Neutral Citation Number: [2023] EWCA Civ 763

Case No: CA-2022-000740

**IN THE COURT OF APPEAL (CIVIL DIVISION)**
**ON APPEAL FROM THE HIGH COURT OF JUSTICE**
**BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES**
**COMPETITION LIST (ChD)**
**Mr Justice Roth**
**[2022] EWHC 369 (Ch)**

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 03/07/2023

**Before:**

**SIR JULIAN FLAUX, CHANCELLOR OF THE HIGH COURT**
**LORD JUSTICE NEWEY**
and
**LORD JUSTICE NUGEE**

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**Between:**

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| **(1) THE SECRETARY OF STATE FOR HEALTH**<br>**(2) THE NHS BUSINESS SERVICES AUTHORITY** | **Claimants/ Respondents** |
| **- and -** | |
| **(1) SERVIER LABORATORIES LIMITED**<br>**(2) SERVIER RESEARCH AND DEVELOPMENT LIMITED**<br>**(3) LES LABORATOIRES SERVIER SAS**<br>**(4) SERVIER SAS** | **Defendants/ Appellants** |

**And between:**

| | |
|---|---|
| **THE SCOTTISH MINISTERS AND OTHERS** | **Claimants/ Respondents** |
| **- and -** | |
| **(1) SERVIER LABORATORIES LIMITED**<br>**(2) SERVIER RESEARCH AND DEVELOPMENT LIMITED**<br>**(3) LES LABORATOIRES SERVIER SAS**<br>**(4) SERVIER SAS** | **Defendants/ Appellants** |

**And between:**

| | |
|---|---|
| **THE WELSH MINISTERS AND OTHERS** | **Claimants/ Respondents** |
| **- and -** | |
| **(1) SERVIER LABORATORIES LIMITED** | **Defendants/** |

**(2) SERVIER RESEARCH AND DEVELOPMENT LIMITED** **Appellants**
**(3) LES LABORATOIRES SERVIER SAS**
**(4) SERVIER SAS**

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**Nicholas Saunders KC, Daniel Piccinin KC and Emma Mockford** (instructed by **Sidley Austin LLP**) for the **Appellants**
**Jon Turner KC and Josh Holmes KC** for the **Respondents** with **David Drake and Philip Woolfe** (instructed by **Peters and Peters Solicitors LLP**) for the **English Respondents**, **Julian Gregory** (instructed by **RPC LLP**) for the **Scottish and Northern Irish Respondents** and **Laura Elizabeth John and Ciar McAndrew** (instructed by **Geldards LLP**) for the **Welsh Respondents**

Hearing dates: 7 and 8 June 2023
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# Approved Judgment

This judgment was handed down remotely at 10.30am on 03 July 2023 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

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**Lord Justice Newey:**

1. This appeal concerns perindopril, a medicinal product which was developed and manufactured by the Servier group of companies, of which the defendants (to which I shall refer collectively as "Servier") are members. Perindopril is an angiotensin-converting enzyme ("ACE") inhibitor ("ACEI") used in the treatment of cardiovascular conditions such as hypertension. Servier marketed perindopril under the name "Coversyl".

2. Servier began to supply Coversyl in the UK in about 1990. At that stage, Coversyl was protected by European patents with a UK designation and a supplementary protection certificate that was due to expire on 21 June 2003. On 6 July 2001 Servier applied to the European Patent Office ("the EPO") for a patent in respect of the alpha crystalline form of the tert-butylamine salt of perindopril, and the patent was granted on 4 February 2004: EP No 1 296 947 ("the 947 Patent"). Opposition proceedings followed which were the subject of a hearing before the Opposition Division of the EPO on 27 July 2006, but the patent was upheld.

3. On the strength of the 947 Patent, Servier obtained interim injunctions against companies wishing to enter the UK market with generic perindopril. On 11 July 2007, however, Pumfrey J held that the 947 Patent was invalid, and his decision was upheld by the Court of Appeal on 9 May 2008: see *Les Laboratoires Servier v Apotex Inc* [2007] EWHC 1538 (Pat) and [2008] EWCA Civ 445. Those decisions applied only to the UK designation of the patent, but an appeal was pending before the EPO Technical Board of Appeal and, on 6 May 2009, the Board of Appeal determined that the European patent should be revoked.

4. The claims before us were issued in 2011 and 2012 by, respectively, health authorities for England ("the English Claimants"), those for Scotland and Northern Ireland ("the Scottish/NI Claimants") and those for Wales ("the Welsh Claimants"). They allege breaches by Servier of competition law. As Roth J ("the Judge") explained in paragraph 9 of the judgment under appeal ("the Judgment"):

> "The present proceedings allege a series of infringements of both EU and UK competition law. In particular, it is alleged that Servier entered into a series of agreements with generic manufacturers and suppliers not to enter the market with a generic version of perindopril and/or to withdraw their challenges to Servier's patent; and that those agreements constituted an infringement of Art 101 of the Treaty on the Functioning of the European Union ('TFEU') and/or the equivalent s. 2 of the Competition Act 1998 ('CA'), and also an abuse of a dominant position which Servier held in the UK, and therefore an infringement of Art 102 TFEU and/or the equivalent s. 18 CA. Moreover, the claims allege that LLS [i.e. Les Laboratoires Servier SAS, the third defendant] obtained the grant of the 947 Patent, and further successfully defended it in opposition proceedings, by misleading or dishonest misrepresentations made to the EPO; and that LLS and SLL [i.e. Servier Laboratories Limited, the first defendant] further repeated or relied on those misrepresentations in obtaining

> interim relief in the English courts. That alleged conduct, which is expressly pleaded as constituting deceit, is said to be a separate abuse of Servier's dominant position and thus contrary to Art 102 TFEU and/or s. 18 CA. Further and alternative grounds of abuse are alleged on the basis that the conduct of LLS and/or SLL by which they 'obtained, defended and enforced' the rights in relation to the 947 Patent was unreasonable or an abuse of process, and that Servier was 'not transparent in its provision of relevant information to the EPO and courts'."

The claims relate to the period between 2003 and 2009.

5. On 9 July 2014, the European Commission ("the Commission") issued a decision ("the Commission Decision") finding that Servier had contravened articles 101 and 102 of the Treaty on the Functioning of the European Union ("the TFEU") and imposing fines: Case AT.39612 *Perindopril (Servier)*. On 12 December 2018, the General Court of the European Union ("the General Court") largely dismissed an appeal by Servier in relation to the article 101 infringement, but it allowed the appeal so far as it concerned the finding that Servier had been dominant on the relevant market and accordingly annulled the Commission Decision as regards infringement of article 102: Case T-691/14 *Servier v Commission*, EU:T:2018:922 ("the General Court Judgment"). Appeals by both the Commission and Servier against the General Court Judgment are pending before the Court of Justice of the EU.

