JUDGMENT : Mr Justice Cooke : Commercial Court. 21st June 2007

Introduction

1. This is an appeal from a Reasoned Opinion of the Pharmaceutical Price Regulation Scheme (PPRS) Arbitration Panel (the Panel), dated 2 August 2006 (the Award) on a question of law, namely "*whether under the terms of the 1999 PPRS, Glaxosmithkline (GSK) was prohibited from including volumes of sales of products sold to fulfil generic prescriptions in the calculation of list price reduction that it had delivered*".

2. Permission to appeal was given under section 69(2)(b) of the Arbitration Act 1996 on 12 December 2006 because of the importance of the issues.

3. At a late stage, an issue of jurisdiction was taken by the defendant (the Department) which it is necessary to determine. Before doing so I shall however set out the nature and effect of the PPRS 1999, which I take from paragraphs 3-23 of GSK's skeleton argument. Whilst this doubtless has a GSK *"slant"* with its stress on *"prices"*, it represents a reasonably fair summary of the PPRS and I did not understand the Department to take serious issue with it.

"THE PPRS 1999

3. The PPRS 1999 was an agreement negotiated between the Department (pursuant to powers conferred upon it by s33 of the Health Act 1999) and the ABPI. Membership of the PPRS 1999 was not compulsory. However, in practice, most or all manufacturers and suppliers of branded licensed NHS medicines consented to its application and thereby became "scheme members". These included Glaxo Wellcome UK Limited, SmithKline Beecham plc and Stafford-Miller, the predecessor companies of GSK.

4. The Scheme governed sales of branded medicines to the NHS worth approximately £7 billion p.a. for each of the five years that it operated (1 October 1999 to 31 December 2004). It has now been replaced by the PPRS 2005, which is a similar type of agreement. The relevant background to the PPRS 1999 appears from the judgment of the Administrative Court in ***R v S/S Health ex p BAEPD*** *[2001] EWHC Admin 183.*

5. Although the Department is a "monopoly payer" where NHS purchases are concerned, it is not a monopoly buyer: the decision to initiate the purchase of individual medicinal products is made by individual medical practitioners (and, in the "secondary" sector, individual hospital trusts or the NHS Purchasing and Supply Authority). The operation of the relationship between buyer and seller is thus very different to that in an ordinary market.

6. The products covered by the PPRS 1999 were specified in its Chapter 7.1 as "all branded, licensed NHS medicines". Generic (i.e. unbranded copies of out-of-patent products) were excluded from the Scheme, as were branded medicines sold to the public without a prescription (e.g. over the counter), or sold predominantly on private prescription: Chapters 7.3 and 7.4. However "branded generics" - defined as "products" which are copies of an out-of-patent product but bear a brand name" were expressly included within the Scheme (chapter 7.5.1), as were branded products supplied through tendering processes and on central or local contracts (chapter 7.5.6).

7. The objectives of the PPRS 1999 were summarised in its Chapter 1. They were to secure the provision of safe and effective medicines for the NHS at reasonable prices, to promote a strong and profitable pharmaceutical industry and to encourage the efficient and competitive development and supply of medicines.

8. The instruments chosen for achieving those objectives were "rules to determine the maximum prices which may be charged by any scheme member in respect of health service medicines, and the maximum profits to be made from the sale of medicines covered by the scheme". Chapter 5.2) This is consistent with s33 of the Health Act 1999, which provides for voluntary schemes to be entered into for the purposes only of:

"(a) limiting the prices which may be charged by any manufacturer or supplier to whom the scheme relates for the supply of any health service medicines, or

(b) limiting the profits which may accrue to any manufacturer or supplier …"

9. Profit control (chapters 10-17) took the form of an allowable return on capital from home sales of NHS medicines (chapter 11), subject to a margin of tolerance (chapter 12) and controls on allowable costs (chapters 14-16) and transfer pricing (chapter 17).

10. Price control…..took the form of a requirement on all companies with NHS home sales above £1 million p.a. to reduce by 4.5%, from 1 October 1999, the NHS list price of medicines covered by the Scheme (Chapter 18 and Annex C). Prices were then to remain unchanged at the level of the cut until 1 January 2001, after which Scheme members could apply for price increases under the rules in Chapter 19.

11. ……..Chapter 18 and Annex C required the 4.5% reduction to be achieved by reference only to list prices. The Department was well aware that manufacturers and suppliers conventionally give discounts on their sales to pharmacists; and that when selling to the hospital sector, they will often respond to invitations to tender for the supply of particular medicines at levels below list price. Chapter 18 (and Annex C) however took no account of discounts, or the level at which tenders were made. In calculating its 4.5% reduction, GSK claimed (and was given) credit only for reductions in the list price.

MODULATION

12. The price reduction (Chapter 18) and price restraint (Chapter 19) provisions were moderated by the rules on modulation (Chapter 21). These rules allowed Scheme members to "modulate" individual list prices (i.e. to reduce them by an amount other than 4.5%, to leave them unchanged or, from 2001 only, to make limited increases) so long as list price reductions equating to an overall level of 4.5% were achieved.

13. *Modulation mitigated the pain that would have been caused to the companies by a 4.5% across-the-board list price reduction, by allowing each company a degree of commercial flexibility. Thus, a company might choose to reduce the list price of a product by more than 4.5% in order to compete more effectively with:*

    (a) parallel imports (i.e. its own medicines, imported from markets where they were on sale for a lower price);

    (b) competing branded products (within the same therapeutic class); or

    (c) generic products.

    Having "banked" a list price reduction of more than 4.5% on one product, the company was free to make a lesser reduction or no reduction at all on another product which was not subject to such keen competition (classically, a patented product in respect of which there was no branded or generic alternative).

14. *The Administrative Court found in the BAEPD case that the power to modulate was regarded by the companies as a critical aspect of the PPRS 1999, and that the ABPI would probably not have agreed to a 4.5% list price cut if modulation had not been part of the deal.*

Modulation against parallel imports

15. *One use of modulation is to help manufacturers of branded NHS medicines compete with shipments of their own products, brought in by parallel importers from other, lower-priced markets within the European Economic Area. Pharmaceutical prices are controlled in most European markets, sometimes by direct governmental decree. This opens the way for parallel traders (or arbitrageurs) to purchase the drug in a low-priced market (e.g. Spain) and re-sell it in the UK, often at a very great profit.*

16. *The BAEPD case was brought by parallel importers, who contended in essence that the modulation provisions were contrary to EC law because they were capable of being used only for the purposes of competing against (parallel) imports. Whilst that contention was rejected, it was not in dispute that the modulation provisions were capable of being used for that purpose, and that they were in fact so used.*

17. *By reducing the list price of a drug by more than 4.5%, to a level equal to or only slightly greater than the price of the parallel imports, the manufacturer could achieve the double benefit of:*

    (a) safeguarding market share, at least in part, against parallel imports; and

    (b) "banking" a relatively large list price reduction, thus enabling smaller reductions than 4.5% to be made to the list prices of goods not subject to so much competition.

