segment are an abuse, the Director relies on a number of factors identified in detail in the Decision. He also considers that the PPRS regulates only the overall profitability of the company and does not prevent Napp from charging excessive prices on individual products.

12. By paragraph 266 of the Decision the Director required Napp to pay him a penalty of £3.21 million in respect of Napp's infringement pursuant to section 36(2) of the Act.

13. In paragraph 269 of the Decision the Director stated his intention to give Napp directions under section 33 of the Act appropriate to bring the infringement to an end. The Directions were in fact given five weeks later by a letter dated 4th May 2001.

The Directions

14. The broad effect of the Directions (at paragraphs 1 and 2) is to require Napp (i) to bring the infringement found in the Decision to an end and to refrain from any conduct having the same or equivalent effect; (ii) to reduce the NHS list price for Napp's MST tablets and capsules by at least 15 per cent within 15 working days from the date of the Directions, and thereafter to supply MST tablets and capsules at a price no higher than the new NHS list price less the normal wholesaler's discount of 12.5 per cent; and (iii) not without the prior consent of the Director to supply or offer to supply MST tablets and capsules to a hospital or hospice in the United Kingdom at a price which is lower than 20 per cent of the NHS list price.

15. The Directions do not immediately apply to Napp's existing hospital contracts. The combined effect of paragraphs 3(1) and 4(2) of the Directions is that Napp may continue to supply its existing hospital contracts, all of which are at prices well below the minimum envisaged by the Directions, for a period of four months. Thereafter, Napp is obliged by paragraph 3(2) of the Directions to enter into good faith negotiations with the other parties, mainly the NHS PASA or regional health authorities, with a view to agreeing revised terms for supplies to hospitals which comply with the Directions. It appears that, in fixing that four month period of grace, the Director took into account the fact that most of Napp's existing contracts may be terminated by Napp on three months' notice.

16. According to the letter of 4th May 2001, the two elements of Napp's pricing conduct criticised in the Decision are inter-related and must be considered as a whole in formulating directions appropriate to bring the infringement to an end. The Director considers that a reduction of 15 per cent of Napp's NHS list price is appropriate. The minimum price to hospitals is designed to prevent Napp from selling to hospitals at below a certain level of cost.

Napp's application

17. Napp's application to suspend the operation of the Directions pending the determination of the appeal was made on 11th May 2001 and was served on the Director by the Registry on the same day. Napp contends that (i) Napp has a good prospect in succeeding on appeal in having the Decision (including the Penalty) and/or the Directions set aside; (ii) the operation of the Directions pending the outcome of the appeal would cause Napp serious and irreparable damage; (iii) the suspension of the Directions pending the outcome of the appeal would not cause any, or any material, damage to competition in the United Kingdom; (iv) the operation of the Directions pending the outcome of the appeal would cause material damage to third parties; and (v) it would be contrary to the Human Rights Act 1998 to subject Napp to the Directions before it has been afforded a fair trial to determine whether it has infringed the Chapter II prohibition.

18. Napp further contends that its application for suspension is urgent because (i) unless the Directions are suspended by 29th May 2001, Napp will be obliged to reduce its current NHS list price for MST tablets, and (ii) unless the Directions are suspended by 4th June 2001, Napp will be obliged to give notice to terminate six or more of its existing contracts. If hospital buyers thereafter seek new bids, Napp believes that it is unlikely that Napp will be re-awarded the contracts in question. There are also two other contracts in issue which contain no provision for early termination.

19. Napp therefore requests the Tribunal to either fix a timetable so as to enable the Tribunal to decide Napp's application for interim relief on or before 29th May or, if that is not practicable, to grant the interim relief sought pending a full hearing and, if necessary, before the observations of the Director have been submitted. Napp also seeks various ancillary directions, and an order that the Director pay Napp's costs.