6. The claimants' case is that, as a result of the anti-competitive agreements and abusive conduct which they allege, the price which they had to pay for perindopril was much higher than it would have been if generic suppliers had entered the UK market and, on that basis, they claim as damages the difference between what they paid and what they would have paid. Servier, however, denies infringement of either article 101 of the TFEU or section 2 of the Competition Act 1998 ("the 1998 Act"), further denies having held a dominant position for the purposes of article 102 of the TFEU or section 18 of the 1998 Act and contends that, even if it was dominant, its conduct did not amount to abuse.

7. When the proceedings pursued by the English Claimants were issued, the claimants included Strategic Health Authorities ("SHAs") and Primary Care Trusts ("PCTs") which had existed in England during the period relevant to the claim. Subsequently, those bodies were abolished and their rights of action vested in the first English Claimant, the Secretary of State for Health.

## The "prescribing argument"

8. In October 2016, Servier was granted permission to amend its pleadings to allege that, were liability and causation established, damages should be reduced or extinguished because the claimants failed to mitigate their losses, for contributory negligence or because the losses were too remote. These defences, which have been referred to as the "prescribing argument", proceed on the basis that the claimants should have taken all reasonable steps to encourage clinicians to opt for cheaper alternative ACEIs in place of perindopril when issuing prescriptions.

9. The prescribing argument is advanced as follows in Servier's re-re-amended defence to the claim by the English Claimants:

> "Failure to take all reasonable steps to encourage switching to cheaper ACE Inhibitors
>
> 83.B. The Claimants were aware or should have been aware that:
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> (a) Alternative ACE Inhibitors were available in generic form. In particular, generic launch of Enalapril took place in or around December 1999, Lisinopril in or around September 2002 and Ramipril in or around December 2003;
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> (b) ACE Inhibitors exert a 'class effect' and there was no clinical difference between Perindopril and the other ACE Inhibitors already available in generic form. NHS prescribers could therefore prescribe these ACE Inhibitors as an alternative to Perindopril; and
>
> (c) The reimbursement prices of generic ACE inhibitors were significantly less than the reimbursement price of Perindopril during the relevant period.
>
> 83.C. In these circumstances, the Claimants should have taken all reasonable steps to encourage switching from the prescription of Perindopril to the prescription of cheaper alternative ACE Inhibitors in generic form. In particular, but without limitation, the Claimants should have:
>
> (a) Removed Perindopril from the local formularies;
>
> (b) Issued national guidance encouraging a switch from Perindopril to the prescription of cheaper alternative ACE Inhibitors in generic form;
>
> (c) Issued local PCT guidance encouraging a switch from Perindopril to the prescription of cheaper alternative ACE Inhibitors in generic form, including through meetings with GPs, through newsletters and through meetings with individual PCT pharmacists or agents;
>
> (d) Used the national Quality and Outcomes Framework to incentivise a switch from Perindopril to the prescription of cheaper alternative ACE Inhibitors in generic form. For example in 2004, GPs were incentivised to meet with their prescribing advisor and review all patients with repeat prescriptions or multiple therapies. This would have provided the opportunity to encourage switching;

> (e) Introduced or encouraged the introduction and use or further use of software such as 'Scriptswitch' which provides a visual prompt for NHS prescribers in order to highlight the availability of an alternative, more cost-effective treatment;
>
> (f) Provided additional support reasonably necessary to facilitate the switching of patients from Perindopril to cheaper alternative ACE Inhibitors, including by providing patient information leaflets and/or template letters for use by GPs when switching patients; and
>
> (g) Taken all reasonable steps and allocated reasonable resources to ensure that the foregoing measures were complied with, including monitoring compliance and taking further steps in circumstances of non-compliance.
>
> 83.D. Pending full disclosure, the Defendants are presently unable to particularise the extent to which each individual Claimant took or failed to take one or more of the above identified steps. However, each of the Claimants either failed to take the steps identified above and/or alternatively having taken such steps, failed to take any or any sufficient steps to ensure compliance with them."

10. In response to a request for further information, Servier explained that they "do not accept that there are any circumstances in which it would not have been clinically appropriate to prescribe another ACE inhibitor instead of Perindopril, except where the patient was allergic to or intolerant of all alternative ACE inhibitors".

11. Very similar amendments were made to the defences to the claims by the Scottish/NI Claimants and the Welsh Claimants. Whereas, however, paragraph 83.C(c) of the English defence referred to "local PCT guidance" and "meetings with individual PCT pharmacists or agents", the Scottish/NI defence spoke of "local Health Board, HSS Board, and NI CSA guidance" and "meetings with individual Health Board, HSS Board, and NI CSA pharmacists or agents" while the Welsh defence focused on "Local Health Board guidance" and "meetings with individual Local Health Board pharmacists or agents". During the period relevant to the claims, NHS policy was implemented at regional/local level by Health Boards in Scotland; through the Health and Social Services Boards ("HSS Boards"), the Northern Ireland Central Services Agency for Health and Social Services ("the NI CSA") and, later, the Regional Health and Social Care Board in Northern Ireland; and by Local Health Boards and, particularly in earlier years, NHS Trusts in Wales.

## Some procedural history

12. When granting Servier permission to introduce the prescribing argument into its defence to the claim by the English Claimants (the Scottish/NI and Welsh Claimants having consented to equivalent amendments), Henderson J observed that, if the amendments were allowed, "careful consideration will need to be given to the

resulting disclosure by the English claimants, and the need to keep it within reasonable bounds, for example by confining it to a representative cross-section of Primary Care Trusts and Strategic Health Authorities": see [2016] EWHC 2381 (Ch), at paragraph 3.

13. The need to give "careful consideration … to the resulting disclosure by the English claimants" was accentuated by the fact that PCTs and SHAs had ceased to exist. At the start of the period to which these claims relate, there were 28 SHAs and 303 PCTs in England. In 2006, SHAs and PCTs were both reduced in numbers and, in 2013, they were abolished altogether and replaced by Clinical Commissioning Groups ("CCGs").

14. Applications for disclosure came before Vos C on 13 December 2016. As Vos C explained in paragraph 8 of his judgment, Servier's position at the start of the hearing was that "there should be a complete disclosure exercise which would throw up hundreds of thousands of documents from each of the various PCTs in order to inform the mitigation questions". Having, however, expressed concern in paragraph 6 that both sides had been "engaged in a shadow war concerning how many millions of documents should be trawled through by way of word searches and other technical exercises", Vos C gave directions for the parties' IT experts to meet with a view to arriving at an efficient and cost-effective means of investigating the relevant questions. Vos C also, in paragraph 16, "commend[ed] to the parties the possibility that it may be possible to agree some preliminary issue or preliminary issues to narrow the gap between them in relation to the questions of quantum".