Modulation against generics

18. *As was found in the BAEPD case, parallel imports were not the only legitimate target for modulation. The Administrative Court dismissed the claim on the basis that in addition to the scope for modulation against parallel imports, "there is, in practice, material scope for the modulation provisions to operate against generic competition" (para 88), that modulation was also possible for other reasons and that the PPRS was accordingly not "targeted at parallel imports" (para 98). The Court of Appeal determined the appeal on other, shorter, grounds but did not dissent from these propositions.*

19. *The scope for modulation provisions to be used against generic competition may be explained as follows. When a branded product goes off-patent, it is liable to face competition from generic manufacturers of copy products. Generic manufacturers have in general not incurred significant research and development costs for their copy products. Their route to regulatory approval (the grant of a marketing authorisation) is also quicker and cheaper than is the case for an innovative manufacturer; and (save in the case of "branded generics", referred to at chapter 7.5.1 of the PPRS 1999) they will not normally go to the expense of building a brand. For all these reasons, the generic product is liable to be priced well below the selling-price that the branded product was able to command whilst on patent.*

20. *When a prescription is written generically by referring to the active chemical compound rather than the brand name (in the example most relevant to this case, ranitidine rather than Zantac), it will be in a pharmacist's interest to fulfil the prescription with the cheapest available product containing the active chemical compound, since the pharmacist will only be reimbursed by the NHS at a price that reflects the generic price (set out in the "drug tariff"). Normally this will be a generic product rather than a branded product such as Zantac.*

21 *If the branded manufacturer is to compete in the market for generic prescriptions, it must reduce the price of its product to a level at which the pharmacist can afford to prescribe it at the drug tariff price. Around the time that a branded product goes off-patent, therefore, branded manufacturers have a commercial interest in either reducing or discounting from their list price, in just the same way as they may have an interest from time to time in reducing their list price (or discounting from their list price) in order to compete with parallel imports.*

22. *The tendency of manufacturers to reduce the price of branded products which were about to go or had gone off-patent, in order to compete for generically-written prescriptions, was common knowledge, well understood by those who negotiated the PPRS 1999. For this reason, the PPRS 1999 imposed …. limits on what would otherwise have been the ability of branded manufacturers to achieve their target of an overall 4.5% reduction in list price by relying upon list price reductions that would have been made anyway because an off-patent product was becoming subject to generic competition.*

23. *In particular:*

    (a) Chapter 21.3 provided:

    > *"Price reductions made on products where the patent or supplementary protection certificate expires after 1 July 1999 and before 1 January 2001 will not be allowed in calculations of modulations or overall adjustments made to achieve the price reduction."*

(b) Chapter 21.7 (dealing with the position after 1 January 2001) provided:

"Scheme members will not be permitted to use price reductions that may be necessary as a result of patent or supplementary protection certificate expiry to justify a price increase on other products. Consequently scheme members will not be allowed to include in their modulation proposals price reductions made on products where the patent or supplementary protection certificate has expired within one year before, or will expire within two years after, the proposed date for modulation. Where a competitor product enters the market within two years of patent or supplementary protection certificate expiry, the exclusion period for modulation purposes will be extended to a maximum of 2 years from the market entry of the competitor product."

……Chapter 21.3 prohibited any reliance for modulation purposes on reductions in the list price of products going off-patent during the first part of the Scheme. Chapter 21.7 prohibited reliance on list price reductions for a period that began 12 months prior to the product going off-patent, and ended between 2 and 4 years thereafter."

Jurisdiction

4. On the Friday before the Tuesday when this hearing began, the Department first raised an argument as to the jurisdiction of this court to hear an appeal under section 69 of the Arbitration Act 1996. It was accepted that the provisions of section 70 of the Act and CPR 11 had not been complied with but, as this was a matter which went to the court's basic jurisdiction, it was submitted that it was a matter of which the court must take cognisance.

5. The essence of these submissions was that the PPRS constitutes a purely non-binding and voluntary agreement and not a contract. It was said that there was no intention on the part of the parties to create legal relations in relation to its terms and that, although Arbitration Agreements are commonly independent of the wider Agreement in which they are found, the Arbitration Agreement within the PPRS was no more binding than the larger whole of which it formed part. Thus there was no obligation on the part of either GSK or the Department to comply with any Award of the Panel or even with the decision of this court.

6. In consequence it was submitted that there were "no arbitral proceedings" within the meaning of section 69 of the Arbitration Act, no "question of law" which arose out of the Panel's decision since there was no determination of legal rights and no "Award" in the proceedings. A non-binding agreement, with no intention to create legal rights or duties, to refer an issue for non-binding determination was not an arbitration that came within the scope of the Act.

7. The Department's position at the Panel hearing was that PPRS 1999 was a voluntary non-contractual species of agreement. In the Award the Panel said this:-

"11.1.1 It seems to the Panel that the essential difference of view on the nature of the scheme is that GSK see it as a strict and precise definition of obligations into which nothing more can be read than appears in the printed text; while DH see the scheme as embodying an agreement that operates with a light touch and requires analysis and a constructive interpretation. The Panel finds more force in the latter view and agrees with it…..

12.1 PPRS is a voluntary agreement, intended to be implemented in practice with a light touch, but needing analysis to deliver its aims. That it is a contract in a technical and legal sense is not central to the determination."

8. It appears to me that the Panel was finding that the scheme did constitute *"a contract in a technical and legal sense"* but that it did not consider this mattered unduly in the context of determining the meaning and effect of the scheme.

