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Case No: CO/1441/2023

IN THE HIGH COURT OF JUSTICE
KING'S BENCH DIVISION
ADMINISTRATIVE COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 10/07/2023

Before :

THE HONOURABLE MR JUSTICE TURNER

- -

Between :

BRITISH GENERIC MANUFACTURERS ASSOCIATION LIMITED	**Claimant**
- and -	
SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE	**Defendant**
- and -	
ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY	**Interested Party**

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- -

Tom Hickman KC and **Tom Lowenthal**
(instructed by **Taylor Wessing LLP**) for the **Claimant**
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(instructed by **Government Legal Department**) for the **Defendant**
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Hearing date: 27 June 2023

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Judgment Approved by the court for handing down (subject to editorial corrections)

The Hon Mr Justice Turner :

INTRODUCTION

1. The commercial relationship between pharmaceutical companies and the NHS with respect to the sale of medicines is one in which it has long been seen to be in the public interest for there to be in place suitable control mechanisms. Such controls may take the form of, for example: restrictions on prices charged; restrictions on profits made; and the payment of rebates to the Secretary of State.
2. In broad terms, the scope and detail of these controls take the form of either statutory or voluntary schemes.
3. The legislative context is to be found under the heading "Price of Medical Supplies" which covers sections 260 to 266 inclusive of the National Health Service Act 2006 ("the Act"). It is to be noted, however, that the statute does not seek to define or circumscribe the power under which the Secretary of State may enter into a voluntary scheme but only makes provision for the enforcement mechanisms which are to apply once such a scheme has been agreed.
4. In contrast, by the operation of section 263 of the Act, the making of a statutory scheme must be preceded by "consultation with the industry body and any other person the Secretary of State thinks appropriate…". Just such a scheme is presently in force under the Branded Health Service Medicines (Costs) Regulations 2018.
5. Section 261 provides:

> "(1) The powers under this section may be exercised where there is in existence a scheme (referred to in this section …as a "voluntary scheme") made by the Secretary of State and the industry body for one or more of the following purposes —
>
> (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,
> (b) limiting the profits which may accrue to any manufacturer or supplier to whom the scheme relates in connection with the manufacture or supply of any health service medicines,
> (c) providing for any manufacturer or supplier to whom the scheme relates to pay to the Secretary of State an amount calculated by reference to sales or estimated sales of any health service medicines (whether on the basis of net prices, average selling prices or otherwise).

(2) For the purposes of this section and sections 262 and 263, a voluntary scheme must be treated as applying to a manufacturer or supplier to whom it relates if—

(a) he has consented to the scheme being so treated (and has not withdrawn that consent)…"

6. It is therefore open to any given manufacturer to choose to subscribe to the terms of a voluntary scheme in preference to those which would otherwise apply under the statutory scheme. Which option is to be preferred will, of course, depend, at least in part, upon the particular activities of the relevant manufacturer. Under the terms of the schemes presently available, most eligible manufacturers have elected for economic reasons to opt for the existing voluntary scheme.

7. There is presently in force the "Voluntary scheme for Branded Medicines Pricing and Access" ("VPAS"). Subject to any agreed extension, this scheme is due to expire at the end of 2023 and negotiations are ongoing between the Secretary of State and the Association of the British Pharmaceutical Industry ("the ABPI") with a view to agreeing the terms of a new scheme.

8. Another industry body, however, now seeks to argue that it should be afforded full rights of participation in the negotiations alongside the ABPI. That body is the British Generic Manufacturers Association Limited ("the BGMA"). In a decision communicated on 16 March 2023, the Minister of State for Health and Secondary Care ("the Minister") declined to afford the BGMA such status.

9. The issue which arises in this case is whether or not such refusal was lawful. The proceedings before me took the form of a rolled up hearing to consider whether or not permission should be granted for judicial review and, if so, whether substantive relief should be afforded and in what form.

THE BACKGROUND

10. A manufacturer who discovers a new drug may apply for a patent the operation of which will usually protect the manufacturer from competition for twenty years. Such protection incentivises the manufacturer to invest in research but has the almost inevitable effect of raising the price of the drug.