15. A "heated dispute" over disclosure was the subject of a hearing before the Judge on 19 July 2017. Servier's "primary position" was that "it will be necessary to determine what each of the 152 PCTs then in existence did over the relevant period": paragraph 16 of the judgment. However, the Judge observed that there was now "no presumption that there is standard or full disclosure" (paragraph 17) and said that his "present view" was that "a sampling exercise is likely to be appropriate and proportionate as a means forward" (paragraph 20). The Judge considered that, in the circumstances, "the sensible way forward is to direct that the economic experts should meet to consider whether a sampling exercise … can be arrived at; what would be the appropriate size of a sample, bearing in mind the desire to avoid incurring excessive costs; and the criterion on which the sample should be drawn": paragraph 21.

16. In the event, as Servier noted in its skeleton argument for a case management conference ("CMC") which took place before the Judge on 22-23 January 2018, there was "profound disagreement" between the parties' experts and so Servier renewed its application for additional disclosure. It pointed out in its skeleton argument that it was "no longer seeking what would have been the norm in litigation of this type in days gone by … : standard disclosure", but argued that, for the purposes of the prescribing argument, it needed disclosure from at least 29 additional PCTs.

17. The Judge, however, raised the possibility of directing the trial of preliminary issues, which, he thought, would "not generate disclosure" and would involve "basically expert evidence". One such issue, the Judge suggested, could be whether it was unreasonable for the claimants, or the PCTs, to fail to take any of the various steps set out in the defence. Servier's counsel responded that it was "slightly perplexed" as to how the issue could be determined "with only a very small dataset in relation to the

English PCTs, because we do not know, without at least some more disclosure, what the English PCTs did know at the time, because we do not know what anyone else was doing". Having, however, commented that Servier's was "essentially a negligence case … on this", the Judge said:

> "If you bring a medical negligence case and you say this surgeon did not carry out the procedure that a reasonable surgeon of competen[ce] should have done, you would establish that by hearing evidence from an expert on what was good practice at the time. You do not go and get disclosure from all the hospitals around the country as to what every other surgeon did. You rely on your expert, as an independent expert helping the court, knowing what the situation was, to inform the court."

18. By an order dated 31 January 2018, the Judge ordered the following preliminary issues to be tried:

> "(a) Would it have been reasonable or appropriate for a clinician to prescribe another ACE inhibitor instead of perindopril in all circumstances, except where the patient was allergic to or intolerant of all alternative ACE inhibitors?
>
> (b) If not, in what circumstances would that have been unreasonable or inappropriate?
>
> (c) Was it unreasonable for either the present three sets of claimants … or the various relevant predecessor organisations (including PCTs and SHAs) to fail to take any (and, if so, which) of the steps set out in paragraph 83C of the Defendants' Re-Re-Amended Defence to the English Claimants' claim or identified in the Defendants' Further Information dated 29 September 2017?
>
> (d) If it is shown that the Defendants were engaged at all material times in conduct whose object was to prevent or discourage switching from perindopril, are they entitled to raise a defence of failure to mitigate loss, or otherwise to seek the recovery of compensation by the Claimants on account of the matters alleged in paragraphs 83C to 83D of the Defendants' Re-Re-Amended Defence to the English Claimants' claim?"

The application for disclosure was adjourned pending the outcome of the trial of the preliminary issues.

19. As the Judge noted in paragraph 29 of the Judgment, the reference in preliminary issue (c) to the further information dated 29 September 2017 related to Servier's "allegations of the respects in which four particular PCT guidance documents, which it had identified in an 'illustrative' list in a previous response, were alleged to be unreasonable or inadequate". With regard to issue (d), it was stated on behalf of the claimants in a letter dated 10 January 2019 that "[u]pon reflection the claimants

consider that as formulated issue (d) identifies a proposition of law for which the claimants do not contend" although "the defendants' marketing efforts remain relevant to the remaining preliminary issues which encompass considerations relating to the standard of unreasonableness that they should apply given the circumstances of this case".

20. In its skeleton argument for a further CMC on 18 January 2019, Servier submitted that the preliminary issues trial should be vacated. There was, it was said, "a very real risk that the Preliminary Issues Trial will ultimately decide nothing or virtually nothing of value, even within the narrow compass of this mitigation defence". The trial, Servier observed, had "expanded beyond recognition from the 9-day trial that was listed in January 2018 with the intention of being a cost-effective means to avoid a tricky and potentially costly disclosure application". The preliminary issues gave rise to "a messy question of fact about what was reasonable at national and local PCT level" and it was "at least possible that the Court may conclude that some or all of the PCTs needed to take at least some steps to satisfy the duty to mitigate, but will be unable to formulate a single set of steps that all PCTs needed to implement across the board". The preliminary issues trial "may therefore", so it was contended, "fail to achieve even its own very limited ambitions".

21. At one point in the CMC, counsel then appearing for Servier agreed with the Judge that, if the claimants were successful on the preliminary issues, "the mitigation defence would fall away". Later, however, she said that the evidence from the claimants "suggests that it is distinctly possible that you could conclude that what is reasonable varied from PCT to PCT" and that the Judge "might not even get to the point of being able to say that there is something that was overall reasonable because you might have to say, 'We will need evidence from each PCT to even say what was reasonable'". In contrast, Mr Jon Turner KC (who then, as before us, was appearing for the claimants) disputed the suggestion that "the question of reasonableness may have to be examined on a very granular and detailed basis", commenting that "[t]he question of reasonableness does not turn on whether PCT A in the north of England took a certain course of action which happened to yield certain results and PCT B in the south of England did not".

22. The Judge concluded that the trial of the preliminary issues should proceed. In paragraph 22 of his judgment, he observed that the preliminary issues "will …, if decided one way, obviate massive and expensive disclosure by a whole series of public authorities" and that that was "a very relevant consideration". Servier asked the Judge to grant permission to appeal, but he refused it, and no application for permission to appeal was made to the Court of Appeal.

23. There was a pre-trial review ("PTR") on 4 May 2021 in advance of the trial of the preliminary issues. In its skeleton argument for the pre-trial review, Servier listed 13 "steps" by way of "additional detail on the minimum steps which it contends, by way of its mitigation defence, that the Claimants should have taken to encourage switching from the prescription of perindopril to the prescription of a cheaper, alternative ACE inhibitor". The claimants objected to item 13, where Servier said that it "also contends that, depending on their particular circumstances (e.g. the level of perindopril in their area) at least <u>some</u> PCTs/HBs [i.e. Health Boards] should have taken the following further steps … ". Giving judgment, the Judge said this about item 13:

> "21. As regards paragraph 13, it is clear to me that the preliminary issue is looking at the conduct of the claimants across the board and is not concerned with the conduct of particular PCTs, even if evidence from PCTs has been served as illustrative.
>
> 22. The whole point … of the preliminary issue was to avoid disclosure at the local level and it doesn't seem to me that those sort of allegations are going to be ones that will form part of a judgment. However, I am not excluding any of the evidence that Ms Kerr [as to whom, see paragraph 24 below] has given. There is, as I understand it, evidence from particular PCTs and that will all be considered within the confines of the preliminary issue that has been ordered on the pleading as it stands. Therefore, I don't see any reason to give any further specific ruling in what is only the annex to a skeleton argument."