20. The application is supported by a witness statement sworn by Napp's managing director, Mr Brogden. In that statement Mr Brogden emphasises the irrevocable losses he considers that Napp will suffer if an immediate reduction of its NHS list price is imposed; the commercial difficulty, as he sees it, of restoring the former list price if Napp wins its appeal; the potential loss to Napp of hospital contracts if competitors bid for those contracts below the 'floor' price before the appeal has been determined; higher prices to hospitals, which Mr Brogden says, will result from the Directions; disruption to hospitals caused by the need to terminate or re-negotiate contracts before the appeal has been determined; possible inconvenience and suffering caused to patients by hospitals switching suppliers; some possible difficulties for competitors; and a number of other factors.

21. Mr Brogden also states, significantly for the purposes of the present application, that in a letter dated 10th May 2001 Napp has indicated to the Department of Health that it is prepared to indemnify the latter against any loss suffered by the NHS as a result of the suspension of the Directions regarding the reduction of the NHS list price if Napp were subsequently to lose its appeal. In its application for interim relief Napp further indicates that it is prepared to approach the relevant hospital buyers with a view to negotiating the termination of its hospital contracts without having to give the three months' notice required by the contracts, in the event that Napp were to lose the appeal.

The Director's response

22. Pursuant to directions given by the President sitting alone under Rule 33(1) on 14th May 2001, the Director submitted written observations on Napp's request for interim relief on 17th May 2001. The Director conceded that Napp would suffer some irrecoverable losses if the Directions were not suspended and Napp were subsequently to succeed on appeal, although he considered Napp's quantification of its losses to be exaggerated. He did not contest the urgency of the application, but submitted that Napp had not presented any material to show that it had a good prospect of succeeding on its appeal. He rejected Napp's arguments that the operation of Directions pending appeal would harm or disrupt third parties such as hospitals, patients or competitors. He also considered Napp's argument under the Human Rights Act 1998 to be unfounded.

23. However, on the assumption that the substantive appeal would be heard in four to five months, the Director considered that the voluntary measures proposed by Napp, namely, the indemnity offered to the NHS, and a possible reduction in the termination period for existing contracts, would, subject to agreement on certain points of detail, provide a mutually acceptable solution pending the hearing of the appeal. The Director also referred to a letter from the NHS PASA indicating that a one month period of termination for the contracts in question would be acceptable.

The Order Sought

24. Negotiations then took place between the parties, the upshot of which is that the Tribunal is now asked to make an order by consent. The general effect of the proposed order is that the Directions will be suspended pending the determination of the appeal. Napp will give an undertaking in terms acceptable to the Director to reimburse the Department of Health for losses caused to the NHS by the suspension of the Directions if Napp loses its appeal, and Napp will write to hospital buyers with a view to ascertaining how quickly the contracts can be terminated if Napp loses its appeal. It is agreed that each side will bear its own costs and that there should be liberty to apply.

The Statutory Framework

25. Before dealing with the various points that arise, it is convenient to refer to the relevant statutory framework. Rule 32, paragraphs (1) to (7) and (10) to (11) provide:

> "**32.**–(1) The tribunal may make an order granting on an interim basis any remedy which the tribunal would have the power to grant in its final decision.
>
> (2) Without prejudice to the generality of the foregoing, if the tribunal considers that it is necessary as a matter of urgency for the purposes of:–
>
> (a) preventing serious, irreparable damage to a particular person or category of person, or
>
> (b) protecting the public interest
>
> the tribunal may make an order giving such directions as it considers appropriate for that purpose.
>
> (3) The tribunal may make an order:–
>
> (a) suspending the effect of the disputed decision in whole or part; or
>
> (b) varying any or all of the conditions or obligations attached to an exemption.
>
> (4) The tribunal shall exercise its power under this rule taking into account all the relevant circumstances, including:–
>
> (a) the urgency of the matter;
>
> (b) the effect on the party making the request if the interim order is not made; and
>
> (c) the effect on competition if the interim order is made.
>
> (5) Any order or direction under this rule is subject to the tribunal's further order or final decision.
>
> (6) A person shall apply for an order under this rule by sending a request for interim relief in the form required by paragraph (7) below to the Registrar.
>
> (7) The request for interim relief shall state:–
>
> (a) the subject matter of the proceedings;
>
> (b) in the case of a request for an order pursuant to paragraph (2) of this rule, the circumstances giving rise to the urgency;
>
> (c) the factual and legal grounds establishing a prima facie case for the interim order being made by the tribunal;
>
> (d) the relief sought;
>
> (e) if no application has been made in accordance with rule 6, in respect of the decision which is the subject of the request for interim relief, the information required by rule 6(4) above.
>
> ...
>
> (10) If the urgency of the case so requires, the tribunal may dispense with a written request for interim relief or grant the request for interim relief before the observations of the other parties have been submitted.
>
> (11) Unless the context otherwise requires, these rules apply to requests for interim relief."