9. Whatever conclusion the Panel reached, I am unable to accept the Department's submission. The Department rely on the phrase "*voluntary schemes*" in section 33 of the Health Act 1999 and the sections and sub-sections which provide for statutory mechanisms in aid of such schemes. It was submitted that the phrase "*voluntary schemes*" was ambiguous and therefore bought into play the dicta in ***Pepper v Hart*** [1993] AC 593. I was referred to that decision and to the further decision of the House of Lords in ***R v Secretary of State for the Environment Transport and the Regions, ex parte Spath Holme Limited*** [2001] 2 AC 349 and in particular to the passage at page 391. There Lord Bingham, referring to Lord Browne-Wilkinson's earlier speech, stated that reference to Hansard was permissible only where (a) legislation was ambiguous or obscure, or led to an absurdity; (b) the material relied on consisted of one or more statements by a Minister or other promoter of the Bill together, if necessary, with other parliamentary material as might be necessary to understand such statements and their effect; and (c) the effect of such statements was clear. Lord Bingham said that each of those conditions was critical to the majority decision in ***Pepper v Hart.***

10. The Department's submission that references to Hansard are admissible here for the purpose of construing the statute falls at the first hurdle. In my judgment there is no ambiguity or obscurity about the Health Act and the provisions which refer to *"voluntary schemes"* and "*statutory schemes",* in contradistinction to one another. Nor does the reading of the legislation lead to any absurdity. It is clear that the 1999 Health Act distinguishes between "voluntary schemes" into which a pharmaceutical company may enter and "*statutory schemes*" which are applicable to those who do not chose to enter into such *"voluntary schemes*". Schemes are "*voluntary"* in the sense that there is a choice whether or not to enter into them. There is nothing in the Act which suggests that a voluntary scheme is a non-binding scheme once entered into, although a pharmaceutical company or the Minister can in certain circumstances bring it to an end as between themselves.

11. Section 33(1) of the Act confers powers on the Secretary of State to limit the prices and limit the profits of any manufacturer or supplier of health service medicines where there is in existence a voluntary scheme. Section 33(2)

provides that a voluntary scheme is to be treated as applying to a manufacturer or supplier, if there is consent by that manufacturer or supplier to the scheme which has not been withdrawn and no notice has been given by the Secretary of State, under section 33(4), to determine that the scheme is not to apply to that manufacturer or supplier where the acts or omissions of that entity have shown that in their case the scheme is ineffective for either limiting prices or limiting profits.

12. Section 33(3) of the Act provides that "*for the purposes of this section a voluntary scheme has effect in relation to a manufacturer or supplier to whom it applies with any additions or modifications made by him and the Secretary of State*". Sub-sections (7) and (8) give the Secretary of State power to require information to be given, to prohibit price increases and to provide for payment of any amount representing an increase made in contravention of the prohibition.

13. It is clear therefore that there are mandatory provisions which operate within the framework of the voluntary scheme. The wording of section 33 which talks of the scheme having "effect" is in itself wording which denotes obligations of a binding nature. The other powers given to the Secretary of State, to which I have referred, plainly create corresponding obligations on the part of the pharmaceutical company when those powers are exercised.

14. This is borne out by section 37 which provides for regulations to be made which set penalties payable to the Secretary of State for contravention of any regulations made under section 33 (as well as regulations made under any statutory scheme). There is also a right of appeal granted against enforcement decisions, which are then defined as decisions by the Secretary of State or any other person to require a manufacturer or supplier to provide information, to limit any price or profit, to refuse to give approval to a price increase or to require a specific manufacturer or supplier to pay any amount, including an amount by way of penalty. Whilst section 37(8) provides that a requirement or prohibition or a limit under section 33 may only be enforced under this section and may not be relied on in any proceedings other than proceedings under this section, the binding nature of the obligations is, in my judgment plain.

15. There is therefore no ambiguity in the use of the words "*voluntary schemes*" in the statute and no basis for any reference to Hansard for the purpose of statutory construction. I come to this conclusion on the wording of the statute alone but it is in any event reinforced by the wording of the PPRS itself.

16. Whilst the Department sought to rely upon Hansard also in the context of factual matrix or background or the expression of both parties' intent, for the purpose of either construing the scheme or showing that there was no intent to create legal relations, I was unable to place reliance on Hansard for those purposes either. There was no evidence adduced by the Department other than the provision of passages in Hansard for particular dates in March 1999 and May 1999 in the House of Commons and the House of Lords. From the terms of those passages it is clear that the PPRS was in the course of negotiation at that time and that what was being expressed was the Department's subjective view or the view of lawyers at the Department, the Government Speaker making it clear that he/she was not a lawyer (as is plain from the suggestion by Mr Denham that *"arbitration cannot be binding"*). The terms of the PPRS constituted a carefully negotiated agreement between the Department and ABPI and the intention of the latter was plainly different from the intention of the former in a number of respects. Hansard therefore says nothing about the mutual intention of the parties nor can it be said to constitute useful factual matrix to the scheme, whether seen as a binding contract or a non-binding agreement.

17. When reference is then made to the terms of the PPRS, there is nothing in the wording used which suggests that the scheme constitutes a non-binding agreement. Chapter 1.1 provides that the PPRS is *"an agreement for the purposes of section 33 of the Health Act 1999"*. The Department was unable to point to any wording in the scheme which suggested that this was to be a non-binding agreement and it is hard to see why the parties would want to enter into an agreement which did not bind them to fulfil its terms.

18. Chapter 3 of PPRS 1999 provides for the effective date of the scheme and for its duration whilst Chapter 4 makes provision for mid term review, for variation of the terms of the scheme with the agreement of the ABPI and the Secretary of State. Chapter 4.2 goes on to prescribe what is to happen *"if the terms of this agreement are altered with the agreement of the ABPI and the Secretary of State"* whereupon companies would be invited to accept "the new terms", with the option of leaving the agreement as set out in Chapter 24.

19. According to Chapter 5.2, the scheme *"sets out rules to determine the maximum prices which may be charged by any scheme member in respect of health service medicines and the maximum profits to be made from the sale of medicines covered by the scheme"* whilst Chapter 6.6 refers to the *"obligations"* of companies and specifically to the obligation set out in Chapter 21. Self-evidently Chapter 8 and Chapter 18 set out the requirement for members to give information and to reduce prices whilst Chapter 12.4 provides for payments to be made to make effective price reductions where necessary.

20. In these circumstances I hold that the PPRS does constitute a commercial contract, a term used by the Department when presenting its case in the Administrative Court in ***R v The Secretary of State for Health ex parte BAEPD and Others*** [2001] EWHC (Admin) 183, a decision of Thomas J (as he then was). That terminology was also used in the judgment.