11. Once the patent expires, other manufacturers are, in general terms, entitled to market generic copies of the formulation upon which the in-patent medicine had been based or, in the case of a biological medicinal product, a similar biological product, known as a biosimilar. For the sake of convenience, I will refer to such drugs collectively as "generics". These generics may also be allocated brand names, but the element of market competition is likely to drive down the profit levels available upon the sale

of branded generics in comparison to in-patent drugs. There is no issue as to the critical role played by the generics market in affordability, patient access and supply resilience.

12. The VPAS in its present form covers only branded medicines but these include not only in-patent products but also branded generic products. As its name suggests, the BGMA specifically represents the interests of manufacturers of generic medicines. It contends that the VPAS has turned out to operate in a way which is disproportionally prejudicial to the interests of its members. This is because it contains provisions under which the Secretary of State is entitled to claw back sums from participants calculated by reference to NHS expenditure in excess of permitted growth in sales. The percentage clawback is applied at a blanket rate to all but, for the most part, it is the growth of in-patent sales which account for the increase. In addition manufacturers of new medicines are afforded a three year exemption from the rebate. As a result of these features, it is contended that the manufacturers of generic and biosimilar medicines have borne a disproportionately high economic burden under the VPAS. It is to be noted, however, that it is by no means inevitable that the terms of any replacement scheme are liable to replicate or reflect the allegedly skewed terms of the VPAS in its present form.

13. It is alleged that the ABPI does not and cannot properly represent the interests of the BGMA members in negotiations with the Secretary of State because its central and predominant role is to promote the interests of in-patent manufacturers to the inevitable detriment of generic manufacturers. Against this background, the BGMA claims to be entitled to a place at the negotiating table which the Minister has hitherto denied it.

THE LAW

14. It is rightly conceded on behalf of the BGMA that the Secretary of State engages in the process of negotiation with the industry body with a view to agreeing a voluntary scheme in the exercise of a common law power. If, but only if, such negotiations result in an agreement covering one or more of the purposes identified in section 261, the statutory enforcement provisions will thereafter take effect.

15. Section 266(6) of the Act provides:

> ""the industry body" means any body which appears to the Secretary of State appropriate to represent manufacturers and suppliers."

16. There is no dispute that the BGMA, in general terms, is a body which represents manufacturers and suppliers and that the wording of the section does not preclude the Secretary of State from engaging with more than one industry body.

17. In my view, however, the question of whether any given body is "appropriate" to represent manufacturers and suppliers for the purposes of negotiating the terms of a voluntary scheme is context specific. For example, the BGMA was afforded the status of the appropriate industry body in respect of the scheme M agreement entered into between the Secretary of State and the BGMA. The scope of this negotiation was limited to manufacturers and suppliers of generic medicines. Accordingly, the BGMA had a stronger claim in those circumstances to be "appropriate" than in the context of a negotiation proceeding within significantly different parameters.

18. It follows that where the Secretary of State concludes that a body falls within the scope of section 266(6) for the purposes of one set of proposed negotiations then this does not thereby afford that body a status which, without more, obliges the Secretary of State to afford that body the same status in different negotiations.

19. I therefore reject the BGMA's argument that "appropriate industry body" is to be elevated to a form of immutable taxonomy which deprives the Secretary of State of any and all discretion to choose not to negotiate with that body however unsatisfactory the practical consequences might be. Indeed, it would be possible to identify several other candidates as industry bodies all of whom would be potentially entitled to claim negotiating status were they minded so to do.

20. I am satisfied that the discretion afforded to the Secretary of State in deciding with whom to negotiate is a wide one. The following points can be made:

    (i) The language of section 266(6) is in broadly permissive terms leaving significant scope for the operation of subjective appraisal by the Secretary of State;

    (ii) There is no statutory obligation or target imposed upon the Secretary of State to initiate any process of negotiations with a view to concluding agreement to a voluntary scheme;

    (iii) There is no statutory obligation or target imposed upon the Secretary of State, having initiated the process of negotiations, thereafter to conclude any agreement to give rise to a voluntary scheme;

    (iv) No voluntary scheme which is the product of such negotiations imposes any duty upon any manufacturer to subscribe to it. The statutory scheme may historically have been considered less economically advantageous to most manufacturers than the present VPAS but the statutory scheme was, in itself, subject to stringent obligations to consult with a broader range of consultees than the industry body. I am not persuaded that it is accurate or helpful to equiparate the operation of any voluntary scheme with a form of taxation. Of course, the general principle is "no taxation without

consultation" but this is not a case about consultation. What the BGMA seeks is a power of veto.

