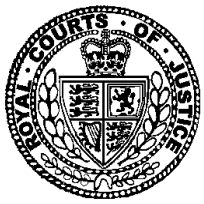

Neutral Citation Number: [2025] EWHC 2834 (Pat)

Case No: HP-2024-000037

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

Rolls Building
Fetter Lane
London, EC4A 1NL

5 November 2025

Before :

MICHAEL TAPPIN KC
(sitting as a Deputy Judge of the High Court)

- -

Between :

DR REDDY'S LABORATORIES (UK) LIMITED	**Claimant**
- and -	
BOEHRINGER INGELHEIM INTERNATIONAL GMBH	**Defendant**
- and -	
BOEHRINGER INGELHEIM LIMITED	**Proposed Part 20 Claimant**
- and -	
SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE	**Intervenor**

- -
- -

Mark Vanhegan KC and Christopher Hall (instructed by **Penningtons Manches Cooper LLP**) for the **Claimant**
Thomas Mitcheson KC, Edward Cronan and Thomas Lunt (instructed by **Kirkland & Ellis International LLP**) for the **Defendant** and the **Proposed Part 20 Claimant**
Andrew Lomas (instructed by the **Government Legal Department**) for the **Intervenor**

Hearing date: 24 October 2025

- -

Approved Judgment

I direct that no official shorthand note shall be taken of this judgment and that copies of the version as handed down may be treated as authentic.

This judgment was handed down at 2.00 pm on 5 November 2025 by circulation to the parties' representatives by email and release to The National Archives.

The Deputy Judge:

1. This is an application by the Defendant ("BI DE") for an interim injunction against the Claimant ("DR"). More specifically, BI DE seeks an order that DR shall not, until the form of order hearing following judgment after the trial of these proceedings, *"do or cause or procure others to do any of the following acts within the UK, namely: dispose of, sell or supply, offer to dispose of or offer for sale any medicinal product comprising the active ingredient empagliflozin"*. I granted permission to the Secretary of State for Health and Social Care ("the SSHSC") to intervene, serve evidence and make submissions.

2. Empagliflozin is an inhibitor of the sodium-dependent glucose co-transporter SGLT2. It is marketed in the UK by Boehringer Ingelheim Limited ("BI UK") in 10 mg and 25 mg tablet forms under the name Jardiance (it is also marketed in the form of various fixed dose combination products, but those can be ignored for the purpose of this application). BI DE is the holder of the UK marketing authorisations ("MAs") for Jardiance.

3. Jardiance was first approved for marketing in the UK in May 2014 for the treatment of type 2 diabetes ("T2D"). The MAs were extended in July 2021 to include the treatment of symptomatic chronic heart failure ("HF") with reduced ejection fraction and in June 2022 to include the treatment of HF regardless of ejection fraction. They were further extended in September 2023 to include the treatment of chronic kidney disease ("CKD").

4. BI DE was the proprietor of EP(UK) 1730131 ("EP131"), which was the patent claiming empagliflozin and its use to treat T2D. That patent expired on 10 March 2025 but SPC/GB14/070 ("the SPC"), which relates to empagliflozin and for which EP131 was the basic patent, does not expire until 26 November 2029. BI DE is also the proprietor of EP(UK) 1888552 ("EP552"), which claims a crystalline form of empagliflozin and is due to expire on 1 May 2026, and EP(UK) 2981255 ("EP255") which is due to expire on 2 April 2034. Claim 1 of EP 255 is to *"Empagliflozin for use in a method for preventing, reducing the risk of or delaying the occurrence of a cardiovascular event in a patient with type 2 or type 1 diabetes mellitus or with pre-diabetes comprising administering empagliflozin, optionally in combination with one or more other therapeutic substances, to the patient wherein said cardiovascular event is selected from cardiovascular death and heart failure requiring hospitalisation"*. BI DE also owns various other patents relating to empagliflozin, including one relating to its formulation and ones relating to other medical uses, which are not due to expire until dates between 2030 and 2034.

5. On 22 March 2024 DR first wrote to BI DE to say that it considered EP131, the SPC, and the claims of EP255 with which it was concerned, to be invalid. On 9 October 2024 DR issued the current proceedings, seeking revocation of EP131, the SPC and EP255. The claim form and accompanying pleadings were served on BI DE on 6 February 2025. BI DE served its Defence on 24 March 2025. On 12 May 2025 DR issued an application for a CMC. The CMC was held before Mellor J on 24 July 2025. The trial of DR's claim for revocation was fixed to be heard starting on 5 October 2026, with a total length of 17 days including 12 sitting days.

6. In correspondence in April 2024 DR said that it had no intention of launching any empagliflozin product until it had received an MA and any relevant market exclusivity period had expired. Marketing exclusivity expired on 22 May 2025, and on 13 May 2025 DR obtained MAs for empagliflozin (10 mg and 25 mg tablets) from the MHRA. Those MAs were published on the MHRA's website on 19 May 2025. They are "skinny label" MAs, with the "Therapeutic Indications" section referring only to the treatment of T2D and not to the treatment of HF or CKD. Some of the wording in DR's MAs led to complaints by BI DE which resulted in a revision of the wording in July 2025.

7. In May 2025 BI DE asked DR whether it intended to deal in empagliflozin products in the UK and, if so, when. DR did not answer that question, so on 19 June 2025 BI DE sought (i) a commitment from DR not to deal in empagliflozin products in the UK pending expiry of EP552 and in any event pending the first instance outcome in the revocation proceedings relating to EP131 and (ii) in any event, provision of 28 days' notice before dealing in empagliflozin products in the UK while EP552 and the SPC remained in force. DR did not respond directly to that request (other than to question the purpose of the reference to EP552). On 21 July 2025 it said that its launch plans for empagliflozin were still being discussed.