21. When reference is made to Chapter 23, which contains the arbitration provisions, it will be seen that the Department, the Association of the British Pharmaceutical Industry (ABPI) and the individual scheme members give undertakings to seek to resolve by discussion any issues which arise. In the absence of resolution by this means, the

issues may be referred to the arbitration procedure which is then set out and which provides, in mandatory terms, for some procedural matters to be observed. Although chapter 23.4 provides that the decision will not be relied upon in the future operation of the scheme, there is no suggestion that it does not bind the parties to the arbitration.

22. The Department relied upon occasional note 3, the date and provenance of which was not clear. The last sentence sets out that "the text of this occasional note has been agreed between the signatories of the 1999 PPRS, that is the Department and the ABPI". It was common ground that the occasional note, which is described as *"a broad outline of the functions of the 1999 PPRS Arbitration Panel"* and which *"describes its work in practice*", was concluded after the PPRS was agreed and after GSK had opted into the scheme by giving its consent under section 33(2). There was no evidence of any agency on the part of ABPI to agree the occasional note, nor was there any indication that the note formed part of the agreement, as opposed to describing the work of the Panel.

23. Nonetheless the Department relied upon clause 10 headed *"After Arbitration"* which read as follows:-

"10.1 The Department and scheme members are expected to abide by the Panel's decisions which are to be provided to both parties in writing as soon as possible after arbitration.

10.2 The voluntary nature of the 1999 PPRS means that a company has, in practice three options:

10.2.1 follow the Panel's decision;

10.2.2 withdraw from membership of the 1999 PPRS; or

10.2.3 ignore the Panel's decision. In such circumstances the Secretary of State will conclude that the scheme is no longer effective in the particular member's case and he will therefore remove the member from scheme membership.

10.3 In cases 10.2.2 and 10.2.3 the company will no longer be a scheme member of the 1999 PPRS and shall thenceforth be subject to any statutory controls in place pursuant to sections 34 to 38 of the Act."

24. Elsewhere in the note at paragraph 2.7 and paragraph 6.1, reference is made to the parties' right to arbitration by the Panel. A series of events is listed which might give rise to a scheme member seeking arbitration by the Panel, which was said not necessarily to be comprehensive. *"In each case it will be for the scheme member to comply with the Department's view or to seek arbitration"*. In the context of a notice given by the Secretary of State that a company's membership of the scheme was to cease, the arbitration was to deal with *"scheme membership, but the substantive matter will be the event giving rise to the decision that the company is no longer a scheme member"*.

25. It is in the context of scheme membership that clause 10 of occasional note 3 has to be read. Whilst the Department submitted that the reference in 10.2.3 to the scheme member ignoring the Panel's decision showed that the arbitration was not binding and that the reason given for this possibility was *"the voluntary nature of the 1999 PPRS"* that does not seem to me to reflect the nature of the arbitration agreement. What is being described in paragraph 10 is the range of options open to the member with regard to scheme membership following an Arbitration Award against it. It does not state that the Arbitration Award is not binding or enforceable. It sets out what the impact might be upon the member's participation in the scheme. If the member is unsuccessful in arbitration, it can follow the Panel's decision for the future and remain in the scheme, it can withdraw from membership of the scheme or it can chose to ignore the Panel's decision in which case the Secretary of State will bring the member's participation in the scheme to an end. What is being spelt out in 10.2.3 is the effect of ignoring the Panel's decision in the context of membership and not in the context of enforcement of any other kind. Indeed it is plain that, if regulations provide for penalties, penalties could be payable.

26. I am satisfied that occasional note 3 does not bear the weight which the Department wishes to place upon it and that the whole tenor of the PPRS and the arbitration provisions militate against any such argument.

27. When regard is then had to the terms of the Arbitration Act, attention is directed to sections 58 and 66. These show that, absent contrary agreement, an Award is binding and may, with the leave of the court, be enforced. I find no agreement between the parties that the Award should not be final and binding.

28. In these circumstances the procedural rules apply because this is an arbitration falling within the meaning of section 67 and the time limits of section 70. So also CPR 11 is applicable. If there had been no arbitration agreement for the reasons submitted by the Department, no arbitration and no Award, then this court would have had no jurisdiction and the court would probably be bound to take cognisance of that, once the matter had been drawn to its attention. That does not however now arise and the lateness of the point taken by the Department is a clear indication that the arbitration has been seen as binding until very shortly before this hearing. I therefore proceed to deal with the appeal brought by GSK.

The Appeal

Brand Equalisation Deals

29. The Department asked the Panel to find that GSK was bound:

i) to exclude volumes of products sold under *"brand equalisation deals"* or *"branded medicines reimbursed as generic medicines"* from the relevant calculations for modulation; and

ii) to reduce NHS expenditure on the medicines concerned by 4.5% from what it would otherwise have been".

It will be seen that this differs from the question of law which this court has to decide, with the focus of the Panel directed to *"brand equalisation deals"*.

30. As mentioned earlier, it is in the interest of the manufacturers of branded off-patent goods to continue to sell the branded product at a premium in circumstances where a prescription is written for the branded product, whilst also being able to compete with generic products where a prescription is written generically. In order to do this many manufacturers or suppliers negotiated *"brand equalisation deals"* with pharmacists. In the case of GSK a copy of the standard form was provided during the course of the hearing. Under this standard form the pharmacist purchased a volume of the branded product at a unified price. This price was intended to reflect both the forecast quantities of the branded product it would in the future dispense under branded prescriptions and the quantity it would dispense under generic prescriptions, for which it would be paid differently by the NHS. GSK had national data from which it could make such forecasts and the pharmacists would be in a position to use their own figures to negotiate the volume and price. The overall price to the pharmacist which would be at a discount to the List price was therefore predicated upon the estimates of the pharmacist's requirement for branded and unbranded products. The branded product of GSK would then be used, as the pharmacist saw fit, to fulfil generic prescriptions as well as branded prescriptions where the use of product was mandatory. There was no prohibition in the brand equalisation deal agreement on the use of the product for resale, whether under branded prescription or generic prescriptions. Nor was there any obligation of the pharmacist to report on the respective quantities of the product purchased that were used to fulfil branded prescriptions and generic prescriptions respectively.