26. Rule 32 is made pursuant to Schedule 8, paragraph 13, of the Act which provides:

> "13.—(1) Rules may provide for the tribunal to make an order ("an interim order") granting, on an interim basis, any remedy which the tribunal would have power to grant in its final decision.
>
> (2) An interim order may, in particular, suspend the effect of a decision made by the Director or vary the conditions or obligations attached to an exemption.
>
> (3) Rules may also make provision giving the tribunal powers similar to those given to the Director by section 35."

27. Paragraph 3 of Schedule 8 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."

28. It is also necessary to bear in mind Rule 10(1), which provides that an applicant:

> "may withdraw his application only with the permission of the tribunal, or if the application has not yet proceeded to a hearing, the President."

Furthermore Rule 28 deals with the circumstances in which various consent orders may be made. Rule 28, paragraphs (1) to (3) provide:

> "**28.**—(1) If all the parties agree the terms on which to settle all or any part of the proceedings, they may request the tribunal to make a consent order.
>
> (2) A request for a consent order shall be made by sending to the Registrar:–
>
> (a) a draft consent order;
>
> (b) a consent order impact statement; and
>
> (c) a statement signed by all the parties to the proceedings or their legal representatives requesting that an order be made in the form of the draft.
>
> (3) A consent order impact statement shall provide an explanation of the draft consent order, including an explanation of the circumstances giving rise to the draft order, the relief to be obtained if the order is made and the anticipated effects on competition of that relief.
>
> ..."

The remainder of Rule 28 then sets out a certain procedure to be followed if the tribunal considers that a proposed consent order may have a significant effect on competition.

29. One issue that arises, which I will come to later, is how far Rules 10 and 28 are applicable to applications for interim relief.

Location of the proceedings

30. Finally as regards the statutory framework, it is necessary briefly to mention Rule 16, which provides:

> "The tribunal shall, as soon as practicable, taking account of the observations of the parties in the application and the defence, determine whether the proceedings are proceedings before a tribunal in England and Wales, in Scotland or Northern Ireland."

That provision, which may seem to be somewhat curious, results from the fact that this Tribunal has jurisdiction throughout the United Kingdom. Both the Decision and the Directions apply throughout the United Kingdom. However, as regards appeals from this Tribunal there is no appellate court, short of the House of Lords, that has jurisdiction throughout the United Kingdom. Section 49 of the Act provides that the question of where an appeal lies from any decision of the Tribunal depends on whether the proceedings are before a tribunal in England and Wales, a tribunal in Scotland, or a tribunal in Northern Ireland. Although the point is now wholly academic for the purposes of the present application, for the purpose of Section 49 of the Act and for any other procedural purpose that could be relevant, I determine, without opposition from either party, that these proceedings for interim relief shall be treated as proceedings before a tribunal in England and Wales.

31. I come now to the exercise of the Tribunal's powers.

The grant of interim relief before an appeal has been lodged

32. It seems to be implicit in Rule 32(7)(e), and for that matter Rule 32(10), that a request for interim relief – such as the suspension of a disputed decision – may be made to the Tribunal before the main appeal has been lodged. Since under Rule 6(2) the time for appealing is two months from the notification of the decision, an order for directions taking immediate effect may well give rise to an application for interim relief being made before the time for appealing has expired. However, while the absence of the substantive appeal is not in itself an obstacle to the grant of interim relief, in those circumstances the Tribunal will normally require from an applicant for interim relief a firm indication as to the date at which the appeal will be lodged, as well as an undertaking to pursue the appeal with all due expedition.