8. On 18 September 2025 DR gave 28 days' notice that it intended to commence sales of its empagliflozin products in the UK. That led to the current application being issued on 25 September 2025. It also led to BI DE seeking to amend its Defence to add a Counterclaim, not only in respect of the SPC and EP255, but also in respect of EP552; DR consented to those amendments.

9. In response to DR taking a point in its skeleton argument for this application that there was no proper evidence that BI DE, as opposed to BI UK, would suffer damage from sales of DR's empagliflozin products in the UK, BI DE sought to introduce BI UK as a Part 20 Claimant on the basis that it was an exclusive licensee under the relevant rights. Mr Vanhegan KC for DR indicated that he was not in a position to consent to that application because he could not take instructions, as the documents relied on in support of the contention that BI UK was an exclusive licensee had been designated as for external eyes only. However, he said that for the purposes of the interim injunction application matters should proceed on the basis that BI UK had an exclusive licence. Therefore I can ignore the distinction between BI DE and BI UK and I will refer to them collectively as "BI".

10. Undertakings were given by DR (and cross-undertakings given by BI) pending the hearing of this application. However, in the run-up to the hearing, DR indicated that it was not prepared to extend those undertakings after the date of the hearing. BI issued an application notice seeking an injunction pending the form of order hearing after judgment on its main application. When the matter came before me on 24 October 2025 DR agreed to continue its undertakings until 5 pm on the day my judgment was handed down, save that it was not prepared to undertake not to discuss the forthcoming availability of its empagliflozin products with potential customers. I decided that the carve-out from DR's undertakings meant that an injunction should be granted in the form sought by BI until 5 pm on the day my judgment was handed down.

11. Given that it was then after 5 pm on the day of the hearing, I said I would give reasons for that decision in this judgment. In brief, BI had explained in section 10 of its application notice that if DR was free to discuss its empagliflozin products with

potential customers that could lead to effects on the behaviour of BI's customers, in terms of either delaying orders in anticipation of availability of generic empagliflozin or using that as a negotiating tool on price. By contrast, DR had no evidence as to why it would suffer if it continued to be prevented from discussing its products with potential customers over the short period between the hearing and the hand down of judgment. In any event, in my view the right course was plainly to preserve the *status quo* for that short period.

12. Given that the injunction I had granted was to expire at 5 pm on the date of hand down of this judgment, it was necessary to hand this judgment down on a date on which a hearing could be arranged to deal with consequential matters. I had originally intended to hand down this judgment on 3 November 2025 but agreed to delay hand down to a date at which counsel could attend the hearing.

The dapagliflozin litigation

13. As will become apparent, DR's explanation for its decision to seek to launch its empagliflozin products now is tied to the dapagliflozin litigation, the impact that has had on the market for dapagliflozin in the UK and the impact that is expected to have on the market for empagliflozin. It will be necessary to examine the market impact in detail later, but it is helpful at this stage to set out an outline chronology of the dapagliflozin litigation and in particular its latter stages.

14. The claims for invalidation of the dapagliflozin SPC (based on invalidity of the basic patent) were commenced in October – December 2023. In early 2024 the claims were listed for trial in March 2025. I heard that trial between 10 and 20 March 2025 and handed down judgment on 28 April 2025, finding the SPC invalid.

15. Shortly before trial, Glenmark indicated its intention to launch its dapagliflozin products and AstraZeneca ("AZ") sought interim injunctive relief pending the form of order hearing after trial. I refused such relief for reasons given in a judgment on 28 March 2025. However, on 9 April 2025 the Court of Appeal heard an appeal against that judgment and indicated that the appeal was allowed. Its reasons for allowing the appeal were provided in a judgment handed down on 16 April 2025: [2025] EWCA Civ 480 ("*Dapa II CA*").

16. On 28 May 2025 HHJ Hacon handed down judgment giving his reasons for continuing the injunctions (by then, against not only Glenmark but also various other generic pharmaceutical companies) until after the appeal against my order declaring the SPC invalid: [2025] EWHC 1339 (Pat).

17. The Court of Appeal had expedited the appeal against my order declaring the SPC invalid. It heard the appeal on 25-26 June 2025 and handed down its judgment dismissing the appeal on 16 July 2025: [2025] EWCA Civ 903.

18. On that date the Court of Appeal also heard argument about whether the injunctions should be continued pending an application by AZ for permission to appeal to the Supreme Court. It granted injunctions until 30 July 2025, but no further. The Court of Appeal gave its full reasons for that course in its judgment dated 21 July 2025: [2025] EWCA Civ 924. The Court of Appeal explained that the application for permission to appeal had no real prospect of success because even if AZ were able to persuade the

Supreme Court that the correct standard was "*ab initio* implausibility" that would not assist it, because the patent in that case did not satisfy that standard. Further, the patent had been held invalid for a second reason, namely arbitrary selection, applying established principles. Therefore it was not necessary to consider the adequacy of damages or the balance of the risk of injustice. However, injunctions should be granted for a short period to allow the Supreme Court time to consider the case.

19. The Supreme Court extended the injunctions until 31 July 2025 but on that date refused permission to appeal. Therefore, on 31 July 2025 the dapagliflozin SPC was finally declared to be invalid and the injunctions came to an end.

The applicable principles

20. It was, of course, common ground that I should approach the application for an interim injunction applying the guidelines laid down by Lord Diplock in *American Cyanamid v Ethicon* [1975] AC 396. They were stated as follows by Arnold LJ in *Dapa II CA* at [18]:

> (1) Is there a serious question to be tried (or, in current terminology, does the claimant have a real prospect of success)? If not, no injunction should be granted.
>
> (2) Would damages be an adequate remedy for the claimant for the loss sustained pending trial as a result of the defendant continuing the acts complained of if the claimant were to succeed at trial in establishing its right to a permanent injunction? If they would, and the defendant would be in a financial position to pay those damages, then no injunction should normally be granted.
>
> (3) If not, would damages on the claimant's cross-undertaking be an adequate remedy for the defendant if the defendant were to succeed at trial in establishing its right to do acts which had been enjoined? If they would, and the claimant would be in a financial position to pay those damages, then an injunction should normally be granted.
>
> (4) Where there is doubt as to whether damages would be an adequate remedy for either side or both, where does the balance of convenience lie? This depends on all the circumstances of the case. Where other factors appear to be evenly balanced, it is a counsel of prudence to preserve the *status quo*. There may be special factors which need to be taken into account.