Earlier in his judgment, in paragraph 4, the Judge had said:

> "The reason for having preliminary issues was in large part to avoid what would have been a hugely elaborate and expensive disclosure exercise involving the various PCTs and SHAs. It was recognised that this could be dealt with by looking at the claimants' conduct at a more general basis."

24. The trial of the preliminary issues occupied 17 days in June and July 2021. By this stage, there had been full disclosure from the Scottish/NI Claimants and the Welsh Claimants and also in respect of 11 PCTs. 12 witnesses of fact gave evidence, including three individuals who had had roles with, respectively, Plymouth PCT, Rhondda Cynon Taff Local Health Board and the Highland Health Board and who addressed in detail the steps taken as regards perindopril by those particular bodies. There was also evidence from five expert witnesses, addressing (a) the clinical qualities and differences as between perindopril and other ACEIs, (b) the prescribing practices of NHS clinicians as regards perindopril and other ACEIs, and (c) prescribing guidance and policies issued by national and local health authorities. On topic (c), the claimants' expert was Professor Stephen Chapman and Servier's was Ms Sarah Kerr.

25. The Judgment, which is very detailed, was handed down on 21 February 2022.

## The Judgment

*Preliminary issues (a) and (b)*

26. Perindopril was licensed for use in the UK to treat hypertension, heart failure and major adverse cardiac events (or "MACE") and also after a stroke or transient ischaemic attack (a "mini-stroke" or "TIA"). A number of other ACEIs were also licensed for hypertension and heart failure (captopril, enalapril, lisinopril and ramipril) and generic versions of these came to be available. As the Judge noted in

paragraph 89 of the Judgment, "[g]eneric enalapril became available around December 1999; generic lisinopril in about December 2002; and generic ramipril was introduced in the UK in about January 2004".

27. Servier's case on issues (a) and (b) was that ACEIs exercised a class effect and were clinically substitutable with another (and should have been regarded as such by prescribers throughout the period relevant to the claims). Every patient who was prescribed perindopril could, Servier maintained, have been prescribed an alternative ACEI that was available in generic form.

28. The Judge addressed preliminary issues (a) and (b) in paragraphs 169-232 of the Judgment. In paragraph 230, he concluded that there was "no simple or binary answer to the questions posed by preliminary issues (a) and (b)". He continued:

> "The answer varies according to the condition for which the ACEI is being prescribed, the time period concerned and whether the question relates to a prescription initiating a patient for treatment with an ACEI or switching a patient already stable in treatment with perindopril, in which case the circumstances of the patient are also relevant. In my judgment, these preliminary issues are to be answered as follows: -
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> i) For 'straight' or uncomplicated hypertension:
>
> a) for patients initiated on an ACEI prior to late March 2005, it would have been reasonable or appropriate to prescribe lisinopril instead of perindopril if the appropriate daily dosage of lisinopril was 20 mg; however, if 40 mg lisinopril was the appropriate dose, it was not reasonable or appropriate to prefer lisinopril as against perindopril (or any other ACEI) since there was no cost advantage.
>
> b) for patients initiated on an ACEI from April 2005 onwards, it was reasonable or appropriate to prescribe lisinopril or ramipril instead of perindopril, except where the appropriate target dose was 40 mg lisinopril or 10 mg ramipril and the GP considered that the need for titration would be a burden on the patient or their practice.
>
> ii) Subject to the qualifications as to timing in (i), it would have been reasonable or appropriate at the patient's next review at the GP surgery to switch a patient being treated with perindopril for uncomplicated hypertension to lisinopril or ramipril except where the patient was elderly or frail or vulnerable because of co-morbidities being treated with other drugs or had previously been switched to

perindopril because of an adverse experience with either of those alternative ACEIs.

iii) For patients being initiated on an ACEI for heart failure or MACE, there was no reason to choose another suitable ACEI instead of perindopril prior to late March 2005 as this brought no cost advantage for the equivalent dosage. For patients initiated from April 2005 onwards, if the clinician followed the respectable body of opinion that one could have greater confidence in the benefit of perindopril for these conditions since it was better supported by evidence, then, to adopt the formulation in Servier's skeleton argument, it would not 'have been reasonable [or appropriate] for that doctor to prescribe an ACEI other than perindopril.' For those clinicians who took a different view, it would have been reasonable or appropriate to prescribe lisinopril or ramipril for heart failure instead of perindopril (unless the patient suffered left ventricular heart failure and administration of ramipril would involve twice daily doses) and to prescribe ramipril for MACE, unless the clinician was concerned about the burden on the patient or the GP practice of more frequent attendance for titration.

iv) For patients being initiated on an ACEI post-stroke or a TIA, a clinician could reasonably regard the evidence supporting treatment with perindopril as significantly stronger than the evidence for ramipril. For those who took that view, it would have been unreasonable or inappropriate to prescribe ramipril instead of perindopril, and no other ACEI would have been appropriate. In any event, there was no reason to prefer ramipril to perindopril prior to April 2005 since there was no cost advantage.

v) For patients initiated on perindopril by a consultant in secondary care for heart failure, MACE or post-stroke, it was unreasonable or inappropriate for the GP to switch the patient to another ACEI prior to March 2005 as that brought no cost advantage; after March 2005, it would have been unreasonable or inappropriate for the GP to make that switch if the GP considered that the consultant had selected perindopril based on his or her more specialised experience and expertise."

29. The Judge added in paragraph 231 of the Judgment:

"I observe that this shows, in my view, that in many cases the prescribing decision to choose among the class of ACEIs was

> not a formulaic exercise but a more evaluative judgment involving varied considerations."

*Preliminary issue (c)*

30. The Judge addressed preliminary issue (c) in paragraphs 233-391 of the Judgment.

31. The Judge considered in turn various ways in which Servier had alleged that the claimants should have taken steps either at national level or more locally to encourage use of alternatives to perindopril. In paragraphs 270-306 of the Judgment, he rejected Servier's criticisms of what was done in terms of national guidance. He then turned on to, among other matters, arguments which Servier had advanced in relation to local formularies, the "Qualities and Outcomes Framework" ("the QOF") and a software programme called "ScriptSwitch".