31. It is the volumes of sales of Zantac under such deals, which was then used by the pharmacists to fulfil generic prescriptions, which is in issue in this appeal. The Department maintains that such volumes should not have been included in the calculation of the list price reduction that GSK had delivered for the purposes of modulation calculations. From the skeleton arguments and during the course of the hearing, it appeared that the Department had understood that the brand equalisation deals into which GSK had entered involved GSK selling a proportion of the product required by the pharmacist at the generic market price, so that the pharmacist could dispense the branded product in satisfaction of generic prescriptions without any commercial disadvantage. It was also the Department's understanding that the pharmacist was not permitted under the terms of the deal to use that proportion to satisfy branded prescriptions (since the pharmacist would otherwise be able to undercut the supplier of the more expensive branded product to him). It was thought that GSK must, through the brand equalisation deals, control or monitor the sales of the respective proportions of product by the pharmacist under branded prescriptions and generic prescriptions. This was a misconception and it was of the essence of GSK's case that it always sold branded products as branded products to the pharmacist at reduced prices, albeit that the calculation of that price was negotiated on the basis that some product would be used to fulfil branded prescriptions and some to fulfil generic prescriptions. This would enable the pharmacist to recover from the NHS at different prices but the utilisation of the branded product was a matter for the pharmacist's decision. No specific product sold to the pharmacist was therefore treated as "*generic*" product.

32. So far as the Department was concerned however, the pharmacists were reimbursed for NHS medicines on the basis of that which had been dispensed under branded prescriptions on the one hand and that which had been dispensed under generic prescriptions on the other. The pharmacist therefore, depending upon the terms of purchase from GSK and his use of the product for dispensing under the different types of prescription, would make variable profits on the unified price paid to GSK, as compared with the branded price and generic price paid by the NHS for the different types of prescription and the volumes dispensed thereunder.

33. The Department said that the NHS derived no cost benefit from the quantities of branded products dispensed and sold by the pharmacist pursuant to generic prescriptions, because those sales would in any event have given rise to payment by the NHS at the generic price at which they were in fact reimbursed, because the generic price was the same regardless of the identity of the product and manufacturer or supplier. It mattered not to the NHS whether Zantac or ranitidine was provided on a generic prescription if the price was the same. GSK however was using the quantities supplied to the pharmacist at reduced list price (ignoring discount from that reduced list price) in the modulation calculations, which allowed higher prices to be charged elsewhere, whilst the overall list price reduction met the 4.5% requirement of the PPRS. The Department therefore does not accept that the PPRS allows pharmaceutical companies to include sales of product used to fulfil generic prescriptions pursuant to brand equalisation deals to count as against price reduction. Only that proportion of the brand equalisation deals product which was sold by the pharmacist as branded products could so count.

34. It was not until 2004 that the Department first raised the subject with GSK. It appears that this was the result of investigations carried out by McKinsey, which was engaged by the Department as a consultant. McKinsey informed the Department that in real terms the 4.5% reductions in list price by GSK gave rise to a net result in savings to the NHS of around half of that figure. Before this, although the Department was aware of brand equalisation deals, it says it was not aware that GSK and a number of other pharmaceutical companies included all their brand equalisation deal figures in their modulation calculations. GSK points out that, at all times, it provided the information required by the Department under Annex D to the PPRS and that it obtained approval for every price modulation in accordance with the terms of the scheme. Nothing at any time was hidden from the Department and Annex D did not require the provision of information relating to sales of branded product which was subsequently used by a pharmacist for the purpose of dispensing under generic prescriptions.

The Department's Case

35. The Department maintained that the PPRS 1999 did not create or identify legal rights and liabilities but that even if it did, as I have found to be the case, the correct approach to construction of it was that set out by Lord

Hoffmann in ***Investors Compensation Scheme Limited v West Bromwich BS*** [1998] 1 WLR 896 and particularly the passage at page 912. The court should seek to ascertain the intention of the parties, approached objectively, but should do so by reference to what the parties intended in the factual circumstances which obtained at the time, if necessary departing from or qualifying the particular words used in order to put into effect the parties' true intention. The Department said that the Arbitration Panel adopted the correct approach. The Panel found that the PPRS did not expressly address the issue referred to arbitration and found that there was no reference in the PPRS expressly dealing with "*branded products sold to fill generic prescriptions*". The Panel concluded that all branded medicines sold as brands were eligible to be included within the calculation of modulation but that the intention of the scheme and the agreement reached with the ABPI was that the 4.5% price reduction equated to a 4.5% reduction in NHS expenditure, relative to what otherwise would have been the case. The modulation provisions were agreed with the intention of producing the same overall result as that produced by the straight-forward, across the board, 4.5% price reduction. The objective was the same, so GSK should not include sales of product dispensed under generic prescriptions in its returns to the Department for the purpose of calculating the achievement of its price reduction target. This conclusion was reached as a matter of construction of the scheme and without the need to imply any terms. The Panel saw itself as interpreting the scheme "constructively", by analysis of the overall tenor of the agreement.

36. The Department's interpretation of the Panel's Award was that it did, alternatively, hold that a term did have to be implied into the agreement because the Panel expressed the view that the structure of chapters 18 and 21 of the PPRS was directed to securing price reductions that would (subject to any marginal distortion such as the effect of pharmacists' remuneration arrangements) mean a price reduction of 4.5% for the purchaser's cost as well as a price reduction of 4.5% for the pharmaceutical companies. Whether or not the Panel did so find, the Department contends on this appeal, in the alternative, that there should be an implied term to the same effect as the construction it advances. The alleged implied term of the scheme is that "*sales of products dispensed against generic prescriptions should be excluded from modulation calculations*" and the underlying basis of that is that the obligation to deliver a 4.5% reduction in prices is effectively an obligation to make approximately the same savings to the NHS.

Analysis and Construction of the PPRS

37. Section 33 of the Health Act 1999, as already mentioned, confers power on the Secretary of State for the purpose of "limiting the prices which may be charged by" or "limiting the profits which may accrue to", any manufacturer or supplier to whom the scheme relates. This, in my judgment, is important since his powers relate specifically to those two methods of controlling savings. The powers are very specific in that respect. The PPRS, which is a voluntary scheme brought in under that section, therefore reflects the proper exercise of these powers and deals specifically with price limitation and profit limitation.