21. In relation to (2) and (3), DR emphasised what Floyd LJ said in *Neurim v Mylan* [2020] EWCA Civ 793 at [16]:

> "As the judge noted, when Lord Diplock spoke of damages being an "adequate" remedy, he was not suggesting that damages must provide a perfect remedy. As the judge also observed, there comes a point where "damages as a remedy falls so far short of the perfect, that the remedy can no longer be described as adequate." I agree with this. The boundary between the adequate and the inadequate is not a precise one. It is a matter for judicial evaluation on the evidence in any given case whether or not the boundary is crossed. If it is not crossed in relation to the claimant's loss then, normally, an injunction will not be granted."

22. The difficulty in ascertaining whether the boundary between the adequate and the inadequate has been crossed is illustrated by the judgments of the Court of Appeal at a later stage in the *Neurim v Mylan* litigation: [2022] EWCA Civ 370, referred to in *Dapa II CA* at [28]-[31]. Arnold LJ held that there had been no material change of circumstances and so damages would be an adequate remedy for the claimants, whereas Birss and Newey LJJ held that they would not (but the fact that damages would not be an adequate remedy for the defendants and the preservation of the *status quo* meant that the injunction should be refused). Birss LJ emphasised that just because a court can conduct a damages enquiry and arrive at a figure it regards as just does not mean that damages are an adequate remedy if the uncertainties are significant.

23. DR pointed out that in *American Cyanamid* at p.408, when speaking of preserving the *status quo*, Lord Diplock said (DR's emphasis):

> "Where other factors appear to be evenly balanced it is a counsel of prudence to take such measures as are calculated to preserve the *status quo*. If the defendant is enjoined temporarily from doing something that he has not done before, the only effect of the interlocutory injunction in the event of his succeeding at the trial is to postpone the date at which he is able to embark upon a course of action which he has not previously found it necessary to undertake…"

24. DR's submission, as I understood it, was that Lord Diplock's words mean that this approach only applies in cases where all relevant matters will remain the same until judgment after trial if an interim injunction is granted, and that if relevant matters will change before judgment after trial even if an interim injunction is granted it is no longer "a counsel of prudence" to grant an interim injunction if "other factors appear evenly balanced". However, DR did not cite any authority in support of such a proposition, and the preservation of the *status quo* is often taken into account even in cases in which relevant matters will have changed by the time of judgment after trial.

25. In *Dapa II CA* at [20] Arnold LJ cited the observation of Lord Hoffmann in *National Commercial Bank of Jamaica v Olint* [2009] UKPC 16 at [17]:

> "In practice, however, it is often hard to tell whether either damages or the cross-undertaking will be an adequate remedy and the court has to engage in trying to predict whether granting or withholding an injunction is more or less likely to cause irremediable prejudice (and to what extent) if it turns out that the injunction should not have been granted or withheld, as the case may be. The basic principle is that the court should take whichever course seems likely to cause the least irremediable prejudice to one party or the other. This is an assessment in which, as Lord Diplock said in the *American Cyanamid* case [1975] AC 396, 408:
>
> > 'It would be unwise to attempt even to list all the various matters which may need to be taken into consideration in deciding where the balance lies, let alone to suggest the relative weight to be given to them.'"

26. I have had that well in mind, along with what Lord Hoffmann said in the *Olint* case at [16]:

> "The purpose of such an injunction is to improve the chances of the court being able to do justice after a determination of the merits at the trial. At the

> interlocutory stage, the court must therefore assess whether granting or withholding an injunction is more likely to produce a just result."

27. BI referred me to what Arnold LJ said in *Dapa II CA* at [22]-[26]:

> "22. Over the last quarter of a century, a considerable number of interim injunctions have been granted in cases where a generic pharmaceutical company has launched a product at risk of patent infringement. This class of cases is distinguished by three factors in particular.
>
> 23. First, the entry of one generic company into a market which has hitherto been monopolised by the patentee is often (but not always) followed by the entry of one or more additional generic companies into that market. This is liable to lead to price-cutting by all the suppliers in order to build or maintain market share, and a resultant downward price spiral. The effect of this on the patentee is liable to be exacerbated, if it continues, by recategorisation of the product under the NHS Business Services Authority ("NHSBSA") Drug Tariff, which affects the reimbursement price of pharmaceuticals dispensed against prescriptions which do not specify a brand.
>
> 24. Secondly, the practical ability of the patentee to restore its previous price if successful at trial is generally constrained by NHS resistance to such price rises. Although in theory there is little to stop patentees raising their prices, at least in the absence of recategorisation, this would lead to a loss of goodwill which is generally regarded by patentees as unacceptable. So far as I am aware, there are very few, if any, cases in which a patentee, having cut its prices due to generic competition following the refusal of an interim injunction before trial, has successfully raised its prices back to where they were after having prevailed at trial. …
>
> 25. The first two factors can lead to the conclusion that damages will not be an adequate remedy for the claimant because of the uncertainty involved. It is usually the case that damages will not be an adequate remedy for the defendant either, however, because it will have no track record of selling the product in question to enable its lost sales to be quantified. Moreover, establishing the relevant counterfactual can be particularly difficult if it is either known or probable that other generic companies would have entered the market in the meantime, because then there will be uncertainty as to the extent to which the defendant would have benefitted from being the first generic entrant (e.g. by establishing relationships with customers for the product in question).
>
> 26. This leads to the third factor, which is that a generic company intending to launch a product at risk must first obtain an MA in order lawfully to be able to market its product and must have a source of supply of a product which has obtained all necessary regulatory approvals. This must be planned some time in advance. Furthermore, the generic company will usually be well aware of the risk of infringement. Typically, it will only launch at risk if it thinks it has a sufficiently strong case that the patent (or SPC) is invalid. In such circumstances the decision of this Court in *SmithKline Beech[am] plc v Apotex Europe Ltd* [2003] EWCA Civ 132, [2003] FSR 31 establishes that it is proper for a court to take into account, when considering the balance of the risk of injustice and

> deciding to preserve the status quo, that the generic company could have "cleared the path" for its launch by bringing proceedings for revocation of the patent sufficiently far in advance."