33. In the present case Napp has indicated its intention to appeal against the Decision and the Directions and to lodge its substantive appeal, so it hopes, by Friday May 25th and in any event no later than May 30th. Napp has also indicated its willingness to pursue the appeal with due expedition, and has stated that the appeal lodged by May 30th will be an appeal both against the Decision and against the Directions.

34. I mention the latter point because in this particular case the Directions have somehow become detached in time from the Decision in that the Directions were made separately, five weeks later. I make no criticism about that, I would simply point out that in such a situation complications may arise in calculating the time for appeal if the Directions are to be treated as a separate decision from the main Decision under Section 46(3), last sentence, of the Act. It would therefore seem desirable, in normal circumstances, that any directions given under

Section 32 and Section 33 of the Act should be made in the same document, or at least at the same time, as the substantive decision of infringement upon which the directions are based.

How far should the merits be taken into account in an application for interim relief?

35. That takes me on to the next question, which has not been argued in this case, but on which I shall make some indicative comments: what, if any, threshold test as regards the merits of the main appeal must be met by an applicant seeking the interim suspension of a decision?

36. Section 46(4) of the Act provides that:

> "Except in the case of an appeal against the imposition, or the amount, of a penalty, the making of an appeal under this section does not suspend the effect of the decision to which the appeal relates."

The lodging of an appeal thus automatically suspends the obligation to pay the penalty, albeit subject to the power of the Tribunal to order the payment of interest pursuant to Rule 27 if the appeal is subsequently unsuccessful. But the position is not the same as regards directions given under Sections 32 or 33 of the Act. Directions are not automatically suspended as a result of the mere lodging of an appeal.

37. In relation to an application to suspend a decision of the relevant Director, Rule 32(4), which is set out above, requires the Tribunal to take into account "all the relevant circumstances", including (a) the urgency of the matter; (b) the effect on the applicant if the Decision is not suspended; and (c) the effect on competition if the Decision is suspended. Since a decision giving directions under Sections 32 or 33 of the Act is not automatically suspended merely by virtue of lodging an appeal, it is difficult to avoid the conclusion that "the relevant circumstances" to be taken into account under Rule 32(4) must include the question of whether the applicant has any prospect of success in the main appeal. That raises the question of how far a tribunal hearing an application to suspend a decision pending appeal should go into the merits of the applicant's case, rather than concentrate on the "balance of convenience" in the light, notably, of Rule 32(3)(b) (effect on the applicant) and Rule 32(4)(c) (effect on competition).

38. In that connection, it is important to emphasise that a principal purpose of interim relief is to preserve the integrity of the appeal, and in particular to ensure that so far as possible, taking into account the other interests involved, the applicant does not suffer serious and irreparable damage pending the hearing of an appeal which may yet succeed. It is undesirable, and may in most cases be anyway impracticable, for the tribunal hearing an application for interim relief to go into the merits of the case any further than is strictly necessary for dealing with the application for interim relief in a way that does not pre-judge the main appeal. There may, however, be other cases where, in order to weigh "all relevant circumstances" pursuant to Rule 32(4) it may be necessary to go more fully into the merits than would otherwise be the case.

39. As to the test to be applied, I have not heard argument on that point so the present remarks are indicative only. I am inclined to the view that the principles normally applied in applications for interim injunctions or similar relief in the civil courts in such well known cases as *American Cyanamid v Ethicon* [1975] AC 396, while providing many useful and relevant analogies, are not in themselves necessarily determinative of the issues likely to arise under Rule 32(4). This is not party and party litigation. The Director is not (or so I shall assume) obliged to offer any cross-undertaking in damages. The matters arise in a specific statutory framework in which the public interest figures prominently alongside the private interests of the applicant. As a further incidental point, the principles of *American Cyanamid* are not necessarily applied in an identical fashion throughout the United Kingdom, for example on a motion for an interim

interdict in Scotland: see *NWL Ltd v Woods* [1979] 1WLR 1294 at 1309 to 1310. Whatever test is applied by this Tribunal it should, so far as possible, be the same throughout the United Kingdom.