38. Chapter 1 of the PPRS, as both parties recognise, sets out the objectives of the scheme as being to *"secure the provision of safe and effective medicines for the NHS at reasonable prices; to promote a strong and profitable pharmaceutical industry capable of…sustained research and development expenditure…; and to encourage the efficient and competitive development and supply of medicines to pharmaceutical markets…"*

39. Chapter 11 sets out the allowable return on capital whilst Chapter 18 sets out the price reduction required by the scheme by reference to Annex C. As GSK points out, Annex C refers to price reductions for the medicines covered by the PPRS by reference to the NHS list price of all products on the market on the day before the date of commencement of the new scheme. The price reduction of 4.5%, which is required, is subject to the provisions of the modulation rules in Chapter 21. There is no reference to savings for the NHS. Both in Chapter 18.2 and paragraph 7 of Annex C there is however reference to agreed "*cost neutral modulation*" as an exception to the across the board reduction of 4.5% in the price of medicines during the initial period of 15 months from the inception of the scheme on 1 October 1999. Thereafter no scheme member could increase the price of any medicine without the Department's prior approval under Chapter 19.

40. GSK also draws attention to the terms of Chapter 21 which again referred to modulation as an alternative to price reduction. Scheme members were entitled to modulate the list price of their PPRS products by reductions that equated to an overall level of 4.5%. GSK relied on Chapter 21.3 and Chapter 21.7, which are set out earlier in this judgment, as showing specific limits which were set to the use of price reductions in modulation calculations, stressing that those limitations specifically related to the expiry of patent on branded products, which then had to be sold at prices which were competitive with the generic market. The Department relied upon the reference to modulation of prices in Chapter 21.4 which was allowed "*provided that the effect of the modulation is cost neutral*". Chapter 21.8 stated that the Department would *"establish monitoring procedures to ensure that scheme members that modulate prices delivered the 4.5% price reduction and that subsequent modulations were cost neutral"*.

41. Whilst GSK focused on all the references to price reduction and pointed out the absence of any reference to the saving of cost to the NHS, the Department stressed the underlying objective as seen by the NHS of achieving such savings. Costs to the NHS was the opposite side of the coin, it maintained, to reductions in price, with the underlying objective of such savings. Whilst it was recognised that a reduction in price of 4.5% might or might not give rise to equivalent savings of 4.5% because of the effect on the market of a reduction, the consequent actions of other suppliers in relation to volume and prices of competing product, and the consequent prescribing and dispensing decisions of doctors and pharmacists, which could lead to purchase of drugs from other manufacturers or suppliers who raised or lowered their prices by reference to market conditions, it was said that the broad thrust

of the PPRS and the clear objective intention of the parties which underlay it was to achieve savings of that order. If therefore any practice was adopted which had the effect of complying with a 4.5% reduction in price but no comparable saving to the NHS, it could not be permitted as part of the modulation arrangements.

42. Both parties agreed that the key to the dispute lay in Chapter 7, read in the light of Chapters 18 and 21 and the objects of the Scheme. Chapter 7.1 provides that the scheme applies to "*all branded licensed NHS medicines*" which are then defined in Chapter 7.2 as *"any human pharmaceutical product for which marketing authorisation has been awarded and to which the proprietor applies a brand name that enables the product to be identified without reference to the generic title"*. Chapter 7.3 and 7.4 make it clear that the scheme only applies to brand name medicine provided under NHS prescription.

43. Chapter 7.5 states that *"to avoid uncertainty it is emphasised that the following products, provided they satisfy the criteria set out above, are covered by the scheme"*. The first sub-paragraph then includes *"branded generics (i.e. products which are copies of an out of patent product, but bear a brand name and therefore come within the overall definition at paragraph 7.2)"*. Both parties relied upon this particular provision in support of their argument. A branded generic, as defined, is a medicine which is sold under a brand name, although it is a copy of someone else's out of patent product and not an original product of the manufacturer in question which had previously been the subject of a patent owned by that entity. This therefore would be a branded medicine sold at generic prices or prices close to generic prices, since a brand can sometimes attract a premium, even in this situation (as found by the Administrative Court in the BAEPD decision). The Department says this is in truth a generic sold as a brand and not a brand sold as a generic but it is clear that a brand which is being sold at prices akin to generic prices at the outset falls within the compass of the scheme. By contrast, products that are blacklisted from NHS prescription by their brand name and which can only be prescribed on the NHS generically are excluded by the terms of Chapter 7.6.

44. There is nothing in the terms of Chapter 7 (or Chapter 18) which exclude from the scheme branded medicines which are sold by manufacturers to pharmacists as branded medicines but which are then subsequently provided by the pharmacist to customers under generic prescriptions. No distinction is drawn between sales of branded product by the supplier used by pharmacists for branded prescriptions on the one hand and generic prescriptions on the other. (There is equally no distinction between sales for primary care purposes and those for hospital (secondary care) purposes.) Whilst I gained little assistance from the argument about Chapter 7.5, the terms of Chapter 7.1 and 7.2 include in the scheme "*all branded licensed NHS medicines*" subject to the express exceptions thereafter set out. There is no exception in Chapter 7 which assists the Department.

45. Similarly, when regard is had to Chapter 21, there are express exclusions in Chapter 21.3 and 21.7 but none which covers any product the subject of a brand equalisation deal which is anticipated to be, or subsequently becomes, a product supplied by a pharmacist in response to a generic prescription.

46. When regard is had to one of the objectives of the scheme which is the provision of medicines for the NHS at reasonable prices, the structure of the scheme provides, as GSK so aptly puts it, for this objective to be attained by two proxies, the use of profit control (return on capital) and price control. It is not, on the face of any wording in the scheme, to be achieved by reference to particular percentages of savings or indeed any savings on the part of the NHS. Whilst the underlying objective from the Department's standpoint was to save NHS money, both the Health Act and the PPRS provided for its achievement specifically by reference to limiting or reducing profit and prices.

47. The reliance by the Department on the phrase "cost neutral" in the context of modulation does not help its case since the phrase is used in the context of modulating price. The precise terms of Chapter 21 make this clear since Chapter 21.1 provides that *"scheme members may modulate the list price of their PPRS products by reductions that equate to an overall level of 4.5%"*. *"Cost neutral"* modulation means reductions that give rise to that overall result. That conclusion is borne out by a passage in paragraph 20 of the judgment of the Court of Appeal in ***BAEPD*** [2001] EWCA Civ 1896. In describing the principal features of the scheme Aldous LJ referred to remodulation, the effect of which had to be "*cost neutral*", which he then defined as being such as not to threaten the delivery of the 4.5% cut in price. That element of the scheme and that definition was taken by the Lord Justice from an affidavit of Mr Brownlee of the Department, where he explained the phrase "*cost neutral*" in that way.