28. However, the question is whether those factors are present in this case. I agree with the submission of Mr Lomas for the SSHSC that one should not proceed on the basis of rebuttable presumptions, but on the evidence before the court in each case.

29. Carrying out the exercise required by *American Cyanamid* in pharmaceutical patent cases can be difficult because it involves assessing the likelihood of events happening in the future on each hypothesis that needs to be considered (injunction 'wrongly' granted and injunction 'wrongly' withheld). However, in many cases the period that needs to be considered is relatively short (often because it is common ground that the trial should be expedited regardless of whether an injunction is granted), and the market is a relatively stable one and will continue to be so in the absence of generic entry.

30. This case is very different. DR has now decided to launch its generic empagliflozin product at a time when the market for empagliflozin is likely to be about to change significantly in a manner which is unpredictable, even without generic entry. Moreover, it has done so having just agreed to a trial date in October 2026, meaning that it is necessary to consider what will happen during and after a period of about 14-15 months until the form of order hearing following judgment after the trial. That means that the uncertainties involved, and the difficulty in assessing whether granting or withholding an injunction is more likely to produce a just result, are increased.

The evidence

31. There was a considerable amount of evidence filed by the parties for this application (approximately 300 pages, excluding exhibits). There were witness statements from the solicitors on both sides (Mr Ooi for BI and Mr Curley for DR) and from commercial managers at their clients (Mr Humbert for BI and Ms Oberte for DR). The parties also served expert reports from economists / econometricians with experience of the pharmaceutical industry (Prof. Cookson for BI and Mr Potter for DR).

32. DR also served evidence from three pharmacists. Ms Alderson is the Prescribing Practice Pharmacist at Appleby Medical Practice, which is part of NHS North East and North Cumbria Integrated Care Board ("ICB"). Ms Kerr is a Commissioning Pharmacist at NHS Hampshire and Isle of Wight ICB. Mr White is an Integrated Care System Chief Pharmacist at NHS Lancashire and South Cumbria ICB. BI responded with evidence from three clinicians. Dr Colvin and Dr Lamba are GPs in North London while Dr McConnell is a GP in Leicester.

33. The evidence from the pharmacists and clinicians was in the form of witness statements which were not prepared in accordance with CPR Part 35. However, some of them strayed into giving opinion evidence about what they thought others would do in certain circumstances. I asked the parties what they said I should do with such evidence. Mr Vanhegan said that I should treat it like that of trade witnesses in trade mark cases and regard it as admissible but give it the weight I consider appropriate. Mr Mitcheson KC for BI did not demur. It is not necessary for me to decide whether that is right, because in the end the parties really relied on the fact evidence of the pharmacists and clinicians.

34. The SSHSC served a witness statement from Susan Grieve, who is head of the Medicines Framework and Reimbursement team within the Medicines Directorate in the Department of Health and Social Care ("the DHSC"). I should explain the background to that statement.

35. As can be seen from the judgment of HHJ Hacon in the dapagliflozin litigation at [73], the DHSC was concerned by the statement of Arnold LJ in *Dapa II CA* at [24] that *"the practical ability of the patentee to restore its previous price if successful at trial is generally constrained by NHS resistance to such price rises"* and by the related conclusion at [72] that if AZ reduced its actual prices it *"would have serious difficulty in raising them again"*. The DHSC wrote to HHJ Hacon to express concern that these paragraphs *"may reflect a misunderstanding, namely that obstacles would be raised to a price increase that would necessarily be difficult or even seriously difficult to overcome"*. Following developments at the hearing before HHJ Hacon, the DHSC wrote again (as can be seen from his judgment at [78]-[79]) to say that, while it was not submitting evidence to the court, it *"in no way accept[ed] that any NHS body would pursue a policy directed to deterring an originator drug company from restoring historic levels of actual selling and/or list prices, following an earlier reduction in the face of generic competition, that was sought to be reversed following the vindication of the originator's patent rights so as to eliminate that competition."* However, HHJ Hacon declined to place any weight on the letters from the DHSC, in the absence of evidence, for the reasons he explained in [113].

36. That led the DSHC to prepare a witness statement of Ms Grieve dated 2 July 2025, and a second witness statement dated 9 July 2025 in response to evidence submitted by AZ. Those statements were before the Court of Appeal at the hearing on 16 July 2025 (see [11] of its judgment of 21 July 2025) but in the event it was not necessary for the Court of Appeal to consider the adequacy of damages at that hearing for the reasons it explained.

37. The SSHSC has served a further witness statement from Ms Grieve in these proceedings, which exhibits her statements in the dapagliflozin litigation. Her statements contain a considerable amount of detail which it is not necessary to set out, but she expresses the broad intention of her evidence to be:

    i) to clarify the position of the DHSC regarding reversing of temporary reductions of list prices covered by the VPAG and approval of revised distribution arrangements;

    ii) to provide an explanation of how categorisation decisions are taken in relation to the listing of prices under Part VIIIA of the Drug Tariff;

    iii) to provide an explanation of the ways in which NHS bodies can properly influence prescribing decisions, and how they can and do react to changed positions on cost effectiveness;

    iv) to provide an explanation of prescriber decision-making autonomy – within that framework of proper influence by NHS bodies – and how prescribers can take into account the resourcing implications of their prescribing decisions.