21. Of course, the Secretary of State remains under an obligation to act rationally in deciding with which industry body or bodies he will enter into negotiations but I am not persuaded that any more intensive level of review is justified in the circumstances of the present application. I am not persuaded, again on the circumstances of this case, that arguments relating to the purpose of the statute, broad reasonableness or natural justice justify any more stringent approach.

THE CONSEQUENCES OF AFFORDING THE BGMA FULL NEGOTIATING STATUS

22. The redacted ministerial submission of 2 March 2023 reveals that four particular options were considered by way of response to the BGMA's request to be treated as a full negotiating partner. One such option, inevitably, was to accede to this request in full.

23. The evaluation of this option was worded thus:

> "May act as a barrier to negotiations in any form as it will be difficult to agree governance across BGMA and ABPI. May also result in more complex/difficult negotiations."

24. I am of the view that such a consideration is one which the Minister was, at least, entitled to take into account in the exercise of his discretion; so long as it was not, in practical terms, fanciful. It was within the scope of his legitimate judgment to conclude, despite the BGMA's view to the contrary, that it would be in the interests of NHS patients for the negotiations to proceed between only two parties.

25. Against this background, it is to be noted that, in an email of 4 May 2018 from the then Director General of the BGMA to the Department of Health and Social Care, the author noted:

> "I am not clear whether the answer to this is to have more industry bodies or representatives around the negotiating table. I can see this may be cumbersome and maybe difficult to agree an industry position. It may be that we can agree amongst the bodies, though I am sceptical."

26. My attention has not been drawn to any subsequent developments which may have undermined the force of such concerns.

27. The BGMA has always realistically conceded that the ABPI must inevitably be a party to negotiations relating to branded medicines. Without their participation, the interests of the in-patent manufacturers would be unrepresented.

28. Accordingly, the Minister was, in practical terms, left with a choice between two way or three way negotiations. The following points fall to be made:
    (i) The assessment of the potentially deleterious impact of expanding the number of parties would necessarily be a predictive exercise best carried out by those with experience of the processes and parties to be involved in them;
    (ii) The involvement of the BGMA would inevitably increase the risk that no voluntary scheme could be reached at all. I do not doubt that this would not be a satisfactory or attractive outcome for any party but to accede to the BGMA's request would inevitably afford them a power of veto over any scheme otherwise acceptable to the other parties;
    (iii) The present aim is to agree a voluntary scheme by the end of the year. Negotiations are already progressing. The arrival of the BGMA at the table is liable to involve a reappraisal of progress already achieved and to complicate progress yet to be made. The potential for delay is real.
29. The question remains, however, whether notwithstanding the factors identified above, the points raised by the BGMA in favour of their inclusion have such force as to render the Minister's decision irrational in any event.

THE ABPI

30. Of central importance to the BGMA's case is that the ABPI is incapable of adequately representing the interests of the manufacturers of branded medicines as a whole.
31. In support of this proposition, my attention has been drawn, in particular, to the Articles of Association of the ABPI which establish that its objects and primary purpose are to make the United Kingdom the best place in the world to research, develop and use new medicines and vaccines in a way which fulfils a series of four subsequently listed aspirations.
32. Indeed, there can be no doubt that the interests of in-patent manufacturers were and are likely to remain a high priority for the ABPI. Had I been satisfied that the ABPI would be liable in practice to deprioritise the interests of generic manufacturers in the course of the negotiations then the argument that it would have been irrational to exclude the BGMA from the negotiating table would have been much stronger. However, the following features cannot be ignored:
    (i) The Minister went a very considerable way towards ensuring that the BGMA could participate as fully as possible in the negotiation process short of being a formal party enjoying a power of veto. He