*Local formularies*

32. By the end of the period relevant to the claims, "virtually all PCTs and many of the Health Boards in Wales and Scotland had produced formularies listing the drugs recommended for prescribing by GPs and most hospital trusts (or groups of hospitals in an area) maintained their own formularies": paragraph 309 of the Judgment. It was Servier's case that the formularies could have been used to limit the use of perindopril. However, the Judge observed in paragraph 312 that "there is no basis on the expert evidence for finding that perindopril should have been removed from the formulary at the start of the Relevant Period" and that Ms Kerr's evidence did not provide support, either, for the contention that it was unreasonable to leave perindopril on the formulary. Servier put forward "an alternative and lesser contention that local formularies should have contained an indication that one or more ACEIs which were available generically (and therefore not perindopril) were the preferred option or 'first line' ACEIs" (paragraph 314), but the Judge rejected that, too. In that connection, he said that "the use of formularies was in the process of development"; that "in some areas the introduction of a formulary that was seen as too prescriptive would have encountered considerable resistance"; that "for a PCT/Health Board issuing a formulary to go further than selecting the recommended drugs so as to set a preference between them imposed a significant additional burden, especially as such an approach could not normally be confined to ACEIs"; that "before lisinopril and ramipril came off patent it would not have been reasonable to indicate that generically available ACEIs should be the preferred choice or first line"; that the October 2004 edition of a publication called "Prescribing Outlook" (incorrectly) indicated that the patent for perindopril had expired; that in July 2007, after Patent 947 had been held to be invalid, "it was clear that the price of perindopril would come down"; that "where local consultant(s) supported the inclusion or retention of perindopril as a first line drug, … the PCT/Health Board was not acting unreasonably if it followed the advice of the hospital consultants specialised in the particular field and not the pharmaceutical adviser"; and that Servier "was very alert to a threat to remove or 'demote' perindopril from local formularies and developed a strategy to mobilise support from local cardiologists to counter this threat": see paragraph 315. With regard to the last of these points, the Judge said in paragraph 315:

> "Of course, Servier's efforts were not necessarily successful. But I do not accept the submission made for Servier that what it

> did at the time is irrelevant to the question before the Court. In my judgment, in the context of this case, such a strategy on Servier's part is very material to the determination of whether a PCT or Health Board was acting unreasonably in failing to mitigate its loss recoverable from Servier because it did not decide to mark perindopril as a second line or less preferable choice of ACEI on its formulary."

*The QOF and local programmes*

33. GPs generally provided their services through "General Medical Services" contracts. With effect from 1 April 2004, a new "General Medical Services" contract was introduced which included the QOF. This "sought to resource and reward GPs on the basis of how well they cared for patients rather than simply paying them for the number of patients that they treated": paragraph 49 of the Judgment.

34. Servier contended that the QOF should have been used to encourage the prescription of cheaper alternatives to perindopril. The Judge, however, said that it was common ground between Ms Kerr and Professor Chapman that the claimants "had multiple competing priorities in relation to safety, therapeutic quality, and cost-effectiveness of prescribing in relation to a variety of medicines", that "[t]he point about competing priorities was a theme of virtually all the factual evidence from those who worked in medicines management or as pharmaceutical advisers", that "[t]he initiative to move all GPs to generic prescribing … applied across all drugs", that "while some PCTs and Health Boards may have chosen to include the level of perindopril prescribing as a priority from about 2004, when ramipril became available generically, … it was eminently reasonable for others to decide that not only statins but also [proton pump inhibitors] and [angiotensin receptor blockers] were greater priorities", that "[m]edicines management was a relatively recent development which was evolving", that "in England the reduction of the 303 PCTs to 152 PCTs with wider jurisdiction in 2006 caused particular disruption" and that "realistically, the view of local consultants would be a significant factor in determining what initiatives could effectively be pursued": see paragraphs 328-347 of the Judgment.

35. With regard more specifically to whether targets relating to ACEIs should have been set, the Judge noted in paragraph 349 of the Judgment that the QOF "envisaged setting a very limited number of targets" and added that "that was doubtless for good reason, in order to maximise effectiveness". In paragraph 351, he said:

> "there were other priorities in prescribing on which pharmaceutical advisers could reasonably have chosen to concentrate in their limited meetings with GPs and the setting of targets under the QOF. Accordingly, I do not think that it was in any way unreasonable if they chose not to make ACEI prescribing a priority."

36. Turning to whether GPs should have been incentivised to switch to ACEIs other than perindopril, the Judge concluded in paragraph 356 of the Judgment that "it was not unreasonable if, either at national or more local level, the Claimants did not include within [an incentive] scheme the prescribing of ACEIs that were available in generic form". Likewise, the Judge thought that it was not unreasonable if a PCT or Health

Board did not introduce a switching programme to discourage perindopril prescribing: see paragraph 361. In that connection, the Judge said:

> "362. My conclusion is reinforced in the context of this case by the fact that Servier was active in seeking to dissuade PCTs/Health Boards from introducing such schemes for perindopril. In June 2006, it produced an internal document with the objective: 'To set in place a pro-active call strategy for negating PCTs that are focussing on a switch from Coversyl to Lisinopril/Ramipril usage.' The 12 page document set out a comprehensive strategy, both proactive and reactive, involving contact with GPs, with PCTs and the use of ['key opinion leaders'] to engage with pharmaceutical advisers. The document summarises relevant clinical arguments (with charts, graphs and footnote references to academic studies), practical arguments in terms of titration and dosages, 'deflection strategies' (pointing out the significantly greater savings from switching among statins or away from ARBs) and further that emphasis can be placed on the GP workload which such a switching programme imposes. Further, in September 2006, when several PCTs in the London area appeared ready to implement a policy of seeking to switch patients on perindopril to one of the ACEIs available in generic form, Servier's strategic response highlighted the fact that the first generic perindopril had just appeared on the UK market – a reference to the short period of supply by Apotex – and that 'it is expected that there will be increased generic availability within the UK in the near future'.
>
> 363. I do not suggest that a PCT or Health Board should necessarily have been influenced by such efforts on the part of Servier. But, in my judgment, when assessing what the Claimants should have done to mitigate the damages which they can claim from Servier as the result of Servier's anti-competitive conduct, the Claimants were not reasonably required to do precisely what Servier made sustained and calculated efforts to dissuade them from doing."

*ScriptSwitch*

37. ScriptSwitch could be purchased by a PCT, downloaded onto the computers of GP practices and programmed with the prescribing messages that the PCT wished to convey to GPs at the time they wrote particular prescriptions. Servier argued that, "where a GP practice had ScriptSwitch, it was unreasonable for the PCT not to use it to encourage prescriptions of less expensive ACEIs available in generic form instead of perindopril, at least for all new patients": see paragraphs 364-367 of the Judgment.