38. In addition to providing those explanations, Ms Grieve makes a number of observations about how the dapagliflozin and empagliflozin markets may develop and how NHS bodies may respond to such developments, though without committing the DHSC to any particular course of action in any set of circumstances. I should add that Ms Grieve makes it clear that her evidence is not intended to cover commercial entities such as community pharmacies that might be regarded as part of the NHS in some respects or medicines wholesalers.

39. Ms Grieve says that the DHSC has no objection in principle to her statements being relied upon in applications for interim injunctions in pharmaceutical patent cases in future, subject to its consent being sought and sufficient notice being given (including enough time to allow any further clarificatory, responsive or updating evidence). She expresses the hope that by setting out the factual position as regards pricing and reimbursement the necessity for future interventions by the SSHSC will be precluded, or at the very least minimised. Ms Grieve's statements contain an extremely valuable account of the pricing and reimbursement system operated by the DHSC and in my view any court hearing an application for an interim injunction in a pharmaceutical patent case would benefit greatly from reading them.

The empagliflozin market and how it may develop

40. A major topic of debate in the evidence and at the hearing concerned the manner in which the UK market for empagliflozin may develop in the 14-15 month period from now until the form of order hearing following judgment after trial. A major plank of DR's argument on the adequacy of damages was that a very large part of the empagliflozin market (it said about 90%) will be lost to generic dapagliflozin in the next 3-9 months. That featured strongly in its arguments about why damages would be an inadequate remedy for it, and also in its arguments that damages would be an adequate remedy for BI, because (it said) there would be no other generic entrants to the market.

41. I shall start by considering the market up to the end of July 2025. For practical purposes there have for several years been three SGLT2 inhibitors on the market in the UK: Jardiance (empagliflozin), Forxiga (dapagliflozin) and Invokana (canagliflozin). There is a fourth SGLT2 inhibitor on the market (Steglatro, ertugliflozin) but its sales have been negligible. In July 2025 the Drug Tariff prices for Jardiance and Forxiga were identical (£36.59 per 28 tablet pack, regardless of dose) while that for Invokana was slightly higher at £39.20. The rate of generic prescribing of empagliflozin is essentially 100%.

42. The data show that empagliflozin reached its peak share of the UK market for SGLT2 inhibitors in 2020, at just under 50%, with dapagliflozin then accounting for about 35% of the market and canagliflozin just over 15%. Since then, dapagliflozin's share of the market has steadily increased and now stands at about 65%, with empagliflozin's share declining to just under 30% and that of canagliflozin reducing to about 5%. It seems that this change has been caused, at least in part, by the fact that indications for HF and CKD were added to the MAs for dapagliflozin significantly earlier than to those for the MAs for empagliflozin, while canagliflozin has never been authorised for those indications. However, there are significant regional variations in market share; in one ICB the empagliflozin market share is five times that in another ICB.

43. However, while empagliflozin's share of the SGLT2 inhibitor market has declined since 2020, total sales of empagliflozin have increased. That reflects a substantial growth in the market for SGLT2 inhibitors in that period. One reason for that growth was a revision to NICE guidance in June 2022 which recommended the use of SGLT2 inhibitors in a wider population. Mr Humbert said that there are currently about 500,000 patients using Jardiance in the UK, while Prof. Cookson said that 5 million packs of Jardiance were sold in England in the year to July 2025 (which equates to about 380,000 people, or about 450,000 people if the figure is extrapolated to the whole of the UK). The value of Jardiance UK sales in 2024 was about £150M.

44. On 20 August 2025 NICE announced draft guidance on the management of T2D in adults, intended to replace the June 2022 guidance. NICE described its proposals as the "biggest shake-up in type 2 diabetes care in a decade". The draft guidance promotes SGLT2 inhibitors from second-line to first-line treatments alongside metformin. It says that adult patients with T2D, or T2D and HF, should be offered metformin and an SGLT2 inhibitor, while adult patients with T2D and CKD should be offered either (i) metformin and either dapagliflozin or empagliflozin or (ii) either dapagliflozin or empagliflozin alone, depending on particular clinical factors. The draft guidance was subject to consultation, which I was told has now closed, and NICE is expected to publish its final guidance in February 2026. It was common ground between the parties that it is likely that NICE's final guidance will be similar to the draft guidance, and that the draft and final guidance are expected to lead to a further significant increase in prescriptions for SGLT2 inhibitors, though it is not predictable what that increase will be, or over what time period.

45. Mr Humbert of BI explained that, as a result of the NICE guidance, *"although there are clinical differences between the different SGLT2 inhibitors and their efficacy profiles, many clinicians in the UK currently (as a matter of prescribing practice) treat dapagliflozin and empagliflozin as direct therapeutic alternatives. This means that, in practice, dapagliflozin and empagliflozin are treated as interchangeable and thus there is an overall market for SGLT2 inhibitors in which dapagliflozin and empagliflozin are in commercial competition."*

46. As mentioned above, on 31 July 2025 the Supreme Court refused permission to appeal with the result that the interim injunctions preventing generic entry to the dapagliflozin market ceased. A number of generic dapagliflozin products were immediately launched. In response to this, in September 2025 dapagliflozin was moved from category C in the Drug Tariff to category M. The category M price was initially reduced to £25.89 for a pack of 5 mg tablets and to £30.15 for a pack of 10 mg tablets. From October 2025 the category M prices were reduced further to £15.05 for 5 mg tablets and £13.92 for 10 mg tablets. It was common ground that this rapid response to generic entry, with reclassification and a reduction in the reimbursement price outside the normal quarterly cycle, was exceptional and a result of the very significant cost savings to the NHS that could result. The expectation is that there will be further downward revisions to the category M reimbursement prices.