48. There are a number of fallacies in the Department's argument. It is clear that there has been a reduction of 4.5% overall in GSK's product list prices which is what Chapter 18 and Chapter 21, on their face, require. The list price reduction is the reduction in the price which the pharmacist is reimbursed by the NHS for the branded product. The Department responded to price change and modulation notification and gave its agreement to each and every notice given by GSK. There is no issue between the parties that GSK complied with the terms of the PPRS in this respect. In order to circumvent this apparent compliance with the express terms of the PPRS, the Department said that branded product was no longer branded product when it was treated as generic product, which is what happened in brand equalisation deals when GSK sold products to a pharmacist who later utilised that product for dispensing against generic prescriptions. The Department used confusing language in this respect in stating that this constituted sales of generic product by GSK. Yet GSK's sales were still of branded product and it was the pharmacist's choice whether or not to dispense that branded product under generic prescriptions (for which he would be reimbursed the generic price by the NHS) or under branded prescriptions. It is however the reduction of the list price of branded products to the NHS which is covered by the scheme and whether branded product, when delivered to the pharmacist is then used to fulfil branded or generic prescriptions is nothing to the point.

49. However much the Department stresses the objective of delivery of savings to the NHS, the PPRS was so structured as to achieve this by reference to price and profit control. The issue of "cost neutrality" is a red herring since all that it means is the absence of any distinction between an across the board 4.5% reduction and an aggregate 4.5% reduction in the list price of branded products.

50. Where the Department suggests that the limited exclusions at Chapters 21.3 and 21.7 support the Panel's interpretation of the PPRS as not applying to branded medicines used to satisfy generic prescriptions, the Department fails to address the point that the PPRS specifically did deal with the question of prices at expiry of patent and made no exclusion for brand equalisation deals. That the Department was aware of brand equalisation deals and accepted that modulation could properly be used by a manufacturer reducing prices to compete against generics, appears from the Department's statement opposing permission to appeal at paragraph 7(b). There can be no competition between branded and generic products for branded prescriptions so that competition only arises where branded product is available for and used for generic prescriptions. Moreover, if the Department was right in its construction of the scheme, Chapters 21.3 and 21.7 were strictly speaking unnecessary, since such matters would have been excluded in any event. The argument that the Department raises that difficult factual questions would arise about savings in such circumstances, and that the provisions were therefore included to avoid uncertainty, is unconvincing. The fact is that difficulties arise in calculating any savings on brand equalisation deals or in relation to any reduction of list price. GSK points out that the reduction in the price of a branded product will often stimulate a reduction in the price of generic competitors, to the benefit of NHS purchasers with a consequent further saving to the NHS.

51. If attention is being paid to the concept of savings, it can only mean true savings, in the sense of net savings. It is accepted by all that it is impossible to calculate the net savings achieved by the NHS in the event of a list price reduction, because of the knock on effect of this upon others involved in the market. Thus actual savings delivered to the NHS depend in large part on factors outside the reducing company's control. The factors include the level of demand for the product in question and the mechanism by which pharmacists are reimbursed by the NHS. No one can know what the NHS expenditure on the medicines concerned would have been without a price reduction, even in the case of a manufacturer who makes a single across the board 4.5% price reduction. The multiple purchasers of medicines that make up the NHS are free to purchase identical branded products either from the manufacturers or from parallel importers. Furthermore in the market for off-patent products they are able also to purchase generic equivalents. It is a matter of historical record, in any given period, how much the Department as "monopoly payer" spent on medicines, but how the market would have behaved and how much the Department would have had to pay in the hypothetical absence of a 4.5% list reduction is a matter for speculation. In the hypothetical situation the higher price of the branded product might have attracted additional parallel importers or generic manufacturers to the market. Existing participants in the market, attracted by the higher margin, might have marketed more aggressively. Individual purchasers might have switched to generic suppliers or to parallel imports. Whilst all this is capable of being modelled by computer or in some other way, it is a complex and ultimately uncertain process. When modulation is introduced into the equation, it becomes necessary to measure actual NHS expenditure on the manufacturer's products against the hypothetical situation in which some of the manufacturer's list prices would have been higher (by varying amounts) but others would have been the same or lower than their actual equivalents. What other entities in the market would or would not have done and how this would have impacted upon doctors and pharmacists in their prescribing and dispensing decisions is extremely difficult to assess. For the reasons set out in paragraphs 49-55 of GSK's Reasoned Statement of Position before the Arbitration Panel, the assessment of true net savings is extremely difficult if not virtually impossible.

52. A 4.5% price reduction does not therefore automatically lead to anything like an equivalent 4.5% saving on the part of the NHS. Indeed GSK argues that, once all the figures are taken into account, including sales to hospitals, there is an actual 4.5% saving to the NHS over the period of the scheme in relation to GSK's products, even if the products sold under generic brand equalisation deals are excluded. Whilst this is outside the scope of the question of law before the court, the point serves to illustrate the difficulty in the Department's argument that a 4.5% price reduction really means "a like overall cost reduction for the NHS".

Implied Term

53. The Department's alternative case is that a term can be implied into the PPRS 1999 to the effect that only price reductions applicable to branded medicines dispensed as brands were eligible for modulation under Chapter 21. It is said that such an implication is necessary to give effect to the obvious but unexpressed intention of the parties.

54. There is however no evidence of any such unexpressed intention in circumstances where the PPRS 1999 was a complex scheme negotiated over a considerable period of time between the ABPI and the Department. The prohibition suggested is inconsistent with the express wording of the contract to which I have already referred and the Administrative Court in the BAEPD decision found that ABPI would probably not have agreed the scheme without the modulation provisions.

55. It is of some significance that the Department told the Panel, through one of the co-principal negotiators of the 1999 PPRS, when asked why it was that Annex D to the PPRS provided no obligation to supply the Department with information that would have been necessary to identify the sales which the Department now says fell to be excluded, that *"it would have been better to have really nailed this down about what was included and what was not included"*. He went on:- *"We would have had to have reached agreement about what was included and in fact the method of calculating the 4.5% price cut was worked out in a series of conversations….we had conversations about:*

what shall we do about parallel imports, parallel exports, how are we going to deal with hospital sector, that sort of thing. I do not remember talking to David about brand equalisations specifically but the idea was to come up with something that was comparatively straight-forward".