The Judge "fully accept[ed] that when a GP was about to initiate a patient with uncomplicated hypertension on perindopril, ScriptSwitch could be a useful tool in encouraging the GP to prescribe an alternative": paragraph 369. He continued, however:

> "But whether it was unreasonable not to use it for that purpose comes down again to a matter of priorities, given the need to avoid alert fatigue, the fact that Ms Kerr considered that the real value would come as regards new patients, and that there was a range of conditions for which it may not have been reasonable or appropriate to select another ACEI. Taking all this into account, I do not consider that it was unreasonable if the medicines management team chose not to include alerts for perindopril on ScriptSwitch."

38. In paragraph 370 of the Judgment, the Judge said:

> "I have addressed in turn all the various steps identified by Servier as each needs separate consideration. However, there are many common themes to the analysis and to some extent the steps have to be considered together as several were mutually supportive and it would be realistic to use them in conjunction with one another. For example, if a PCT had an incentive scheme, that could be featured in a newsletter and also be the basis for inserting an alert on ScriptSwitch, and the pharmaceutical advisers in their meetings with GPs would discuss the evidence base and savings that underpinned those steps so that the GPs would appreciate and support the objective. I found persuasive the evidence … that to change GPs' prescribing practice was complex and did not involve just one kind of approach. This was appreciated by the medicines management teams who gave considerable thought to selecting and developing their strategies. Some PCTs and Health Boards considered it appropriate and important to take steps to encourage or reward prescribing of other ACEIs instead of perindopril at certain times during the Relevant Period, but choices had to be made and others saw their priorities elsewhere, possibly because of the influence of local consultants or a belief that the entry of generic perindopril was not far off. That reasoning applies also to those PCTs/Health Boards with higher than average levels of perindopril prescribing. As Prof Chapman put it during cross-examination:
>
> > '… you may recognise there is an area of particularly aberrant prescribing, but you may not choose to direct your resources to that because there are greater gains elsewhere.'
>
> In my judgment, that was entirely reasonable."

*Conclusions*

39. The Judge summarised his conclusions on preliminary issue (c) in these terms:

> "386. The answer to issue (c) is of course affected by my conclusions on issues (a)-(b). Taking account of those conclusions, for all the reasons set out above I do not consider that the Claimants from any of the four nations failed unreasonably at national level to take steps to encourage clinicians to prescribe other ACEIs instead of perindopril.
>
> 387. By the end of the trial, Servier's approach to mitigation measures at the local level had considerably shifted. It submitted that the Claimants should have taken steps to ensure that new patients were initiated on a generically available ACEI in all cases (except where the patient was allergic to or could not tolerate alternatives to perindopril), but that a programme to switch existing patients on perindopril to an alternative ACEI should have been undertaken only by PCTs/Health Boards with a high level of perindopril prescribing. Servier did not suggest that all the pleaded steps should reasonably have been taken in every local health area. But it contended that: 'at least some of these steps should have been taken by each PCT/HB in the UK.' For the reasons I have fully set out, I reject that contention.
>
> 388. However, Servier developed an alternative contention that even if not all PCTs and Health Boards should reasonably have taken some steps, those with 'higher' rates of perindopril prescribing should have done so. Servier accepted that the standard of the required reasonable conduct which the Court has to apply is a general one across all PCTs and Health Boards, but submitted that what constituted reasonable conduct that complied with this standard varied as between different PCTs and Health Boards according to their individual circumstances.
>
> 389. This allegation was not pleaded in Servier's Amended Defence. Servier did not put forward any clear criterion according to which 'higher' perindopril prescribing PCTs/Health Boards would be distinguished – whether it would be any that were above the national average, or only those exceeding the national average by some unspecified margin. Nor did Servier say whether for this purpose it was sufficient for that higher level to apply in one year or whether it had to be for two or more consecutive years,

given that most of the measures Servier argued should have been adopted took several months to prepare. If this allegation had been pleaded, I expect such matters might have been the subject of a CPR Part 18 Request. But as I understood it, the argument was that the third preliminary issue should be resolved in such a way as to allow the prescribing argument to proceed to trial, at least for 'higher' perindopril prescribing PCTs and Health Boards, so that they (or the various successor bodies to which their documents have passed) would provide disclosure to reveal what steps each of them took regarding ACEI prescribing, their individual assessment of their other priorities at the time, the resources and experience of their then medicines management teams, the extent of any opposition from local consultants to any proposal to discourage perindopril prescribing and any other reasons why they did not take various other steps which it is alleged they should have taken. Indeed, Servier's closing submissions assert: 'Without giving proper disclosure, [the Claimants] cannot prove that every PCT and Health Board that had high levels of perindopril prescribing did so because of local factors that could not be overcome by modest and obviously sensible steps.'

390. However, the burden of showing a failure to mitigate (or contributory negligence) rests on Servier. I observed at the outset that this trial was not a general inquiry into the operation of medicines management in the NHS in the four nations over the Relevant Period. The question is, to adopt the language of Lord Nicholls in [*Kuwait Airways Corpn v Iraqi Airways Co (Nos 4 and 5)* [2002] UKHL 19, [2002] 2 AC 883], what is the extent of the loss for which Servier ought fairly or reasonably or justly to be held liable, given the reasons why the law has recognised a cause of action for anti-competitive conduct in the form of agreements between a patent-holder and generic suppliers whereby the generics stayed out of the market and the high patent price of a drug was maintained. Servier's rights to raise mitigation and contributory negligence defences must be observed. But as Green LJ recently observed in the Court of Appeal as regards a mitigation defence to a competition damages claim:

> '… where a claimant has a justiciable right the procedural and evidential rules governing the enforcement of that right must not be allowed to become so onerous that they undermine or

> weaken the very right itself by making it too hard to vindicate.'
>
> *NTN Corp v Stellantis NV* [2022] EWCA Civ 16 at [26].

> 391. Unless Servier can show that the Claimants, at least to some extent, failed unreasonably to observe clear standards in the provision of medicines management which applied at the time, then given Servier's efforts not only to persuade clinicians to prescribe perindopril but to forestall any initiatives by PCTs and Health Boards to dissuade them from prescribing perindopril, I consider that it would not be fair or reasonable or just to reduce by reason of Servier's prescribing argument the amount which the Claimants would otherwise recover for purchasing perindopril at the higher prices which resulted from Servier's actions to delay generic entry. Far from finding that there was such a failure to do what was reasonably required, I found that the evidence from all four nations demonstrated a considered and thoughtful effort to apply the evolving approach of medicines management to promote more cost-effective prescribing, within the limits of their resources and taking account of national and local considerations and priorities. And I do not consider it either proportionate, necessary or just to postpone an answer to the third issue to allow for detailed disclosure from individual PCTs and Health Boards. Accordingly, my answer to the question in the third preliminary issue is: No."