47. I was provided with the IQVIA data on SGLT2 prescriptions from the end of July until the start of October 2025. The numbers are confidential, but they show that there was initially a very substantial decline in the market share of Forxiga at the expense of generic dapagliflozin (though that decline appears now to have tailed off) while the market share of Jardiance has remained essentially constant.

48. However, on 6 October 2025 NHS England sent a letter to Regional Chief Pharmacists, Medical Directors and Primary Care Medical Directors and to ICB Chief Pharmacists, Medicines Optimisation Leads, Chief Finance Officers and Chief Medical Officers ("the 6 October letter"). The 6 October letter is headed "Optimising prescribing of SGLT2 inhibitors with generic dapagliflozin". It begins by identifying the clinical conditions for which SGLT2 inhibitors are indicated, noting that dapagliflozin is the most commonly prescribed SGLT2 inhibitor, followed by empagliflozin, and that the two drugs are considered by NICE to have similar clinical effectiveness.

49. After noting the outcome of the dapagliflozin litigation, the launch of generic dapagliflozin and the opportunity for savings by ensuring that prescriptions for dapagliflozin are written generically, the 6 October letter turns its attention to switching from other SGLT2 inhibitors to generic dapagliflozin (original emphasis):

> "Furthermore, depending on indication (Appendix 1), switching from other SGLT2is (empagliflozin, canagliflozin, ertugliflozin) to generic dapagliflozin also offers enhanced value, with an additional £266m estimated annualised cost avoidance possible from switching eligible patients to generic dapagliflozin, over a three-month period. Switching patients more gradually over 12 months reduces the estimated in year saving by £57m.
>
> The greatest volume of prescribing is in T2DM, and this is where initial focus is recommended. A second medical use patent has been granted for the use of dapagliflozin in the treatment of chronic kidney disease (CKD) in patients who do *not* have T2DM. This patent became effective from 17 September, and so, for the time being, treatment of CKD in *patients without T2DM* should be considered a patent protected indication.
>
> **We recommend that ICBs take the following action:**
>
> 1. **Update clinical pathways, guidelines, and formularies** to recommend generic dapagliflozin as the first-line SGLT2i for indications other than CKD in patients without T2DM, considering clinical appropriateness.
>
> 2. **Review potential savings opportunities** from switching other SGLT2is to generic dapagliflozin. A tool has been developed to support ICBs to estimate potential savings. By the end of 2025, metrics will also be available in ePACT2 to help monitor changes in prescribing to dapagliflozin for patients switched from another SGLT2i or for new initiations.
>
> 3. **Support switching in GP practices**, using proactive approaches (e.g. system searches) and reactive tools (e.g. prescribing pop-ups) to facilitate change.
>
> 4. **Assess and monitor SGLT2i uptake** - data from the National Diabetes Audit and CVDPREVENT suggests that fewer than 50% of people eligible for SGLT2is are currently prescribed these medicines. Take action to support quality improvement and ensure generic dapagliflozin is offered first-line where indicated and licensed.

> Clinical appropriateness should always be considered, and any switches should be discussed and agreed with patients through shared decision-making.
>
> We appreciate your continued efforts to improve outcomes and value in medicines optimisation. Please cascade this information to relevant teams and stakeholders within your system."

50. Appendix 1 identifies eligibility for generic dapagliflozin, as of 17 September 2025, for patients with T2D (including with other co-morbidities including HF and CKD) and for patients with HF. It says that patients with CKD without T2D are not eligible, due to the grant of the AZ patent for the use of dapagliflozin in patients with CKD who do not have T2D.

51. The tool referred to in recommendation 2 of the 6 October letter allows ICBs to enter their local figures for matters such as prevalence of T2D, growth rate of T2D and dapagliflozin market share or to use national default figures. It also allows them to enter a proposed start date for a switching programme and a figure for the proportion of patients to be switched to generic dapagliflozin. Once the necessary figures have been entered (or defaults used) the tool calculates the savings which could be made, depending on whether the switching programme is conducted over 3, 6, 9 or 12 months.

52. There was no evidence about whether the relevant NHS authorities in Scotland, Wales or Northern Ireland would be likely to take action similar to that taken by NHS England in the 6 October letter.

53. The parties were far apart in their assessments of the likely evolution of the market for empagliflozin in the period between now and December 2026. DR submitted that the evidence pointed towards the loss of 90% of the empagliflozin market to generic dapagliflozin within 3-9 months, as ICBs implement switching programmes following the recommendations set out in the 6 October letter. However, the source of the 90% figure was the default assumption in the tool accompanying the 6 October letter for the proportion of patients that would be switched as a result of a programme. However, the tool does not indicate the basis for the assumption that only 10% of patients would not be switched, nor provide information allowing an assessment of the validity of that assumption.

54. The first step that the 6 October letter recommends ICBs to take is to update clinical pathways, guidelines and formularies to recommend generic dapagliflozin as the first-line SGLT2 inhibitor (save for patients with CKD but not T2D), considering clinical appropriateness. The aim of this is to increase the proportion of new patients prescribed generic dapagliflozin. BI did not identify any reason why ICBs would not take relatively swift action to implement this recommendation; for example it did not suggest that it would involve significant resources. In fact 11 out of the 42 ICBs in England had, even before the 6 October letter, already listed dapagliflozin as the first-line SGLT2 inhibitor in their formularies, including the three ICBs from which DR's pharmacist witnesses come.

55. BI pointed out that, in those three ICBs, the listing of dapagliflozin as the first-line SGLT2 inhibitor does not appear to have led to a change in prescribing practice in favour of dapagliflozin at the expense of empagliflozin – the data show that the growth in prescriptions for each drug has continued at much the same rates in the case of each

of those ICBs. This does cast some doubt over the efficacy of updating formularies, but the 6 October letter additionally recommends updating clinical pathways and guidelines (which Prof. Cookson accepted could affect prescribing behaviour). Further, the data end in July 2025 and so do not show the effect of listing dapagliflozin as the first-line SGLT2 inhibitor at a time when the price of dapagliflozin is significantly lower than that of empagliflozin.