40. In my judgment the nearest analogous situation to hand is that of an application to the Court of First Instance of the European Communities for interim relief, pending an appeal to that court against a decision taken by the European Commission under Articles 81 and 82 of the EC Treaty.

41. Although Rule 32 is not identical in all relevant respects, its provisions are similar to those governing the grant of interim relief to be found in the Rules of Procedure of the Court of First Instance and of the Court of Justice of the European Communities.

42. I also have regard to Section 60 of the Act, which provides that "so far as is possible (having regard to any relevant differences between the provisions concerned), questions arising under this Part 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 Community law in relation to competition within the Community."

43. In those circumstances it is, in my judgment, appropriate to have regard to the decisions of the Court of First Instance, and the Court of Justice, made in analogous circumstances, when dealing with applications for interim relief under the Act.

44. As regards the threshold test to be applied, that has been the subject of a large number of decisions including notably the order of the President of the Court of Justice of 19th July 1995 in Case 149/95P (R) *Commission of the European Communities v Atlantic Container Line AB and Others* [1995] ECR I-2165. In that case, the President of the Court of Justice said at points 26 and 27:

> "26 In that regard, it must be noted that a number of different forms of wording have been used in the case-law to define the condition relating to the establishment of a prima facie case, depending on the individual circumstances. The wording of the order under appeal, referring to pleas in law which are not, prima facie, entirely ungrounded, is identical or similar to that used on a number of occasions by this Court or its President (see, *inter alia*, Case 56/89 R *Publishers Association v Commission* [1989] ECR 1693, paragraph 31; Case 246/89 R *Commission v United Kingdom* [1989] ECR 3125, paragraph 33; Case C-195/90 R *Commission v Germany* [1990] ECR I-2715, paragraph 19; Case C-272-91 R *Commission v Italy* [1992] ECR I-457, paragraph 24; and Case C-280/93 R *Germany v Council* [1993] ECR I-3667, paragraph 21). Such a form of wording shows that, in the opinion of the judge hearing the application, the arguments put forward by the applicant cannot be dismissed at that stage in the procedure without a more detailed examination.
>
> 27 It is clear from the case-law cited above that the judge hearing an application may consider that, in the light of the circumstances of the case, such pleas in law provide prima facie justification for ordering suspension of the application of an act under Article 185 or interim measures under Article 186."

The President of the Court of Justice in the *Atlantic Container* case thus upheld the approach of the President of the Court of First Instance, who had asked himself the question whether the pleas in law raised by the appellant on an application for interim relief were prima facie "relevant and not entirely ungrounded", see [1995] ECR II-595, point 49.

45. Subject to further argument, in a case where the Director makes mandatory directions of the kind in issue here, to come into effect before the appeal can be heard, a test along the lines that

the applicant has to show that its appeal is not manifestly unfounded, may well be the appropriate test to apply. Circumstances, however, alter cases and there is no hard and fast rule.

46. Although this matter has not been argued, it would seem to me that the threshold is met in the present case. This is the first case under the Act. It is a case that deals with excessive prices, and makes a direction in that regard – matters which raise new and important issues, particularly in the context of the pharmaceutical industry. Although the judicial path as regards what is known as predatory pricing is perhaps better trodden, we are also dealing there with specific issues arising in the particular circumstances of this case, as well as the appropriateness of the direction in issue. So I would have no doubt that the threshold for the grant of interim relief as regards the merits is met in the present case.