*Refusal of permission to appeal*

40. Servier asked Roth J to grant permission to appeal on, among others, the ground that he had been "wrong to reject Servier's case in its entirety on issue (c)" and "should have found that some PCTs/Health Boards should have taken some of the steps set out in Servier's Amended Defence under the prescribing argument". Declining to grant permission to appeal, the Judge said in a written ruling dated 5 April 2022 ("the PTA Decision"):

> "10. As regards issue (c), the fact that PCTs and Health Boards could take steps to encourage more cost-effective prescribing was never in dispute. The Claimants' witnesses gave abundant evidence of the various steps that could be taken, and in most cases were taken as regards other drugs. The question before the Court was a very different one: it was whether *it was unreasonable* for the Claimants or their predecessor organisations not to take such steps *as regards the prescribing of perindopril*. The Judgment

held that it was not unreasonable having regard to a host of considerations and addressing each of the different steps on which Servier sought to rely. Those considerations included the priority that could reasonably be given for cost-effective prescribing in other areas. They included also the sustained and calculated efforts made by Servier at the time to prevent some of those steps from being taken: see Judgment e.g at [315(vi)]; [362]-[363]. Servier's grounds of appeal do not seek to assert that this was an irrelevant consideration.

11. Secondly, the thrust of this ground of appeal appears to be that it was wrong to reject Servier's alternative contention advanced only at trial that *some* PCTs/Health Boards should have taken at least *some* of those steps, given the acknowledged variation between the circumstances in individual PCTs and Health Boards: Judgment at [388]-[391]. As Servier acknowledges in its submissions under Ground 1, its pleaded case was framed in absolute terms:

> 'Servier's pleaded case was that all PCTs and HBs should have taken all of the steps set out in Servier's Amended Defence.'

12. Servier accepted at trial that for the purpose of preliminary issue (c) it had to establish a general standard that could be applied across all PCTs and Health Boards: Judgment at [388]. The Court did not reject Servier's alternative case because Servier did not 'identify at trial which PCTs/HBs should have taken additional steps and failed to do so' as its submissions under Ground 1 suggest. The alternative case was rejected because Servier did not advance any clear criteria that could be used for the purpose of such identification: see the Judgment at [389]. This is not a technical pleading point. If Servier's case had been that steps should have been taken by any PCT/Health Board where more than, say, 40% of ACE prescribing was of perindopril for at least two consecutive years, then that would have put forward a general standard. It could have been addressed by the expert and factual witnesses and they could have been questioned to determine whether this was a reasonable or practicable standard. But Servier's case on this, raised only at trial, remained entirely vague.

13. As for the contention that Servier should be permitted to maintain its mitigation defence as regards issue (c) because if that defence had been raised in a case

> involving only a single PCT then full disclosure and exploration of all the individual circumstances would have been permitted, that is wholly misconceived. Irrespective of how such a hypothetical case might have been conducted, it cannot be equated with the present claims, which in England alone involve 303 PCTs for the earlier years and 152 PCTs for the later years. The decision to order preliminary issues to establish general standards was taken as a means of proportionate case-management, whereas the course advocated by Servier would fly in the face of the overriding objective. See also the observations of Green LJ in *NTN Corp v Stellantis NV*, quoted in the Judgment at [390]."

## The main ground of appeal

41. Servier's main ground of appeal is to the effect that the Judge could not properly dismiss the entirety of its defence on preliminary issue (c) at this stage, without fuller disclosure having been given by the claimants. Mr Nicholas Saunders KC, appearing for Servier, explained that it did not challenge the Judge's findings of fact. He argued, however, that Servier's pleaded case was not limited to an allegation that *all* PCTs/Health Boards should have taken certain steps but encompassed an allegation that *some* PCTs/Health Boards should have taken *some* of the steps identified in Servier's defences. The Judge nonetheless rejected Servier's case altogether, rather than examining what had been done by (say) individual PCTs, on the basis that Servier had not advanced a case expressed in formulaic terms (i.e. any PCT/Health Board in clearly defined circumstances X needed to carry out defined step Y). That was not a permissible approach. To suggest that Servier should have proceeded in that way in the absence of more extensive disclosure was unfair: how could Servier have framed detailed particulars of this type without knowing what steps PCTs/Health Boards with particular levels of ACEI prescribing had taken? The trial showed that what should have happened at the local level depended on local circumstances. The Judge was not, in the circumstances, entitled to conclude that *no* PCT/Health Board should reasonably have done more and so ought not simply to have given judgment for the claimants on the defences Servier was advancing. Servier, Mr Saunders said, should have an opportunity to examine whether particular PCTs/Health Boards which prescribed perindopril in larger quantities should have done more than they did. The exercise need not be all that onerous since sampling and/or other case management techniques can be used to limit what is involved.

42. During his reply submissions, Mr Saunders focused on use of ScriptSwitch by way of illustration. Echoing evidence given by Ms Kerr, he initially suggested that, where a GP practice already had ScriptSwitch, it was unreasonable for the relevant PCT not to use it to encourage the use of an ACEI other than perindopril. Reference having been made to Ms Kerr's recognition of the risk of "alert fatigue", Mr Saunders spoke of the need to install an appropriate prompt where a GP practice already had ScriptSwitch and the PCT was one with high perindopril spending.

43. One difficulty with these submissions is that the Judge stated in unqualified terms, in paragraph 369 of the Judgment, "I do not consider that it was unreasonable if the

medicines management team chose not to include alerts for perindopril on ScriptSwitch". The Judge did not therefore find merely that it was not unreasonable for *all* PCTs with ScriptSwitch not to include perindopril alerts. As I read the Judgment, it also involved the conclusion that *no* PCT was reasonably required to have such an alert.

44. Aside, however, from points such as that, there are more fundamental objections to Servier's appeal.

45. In *Fage UK Ltd v Chobani UK Ltd* [2014] EWCA Civ 5, [2014] FSR 29, at paragraph 114(ii), Lewison LJ observed in a much-quoted passage that a trial is "not a dress rehearsal" but "the first and last night of the show". That was as true of the trial of preliminary issues in these proceedings as it is of a full trial. The Judge noted in paragraph 389 of the Judgment that Servier's "alternative contention" involved preliminary issue (c) being "resolved in such a way as to allow the prescribing argument to proceed to trial, at least for 'higher' perindopril prescribing PCTs and Health Boards, so that they (or the various successor bodies to which their documents have passed) would provide disclosure to reveal what steps each of them took regarding ACEI prescribing, their individual assessment of their other priorities at the time, the resources and experience of their then medicines management teams, the extent of any opposition from local consultants to any proposal to discourage perindopril prescribing and any other reasons why they did not take various other steps which it is alleged they should have taken". On the face of it, however, the time to determine preliminary issue (c) was at the trial that had been ordered in respect of it, not at a future date after additional disclosure.