56. The 6 October letter also recommends ICBs to initiate switching programmes, including providing support to GP practices to facilitate change. The 6 October letter and the accompanying tool highlight the costs savings that can be achieved by a switching programme, and the increased savings that can be achieved by implementing a more rapid switching programme. However, initiating and supporting switching programmes will require ICBs to invest funds. Ms Kerr explained that there are significant costs pressures on ICBs with an instruction to reduce running costs by 50% by the end of 2025, which is expected to result in a large number of job losses, including in Medicines Optimisation teams. Each of the ICBs has its own budget to control, and each will have to make a decision about whether to invest the funds necessary to implement a switching programme and, if so, when and over what period. That is likely to depend on, amongst other things, the market share of empagliflozin in the area of the ICB in question. In addition, the NHS in England is in the process of being restructured. NHS England is to be abolished, and the 42 ICBs reorganised into 26. It is unclear to what extent, if at all, that will affect the actions of the ICBs over the next year or so.

57. Ms Kerr said that her ICB *"has not yet decided its approach, but I expect that we would aim to deliver the switch and try to get it completed within 3 months, starting in the first quarter of 2026."* Mr White said that the 6 October letter had reinforced his decision that in his ICB, which has a higher than average spend on empagliflozin, work should start in December 2025 on switching from empagliflozin to generic dapagliflozin. He said that he expected the switch to dapagliflozin to be largely completed in a few months or even sooner if specific incentives were offered to GPs (which, as I understand his evidence, he said would be done) and that he did not expect any significant resistance from GPs to a switch programme.

58. However, Ms Kerr and Mr White represent only two of the 42 ICBs. Ms Kerr acknowledged that the speed at which a switch can be achieved will vary across ICBs, depending on their resources and their potential savings. Mr White said that ICBs in financial surplus may decide to plan their switch programmes for early in the next financial year. All of this makes it very difficult to assess when ICBs will decide to implement a switching programme, and over what period. Mr Potter said he expected that *"most ICBs will set a plan to implement or consider some form of switching programme early in 2026"* and that *"many (if not most) ICBs will have initiated some switching activity, whether active or passive, before the trial is due to be heard in October 2026"*. That is very far from DR's submission that 90% of the empagliflozin market will have been lost in 3-9 months.

59. Further, as can be seen from the 6 October letter, switching requires a medical review of the patient by a GP. As Ms Alderson explained, while dapagliflozin and empagliflozin are to a large extent treated as being interchangeable, they are not bioequivalent and a medicines review of a patient on empagliflozin will always be needed to check that dapagliflozin is suitable for them, and the switch would only be

made once the patient had given informed consent. Accordingly, a switch requires GPs to invest time and resources in conducting such medical reviews, as well as patients to consent to being transferred to a different medicine.

60. BI questioned whether a switch programme could be conducted as rapidly or completely as Ms Kerr and Mr White suggested. It pointed out that Ms Kerr's evidence was that moving the 200 patients in her ICB on Forxiga onto generic dapagliflozin was a simple task, but yet it would take up to 3 months to achieve that for most of those patients. It also relied on Dr Lamba's evidence (seemingly based on experience of a switching programme relating to oral anticoagulants) that ICB-led switching programmes could take 1-2 years from identification of the need to switch to prescribing the new medication; BI also drew attention to his opposition to switching patients between different drugs for reasons of cost rather than for clinical reasons. BI also pointed to the example of a switch programme given by Ms Kerr, namely that involving switching patients from the oral anticoagulant Lixiana (edoxaban) to generic apixaban or rivaroxaban. The switch programme appears to have been initiated in March 2025 and Ms Kerr says that it was "largely completed within three months". However, the data show that as of August 2025 edoxaban prescriptions in Ms Kerr's ICB had decreased by only 40-50%. On the other hand, I do not have evidence about whether the degree of clinical equivalence between edoxaban and apixaban or rivaroxaban is the same as that between dapagliflozin and empagliflozin, and Mr Vanhegan pointed out that the guidance issued by the ICB did not mention a timescale for the switch programme.

61. BI also relied on the fact that doctors showed a low level of compliance with the NHS England guidance to prescribe by brand name (Lyrica) during the pregabalin litigation (full compliance would have suggested that about 70% of prescriptions should have been by brand name but in fact only about 25% were). However, as DR pointed out, that is not a good analogy, because the guidance was at the time unprecedented and required doctors to move away from a practice of generic prescribing which had been instilled in them, and because the only beneficiary of the guidance was Warner-Lambert rather than (as in the current case) the NHS.

62. BI also said that there were a number of factors that would tend to offset the effect of the introduction of generic dapagliflozin and the 6 October letter on the market for empagliflozin. First, it relied on the likely impact of the draft NICE guidance of August 2025, and the final guidance expected in February 2026, in increasing the size of the market for SGLT2 inhibitors (and dapagliflozin and empagliflozin in particular). Mr Humbert estimated that full implementation of the draft guidance would almost triple the size of the SGLT2 market. However, if ICBs implement the first recommendation in the 6 October letter effectively, most of those new patients are likely to be prescribed generic dapagliflozin.

63. Secondly, BI said that AZ had reduced (and/or would reduce) marketing support for dapagliflozin following generic entry, which would tend to reduce the growth of the dapagliflozin market and also provide BI with the opportunity to promote Jardiance without competition from AZ. Thirdly, BI said that it would continue its marketing efforts for Jardiance, including emphasising what it says are the benefits of empagliflozin over dapagliflozin in terms of cardioprotection. Dr Lamba gave evidence that such benefits were recognised in the medical community and they also appear to be recognised by the 2022 NICE guidance. Finally, BI noted that the grant to AZ of a

patent for the use of empagliflozin in patients with CKD but not T2D had the potential to disrupt the generic dapagliflozin market. I agree that each of these factors has the potential to offset some of the effect on the empagliflozin market that is likely to result from implementation of the recommendations in the 6 October letter.