47. I would, however, observe in passing – again, not as any kind of criticism – that Napp in its application has not developed to any extent the detailed grounds of its substantive appeal, nor dealt with those passages in the Decision where the Director deals with Napp's particular arguments. Had it been necessary to do so, I would have invited Napp to spell out its substantive arguments in more detail, as I am sure it will in the main appeal.

Balancing of interests and timing of the appeal

48. That takes me to the question of the balancing of interests and related matters. Even where urgency is established and a minimalist threshold test is passed as regards the merits, balancing all the other relevant factors under Rule 32(4) may be a complex exercise. Even if an applicant for interim relief can plainly demonstrate serious and irreparable damage, it is not to be assumed that the relief will necessarily be granted if the damage to competition or third party interests would be significant. All will be depend on the circumstances.

49. A crucial element in the circumstances is the timing of the hearing of the appeal. As the tribunal has indicated in its *Guide to Appeals under the Competition Act, 1998*, the present intention is to complete straightforward cases within 6 months. In the present case, having discussed it briefly with the parties, I can see no obvious reason why the appeal should not be disposed of within that timescale, perhaps well within that timescale, so that the relief granted on this interim application is likely to be of short duration. In that regard, it goes without saying that in an interim case such as the present, the co-operation of the parties in assuring that the appeal is dealt with expeditiously is a matter to which the Tribunal attaches a particular importance.

50. As far as other factors are concerned a prominent, if not the most important, factor in the present case, has been Napp's undertaking, properly and responsibly made, to indemnify the Department of Health in respect of losses suffered in the interim if Napp's appeal is unsuccessful. That offer, coupled with the steps taken to secure early termination of the hospital contracts in the event of an unsuccessful appeal, has led the Director to state to the Tribunal that the undertakings offered by Napp substantially remove the competition concerns of the Director, pending determination by the appeal.

51. Since the Director accepts that the undertakings represent an acceptable balance of the various interests involved, in all those circumstances I can see no objection to making the consent order along the lines proposed.

The Mechanics of the Order

52. As far as the mechanics of any order are concerned it appears to be the combined effect of paragraphs 3(2), 3(3) and 10 of Schedule 8 of the Act, as applied by Rule 32(11), that the Tribunal can itself vary the Directions, and that any such variation would then be enforceable

by the Director before the Court. The Director contends that he could, if so advised, deal with the present situation by unilaterally amending his directions under Section 33 of the Act. That latter point does not however fall to be decided now because the Director is, in any event, content for the Tribunal to make an order.

53. Appeals to the Tribunal, including requests for interim relief, that require the making of an order raise the question of how such an order should be enforced if the unexpected should happen. There is no suggestion in the present case that Napp would, or could, renege on its undertaking; quite the contrary, that particular eventuality is so unlikely as to be disregarded. Nonetheless, it appears to the Tribunal, as a matter of principle, that any order that it makes should be in a form that is readily enforceable. No tribunal should make an order that is only doubtfully enforceable should unforeseen circumstances arise.

54. There has been some discussion as to the form the order should take in that regard, and as to how the concern of the Tribunal should be met. The Tribunal has proposed to the parties that the relevant terms of the order should be to the effect that:

    (1) The Directions shall be varied so as not to take effect pending the determination by the Tribunal of Napp's appeal against the Decision and the Directions; and

    (2) Napp's undertakings [referred to in paragraphs 1 to 5 of the order] should take effect as if the Tribunal had given directions to that effect and should be enforceable accordingly.

55. The Director has expressed his preference for an order in that form and invites the Tribunal to make such an order. Napp, for its part, while being fully co-operative with the object that the Tribunal wishes to achieve, has offered as an alternative to enter into a deed of settlement with the Department of Health so that the undertaking given to the Department of Health could be enforceable by the Department without more in the event of any breach of the undertaking.

56. That is an offer which I welcome – although I would not impose it as a condition of granting interim relief – but it would not in my judgment entirely meet the question of what would happen if certain other parts of the undertakings in question should not be observed, particularly in relation to the existing contracts.