46. Of course, Servier was not in a position to conduct a PCT-by-PCT critique of the steps taken to discourage prescribing of perindopril at the trial. The Judge had expressly stated in the judgment he gave at the PTR on 4 May 2021 that the preliminary issues were "looking at the conduct of the claimants across the board" and were "not concerned with the conduct of particular PCTs, even if evidence from PCTs has been served as illustrative". Even, however, if the Judge had been willing to allow Servier to examine PCTs individually, Servier would not have been in a position to do so. Disclosure had been given in respect of only 11 of the numerous PCTs.

47. That this was the position should not, however, have come as any surprise to Servier. To the contrary, it reflected decisions made earlier in the litigation. In fact, the preliminary issues were directed *with a view to* obviating the need for disclosure as regards all the PCTs and SHAs. Thus, it can be seen from the transcript of the CMC on 22-23 January 2018 that the Judge was ordering the preliminary issues to be tried on the basis that they would not require extensive additional disclosure and, consistently with that, the order of 31 January 2018 provided for Servier's application for further disclosure to be adjourned pending the outcome of the trial of the preliminary issues. It was already evident at that stage, therefore, that the preliminary issues were to be tried without more disclosure and, hence, that the issues would not be assessed PCT by PCT. Servier nonetheless made no attempt to appeal the Judge's decision.

48. A year later, at the CMC on 18 January 2019, Servier argued against the trial of the preliminary issues proceeding. In doing so, moreover, it suggested that the Judge

might "conclude that some or all of the PCTs needed to take at least some steps to satisfy the duty to mitigate" and that he might find himself having to say, "We will need evidence from each PCT to even say what was reasonable". The Judge, however, declined to vacate the trial and clearly indicated that he considered that, if the claimants were successful on the preliminary issues, "the mitigation defence would fall away" and "massive and expensive disclosure by a whole series of public authorities" would be rendered unnecessary.

49. On this occasion, Servier asked the Judge for permission to appeal but, he having refused it, Servier did not renew its application before the Court of Appeal. The Judge's decision thus stood and, accordingly, it was apparent that the trial of the preliminary issues was to be undertaken without either disclosure from other PCTs or an examination of what was done PCT by PCT.

50. When, therefore, the Judge said in his judgment of 4 May 2021 that the "whole point" of the preliminary issues was "to avoid disclosure at the local level", he was saying no more than ought to have been obvious to Servier from previous decisions. It should also have been evident to Servier already that the trial would look at the conduct of the claimants "across the board", not at "the conduct of particular PCTs".

51. By this point, the trial was only about six weeks away. Even so, Servier could have tried to challenge by way of appeal the approach which the Judge had explained that he would be taking at the trial. It is by no means inconceivable that the Court of Appeal would, if necessary, have heard an appeal before the date fixed for the beginning of the trial. Be that as it may, however, the simple fact is that, come the trial, there was no question of Servier being entitled to require the Judge to assess what was done by individual PCTs or to defer the determination of any of the preliminary issues pending disclosure from more PCTs. Those boats had sailed. The Judge was in the circumstances amply entitled to consider that it was not "either proportionate, necessary or just to postpone an answer to the third issue to allow for detailed disclosure from individual PCTs and Health Boards" (to quote from paragraph 391 of the Judgment). As the Judge said in paragraph 13 of the PTA Decision, preliminary issues were ordered "as a means of proportionate case-management, whereas the course advocated by Servier would fly in the face of the overriding objective".

52. The fact that the preliminary issues were to be determined without more disclosure will not, as it seems to me, have prevented Servier from seeking to persuade the Judge that, if certain conditions were satisfied, a PCT ought reasonably to have taken a particular step. To revert to ScriptSwitch, for example, Servier might have proposed that a PCT where perindopril was prescribed to a specified value in a particular period should reasonably have used ScriptSwitch to encourage switching to another ACEI where GPs practices had it. Had the Judge accepted such standards, it would have been possible to apply them to relevant PCTs after the trial.

53. Paragraph 12 of the PTA Decision is relevant here. The Judge explained there that Servier's "alternative case" had been rejected because "Servier did not advance any clear criteria that could be used for the purpose of such identification". The Judge went on:

> "If Servier's case had been that steps should have been taken by any PCT/Health Board where more than, say, 40% of ACE prescribing was of perindopril for at least two consecutive years, then that would have put forward a general standard. It could have been addressed by the expert and factual witnesses and they could have been questioned to determine whether this was a reasonable or practicable standard. But Servier's case on this, raised only at trial, remained entirely vague."

54. Mr Saunders submitted that Servier was not in a position to frame such standards. I do not see, however, why this should have been the case. I should have thought that Servier ought to have been able to formulate standards that, on its case, the PCTs and Health Boards should have met without knowing what the PCTs and Health Boards had in fact done. Even, however, if that is wrong, the fact remains that the Judge's various pre-trial decisions, none of which was even the subject of an appeal, meant that Servier had to conduct the trial of the preliminary issues, and to prepare for it, on the basis that no further disclosure would be ordered.

55. In the circumstances, if it wished to contend that *some* PCTs/Health Boards should have taken *some* steps, it should have put forward standards by which their conduct could have been judged. Had it done so in good time, it would, as the Judge said, have been possible for expert and other evidence to be adduced in relation to them. In the event, however, not only did Servier not advance any such standards in sufficient time for evidence bearing on them to be prepared, it never did so. That being so, it cannot complain that the Judge did not rule on such standards.

56. In short, I do not consider that the Judge can fairly be criticised either for deciding preliminary issue (c) without awaiting further disclosure or for failing to rule on whether *some* PCTs/Health Boards should have taken *some* of the steps specified in Servier's defences. Not only had it been clear well in advance of the trial that the preliminary issues were to be determined without any more disclosure, but they were ordered in order to avoid such disclosure. Servier's contentions on this appeal thus run entirely counter to the basis on which the trial was directed and maintained. Moreover, although the Judge had made it plain that the preliminary issues would be addressed on a general basis rather than PCT by PCT, Servier did not put forward any standards by which the conduct of individual PCTs could subsequently have been assessed.

57. I would, accordingly, reject the main ground of appeal.

## The other grounds of appeal

58. Servier advanced two further grounds of appeal, relating to particular aspects of the Judge's conclusions on preliminary issues (a) and (b). It recognised, however, that these could not affect the outcome of the proceedings unless it also succeeded on its main ground of appeal. Since I have concluded that the main ground of appeal fails, I do not need to address the other grounds of appeal.

## Conclusion

59. I would dismiss the appeal.

## Lord Justice Nugee:

60. I agree.

## Sir Julian Flaux, Chancellor of the High Court:

61. I also agree.