56. It does appear that the Department, although aware of brand equalisation deals, did not raise the subject in negotiations prior to the PPRS coming into existence. The speaker accepted that they would have had to have reached agreement about what was and was not included in the context of such deals, thereby recognising that the obvious unexpressed intention for which the Department contend was not obvious at all.

57. Throughout the currency of the PPRS 1999 there was no suggestion by the Department of such an obvious but unexpressed intention. The Department repeatedly approved the use for modulation purposes of products proposed by GSK including those subject to brand equalisation deals, without any investigation of the likely consequences in terms of savings to the NHS drugs budget. Over that period it seems that the Department gave regular assurances to GSK that it was complying with its price reduction obligations, without mention of the need or desirability of ensuring any given saving. Its position was and is that modulation can properly be used by a manufacturer reducing prices to compete against generics.

58. In my judgment, the reality is that the Department knew of brand equalisation deals but did not appreciate how they worked in practice and what the net effect might be. Thus, there was no prohibition on the use of volumes of branded products ultimately dispensed as generics, in modulation calculations, on the wording of the 1999 scheme, because the net effect was not appreciated. In the 2005 scheme, express provision is now made. This doubtless followed from the raising of the point by McKinsey in 2004 who pointed out that the 4.5% price reductions were not resulting in anything like an equivalent saving in the primary care costs of the NHS, at least on the simplistic basis upon which "costs" and "savings" were assessed (without taking into account hospital purchases and the complex knock on effect of these deals on the market and the impact of those consequences on the NHS net position).

59. If there had been an obvious but unexpressed intention, it is hard to see how the point could have escaped attention until 2004. Whilst the focus must be on the position at the time of entering into the contract, and upon what an officious bystander would have made of the position at the time, what has happened since is evidence which is highly material to an evaluation of any mutual intention at the time.

60. I therefore reject the Department's alternative case of an implied term, holding that there is no basis for saying that the term for which the Department seeks was "something so obvious that it goes without saying: so that, if while the parties were making their bargain, an officious bystander were to suggest some express provision for it in the agreement, they would testily surpress him with a common "oh of course"" (see Shirlaw v Southern Foundaries [1939] 2 QB 206 at page 227 (affirmed at [1940] AC 700)).

BAEPD Decision

61. Whilst the subject of brand equalisation deals was not one with which the Administrative Court or the Court of Appeal had to grapple in the ***BAEPD*** decision, I am fortified in my conclusions by the decision of Thomas J (as he then was) at first instance. At paragraphs 81-88 he dealt with the subject of competition from generic products and at paragraph 82 spoke particularly of the pharmacists' decision as to what product to use, in the context of price competition between a branded product and its generic equivalent. Having referred to Chapters 21.3 and 21.7 of PPRS 1999 in paragraph 84 he then said this at paragraph 85:- *"However the exception provided for in Chapters 21.3 and 21.7 does not mean that price reductions against generics outside the specified period cannot be brought into account in modulation. For example, in the case of a branded product where the patent expired in the early 1990s, any price reduction in respect of that branded product can be brought into account."*

62. He then went on to reject the contention that the preponderance of price reductions that could and would be made were reductions which were excluded by the exceptions in Chapters 21.3 and 21.7. He went on in paragraph 87 to say this:- *"However there was no evidence which supported that assertion. Although it was clear on the evidence that a dramatic price reduction would usually be made at the time the patent protection expired, a branded product could still come under premium over its generic product, as a premium is inherent in the value of the brand. Thus although the price would move sharply downwards at around the time the patent protection was lost and thus within the specified periods in Chapters 21.3 and 21.7, there could remain a relatively large price gap between the branded product and its generic competitor; there was therefore scope for further price cuts under the modulation provisions. There was some evidence from Mr Brownlee that there were price cuts outside the period specified in Chapters 21.3 and 21.7 where a branded product had lost a market share to generics or where the manufacturer gradually reduced prices [list prices for branded products] over a period of 3 years before brand expiry to lessen the impact expected when the patent expired. Similar general evidence was given on behalf of ABPI, through Mr Bailey, President of the ABPI and Corporate Affairs Director of Glaxo Wellcome and Ms Charlesworth of ABPI; each gave two specific examples of branded products where the price had been reduced to meet competition from generics - Beconase and Zantac in the case of Mr Bailey and Voltair and Planquenil in the case of Ms Charlesworth. There was some other specific evidence to this effect. Thus on the evidence some price reductions are in practice made outside the period specified in Chapters 21.3 and 21.7."*

63. He went on to say that on the evidence before the court there was in practice material scope for the modulation provisions to operate against generic competition in the circumstances he had specified. Whilst the court did not exclude the possibility that some competition between branded products and generics could be at the level of GP

decision making, it is plain from paragraph 5 of the judgment that therapeutic need was found to be the major determinant for a doctor when prescribing a drug and that there was limited sensitivity to price. Paragraph 82 makes it plain that it is competition at the pharmacy level which is essentially in mind in what is said in paragraphs 85 and 87. When therefore Thomas J spoke of competition between branded drugs and generic drugs in those paragraphs in the context of competition about what was to be dispensed against generic prescriptions, since there could, ex hypothesi be no competition in respect of a branded prescription.

64. Thus, although brand equalisation deals were not the subject of the debate in that case, the terms of paragraphs 85 and 87 of the judgment show that the court found that "price reductions against generics which did not fall within Chapters 21.3 and 21.7 were eligible for inclusion in the modulation calculations". The branded product used in competition with generics by the pharmacists, in consequence of the brand equalisation deals, falls into this category in the judgment of Thomas J.

Conclusion

65. For all these reasons GSK's appeal succeeds and I answer the question of law posed in the negative. The answer to the question "*whether under the terms of the 1999 PPRS, GSK was prohibited from including volumes of sales from [branded] products sold to fulfil generic prescriptions in the calculation of the list price reduction that it had delivered"* is no.

66. If there are consequential matters to be dealt with in the order or consequential issues to be addressed, they can be argued at the handing down of this judgment. It appears to me that, absent special circumstances of which I am unaware, costs must follow the event.

Mr D Anderson QC and Mr J Dawid (instructed by Simmons & Simmons) for the Claimant
Mr J Herberg (instructed by Treasury Solicitor) for the Defendant