57. As a matter of principle, the Tribunal feels that it should be clear that any orders made at the interim stage should be enforceable and the obvious mechanism for such enforcement is to provide the Director with the means of enforcing the directions before the court under Section 34 of the Act if the unexpected should arise. In my judgment, that object can be achieved if the Tribunal itself varies the Directions using the powers to which I have already referred [under paragraphs 3(2)(d) and (e) of Schedule 8 of the Act, applicable in cases of interim relief by virtue of paragraph 13 of that Schedule] in such a way that, in the case of a breach of the undertakings given, it is open to the Director himself to enforce the directions made pursuant to the Tribunal's order: see paragraph 3(3) of Schedule 8 to the Act.

58. I would therefore propose to make the order in the terms that I have just outlined.

Is the consent of the Tribunal necessary?

59. That leaves two last points. One is the question of whether, the Tribunal having been seized of an application for interim relief, the Tribunal's consent is required before the application can be withdrawn or settled, pursuant to Rule 10(1) or Rule 28. The Director contends that those rules apply to the main proceedings and do not apply to interim proceedings, and he draws attention in particular to the fact that rule 28 sets out a procedure which is not obviously applicable to interim proceedings.

60. Without deciding the point, I am inclined to the view at present that, once the Tribunal is seized of an application, including an application for interim relief, the Tribunal's permission is required before that application can be withdrawn or settled. If rule 28 were to be applicable, one of the requirements would be that a consent order could not be made without the Tribunal having been furnished with what is referred to as a consent order impact statement under rule 28(2)(b). Such a statement must provide an explanation for the draft consent order, including an explanation for the circumstances giving rise to the draft order, the relief to be obtained if the order is made, and the anticipated effects on competition on that relief: see Rule 28(3).

61. I take the view that, if such a consent order impact statement is necessary for the purposes of disposing of interim applications such as the present, the statements made by the parties, in this case in writing and orally, explaining the circumstances of the consent order and its anticipated consequences for competition, suffice in an interim context to comply with the requirements as to consent order impact statements under Rule 28(2)(b) and (3). There is in my judgment no need to take any of the further steps contemplated by the subsequent paragraphs of Rule 28 in this particular case.

The Human Rights Act 1998

62. The only other comment I would make, because it is a matter that only arises in the interim relief context and therefore does not affect the merits of the case, concerns Napp's argument (which has not been pursued or argued since this application has been disposed of by consent) that the Director would have no power to make any order at all taking effect before Napp's rights and obligations had been determined by an independent and impartial tribunal within the meaning of Article 6.1 of the European Convention on Human Rights and Fundamental Freedoms ("ECHR") pursuant to the Human Rights Act 1998.

63. I think I can briefly indicate my provisional view that the power to regulate, in the general interest, the economic activities of natural and legal persons is well recognised. In the present case, as has been seen, Napp has been able to come before this Tribunal in an expeditious way, and this Tribunal has been able to fully supervise the Directions to be made in the interim period before the hearing of the main appeal. The Tribunal will in due course judicially determine whether the Directions are lawful and appropriate. In those circumstances, I would not myself have been minded to accept the argument under the ECHR put forward by Napp.

Conclusion

64. There will therefore be an order by consent in the terms that I have indicated. The Directions will be varied so as not to take effect pending the determination by this Tribunal of Napp's appeal against the Decision and the Directions. Napp's undertakings, referred to in paragraphs 1 to 5 of the order, which essentially reproduce the terms of the indemnity to the Department of Health, Napp's undertakings regarding the termination of existing contracts, and one point in relation to tendering for new contracts, shall take effect as if the Tribunal had given directions to that effect and shall be enforceable accordingly.

65. Each party shall by consent bear its own costs of and incidental to the interim measures application and this hearing. There will be liberty to apply.

66. I would like to thank both the parties for their exceptionally professional co-operation with the Registry in enabling this appeal to be dealt with expeditiously and in accordance with the timetable laid down. The amended transcript of this judgment will be published in due course on the web site and elsewhere.