offered formal observer status to the BGMA. I reject the BGMA's argument that somehow he was precluded from following this course because observer status "is not a status under the statute". In my view, since the formation of a voluntary scheme is governed by the common law, no purpose would be achieved by looking to the statute for the provision of such a status. Furthermore, a mechanistic and binary approach to status would unduly and deleteriously fetter the legitimate scope of the Minister's discretion as how best to proceed in negotiations. As proposed, the status of formal observer would entitle a representative of the BGMA to be in the room for any negotiation session. They would have sight of all materials and proposals tabled during the course of negotiations. They would be empowered to make comment during the negotiations on matters of specific interest to its members. They would be signatories to the negotiating protocol. In addition, the Minister stressed to the ABPI that its continued role as designated negotiator was contingent upon representing the full scope of the sector and upon recognising the status of the BGMA as formal observer. The BGMA was invited to start by setting out in outline its key priorities for a successor scheme to the VPAS. This offer was expressed to be contingent upon the BGMA agreeing not to proceed to judicial review on the reasonable ground that such proceedings were liable to distract from the substantive progress of the negotiations. The BGMA, as it was entitled to, elected notwithstanding to proceed with the application for judicial review;

(ii) The ABPI retains a strong interest in advancing the cause of generic manufacturers. For example, 53 out of 67 of the ABPI's full members supply generic medicines and these account for 38% of all VPAS sales by value. This is a higher share of the market than the BGMA and British Biosimilars Association combined which amounts to 28%;

(iii) Although the ABPI continues to advance the cause of research in many of the capacities in which it operates, it expressly takes on a responsibility to act as an "All-Industry" body in the fulfilment of other functions. One such function is the role of designated negotiator with the Secretary of State with respect to formulating the terms of a voluntary scheme. The terms of reference of the ABPI negotiating team makes it clear that its responsibility is to ensure a successful outcome for the entire branded pharmaceutical industry in the UK. The ABPI has also engaged in an all-industry engagement exercise by way of preparation for the negotiations. The fact that the ABPI strongly opposes the involvement of the BGMA would not be a factor to be taken into account by the Minister if it were a position

shown to be based solely on the self interest of its members. In my view, however, this somewhat sceptical analysis is not made out in the context of the observations I have made above. Furthermore, the fears that affording the BGMA full participation and a power of veto in the negotiations may bring about disruptive delay and threaten a concluded agreement on the contents of a replacement scheme are by no means fanciful and would have a potential impact upon the position not only of the Secretary of State but upon the membership of the ABPI.

PROMPTNESS

33. For the sake of completeness, I am not satisfied that if the BGMA's claim had substantive merit then it should nevertheless be rejected as being out of time. I take the view that the BGMA proceeded with reasonable and proportionate dispatch throughout.

CONCLUSIONS

34. I am satisfied that the Minister's decision fell very comfortably within the parameters of *Wednesbury* reasonableness. Indeed, even if, contrary to my primary conclusions, the level of review were so intense as to demand anxious scrutiny I would have remained satisfied that the decision was unimpeachable. The BGMA is, in effect, inviting this court to arrogate the decision-making power of the Secretary of State to itself against the background of undisputed primary facts and a necessarily predictive exercise.
35. I conclude that there is no arguable ground for review with a realistic prospect of success such as to justify the giving of permission which is therefore refused.
36. I am conscious of the fact that this judgment is very concise in comparison to the volume of materials which had been placed before me. The Authorities Bundles stretches to 1,681 pages. The Core Bundle is 285 pages long. There are two Additional Bundles which comprise 1,101 pages of documents. There is a Supplementary Bundle of 112 pages. Skeleton arguments run to a total length of 75 pages. The law of diminishing returns has been fully engaged. It is inevitable that a balance must be struck between the appropriate level of analysis to be deployed in the reasons given in this judgment and the strong desirability that the parties should know where they stand as soon as is practicable. I can, however, assure the parties that I have had regard to all the matters and issues which have been raised before me both in writing and in oral submissions. Where I have omitted reference to them, it is because their resolution would make no difference to my conclusions.

37. I note in passing that it may not be too late for the Minister to consider re-instating the BGMA to formal observer or similar status now that the challenge by way of judicial review has been concluded.