64. Given the number of factors involved, and the uncertainties involved in each of them, it is very hard to assess how the market for empagliflozin will evolve over the next 14-15 months. However, in my judgment DR's contention that 90% of the empagliflozin market will have disappeared in the next 3-9 months is unlikely to be correct. While it seems likely that most new SGLT2 patients will be prescribed dapagliflozin, I am not persuaded on the evidence before me (see in particular paragraph 58 above) that most switching programmes will be implemented and completed within the next 9 months, and the level of success that those programmes will achieve (taking into account the factors in paragraph 63 above) is not at all clear. Further, it must be remembered that the market for empagliflozin was about £150M in 2024. The market will remain a substantial one even if there is a significant decrease in its size over the coming months.

DR's plans

65. DR's plans for its empagliflozin products are confidential (and have been designated for external eyes only). I believe it is sufficient to record that Ms Oberte said that the price would be within a range which was fairly narrow and fairly close to the price of Jardiance. Further, she set out the distribution channels which DR intended to supply and identified the share of the empagliflozin market which DR expected to achieve and the time frame within which it expected to achieve that.

66. Ms Oberte did not suggest that DR had any intention of trying to achieve a greater market share, or of decreasing its price relative to the price of Jardiance, at any point between now and judgment after trial. Conversely, BI did not suggest that DR was likely to have any difficulty in achieving the market share it proposed, within the stated time frame, with a price in the range which Ms Oberte had given, at least in the absence of further generic competition. While DR's plans were designated for external eyes only and so Mr Humbert was unable to comment on them, Prof. Cookson, with his experience of the industry, did not suggest that DR was likely to have any difficulty achieving its stated objectives.

Possible further generic competition

67. Another major debate between the parties, in their evidence and at the hearing, was whether there was a likelihood of other companies being ready and willing to launch generic empagliflozin in the UK in the next 14-15 months.

68. Until just before the hearing, DR was the only company with UK MAs for generic empagliflozin. However, on 22 October 2025 Medreich was granted MAs by the MHRA. Ms Oberte gave a number of reasons why she did not expect Medreich to launch a generic empagliflozin product in the UK before trial, including that they were primarily a contract manufacturer, only sold older pharmaceutical products for which patent protection had expired, had never been engaged in patent litigation in the UK, and had obtained MAs which included HF and CKD indications notwithstanding BI's patent portfolio, so that a launch would expose them to a significant level of litigation risk. Mr Mitcheson informed me that BI had been in contact with Medreich through its

solicitors and had been assured that there was no imminent threat to infringe. While Medreich's position could change, I regard the reasons given by Ms Oberte as strongly pointing away from any threat by Medreich to launch a generic empagliflozin product at risk into the UK market.

69. BI pointed out that there were eight companies with MAs for generic empagliflozin products in various EU member states, namely Devatis, Huahai, Medochemie, Polpharma, Adalvo, 089PHARM, Denk and KRKA. Mr Humbert said that the MAs could be converted into UK MAs within as little as 5½ months under the international recognition procedure, and that such a conversion might already be underway. Ms Oberte did not dispute the fact that conversion of an EU MA to a UK MA could be achieved within 5½ months. She said it was common for the MHRA to ask questions which caused delays of 1-3 months, but Mr Humbert said that was not common for applications under the international recognition procedure, and backed that up with statistics published in the Pharmaceutical Journal.

70. Ms Oberte pointed out that, in addition to obtaining a UK MA, a company would need to procure packaging material based on the artwork approved by the MHRA, obtain manufactured drug product and conduct testing and batch release. She said that if conducted sequentially those steps would take 5 months. Overall, therefore, she said the process of converting an EU MA to a UK MA and being ready to launch product would take 10½ months, though it might be possible to carry out steps in parallel and reduce the time to 7-9 months. Mr Humbert said that even that was unduly long and assumed proceeding at an unusually slow speed.

71. Ms Oberte also pointed out that unless a company sourced its empagliflozin from one of the manufacturers specified in the EU MAs, it would need to find a source of supply in bulk. However, Mr Humbert noted that there were over 30 companies supplying generic empagliflozin in India, indicating that sources of supply were available. Further, Mr Ooi exhibited a IPD Analytics list of empagliflozin suppliers which showed that there were a large number of commercial suppliers with certification from the EMA and FDA, including a well-known supplier of generic pharmaceutical products in the UK.

72. More importantly, Ms Oberte also gave reasons why each of the companies with an EU MA was unlikely to launch a generic empagliflozin product at risk in the UK. In brief (and without being comprehensive): Devatis, Huahai, Medochemie and Denk do not appear to have UK operations capable of doing so, nor do they have any track record of UK patent litigation; Polpharma/089PHARM and Aldavo operate as dossier licensing companies rather than selling products in the UK; while KRKA has a UK operation and has in the past been engaged in UK patent litigation, it is cautious about litigation risk in the major EU markets and its manufacturing site is in Slovenia where there is an SPC based on EP131 in force. In my view, the reasons given by Ms Oberte are generally persuasive, though less so in the case of KRKA.

73. In any event, even if the companies with EU MAs are unlikely to launch a generic empagliflozin product in the UK before trial (though as I say I am doubtful that Ms Oberte's reasons allow KRKA to be discounted) that does not mean that other generic companies will not be prepared to do so (either having developed their own dossier or having licensed it, albeit at a cost, from another company). Because there is no visibility of applications to the MHRA before MAs are granted, it is impossible to

know whether there are applications (whether under the international recognition procedure or otherwise) in the pipeline.

74. BI pointed out that Teva, Sandoz, Zentiva, STADA and Generics UK have each opposed EP255 (as well as other BI patents relating to empagliflozin formulation and medical uses) and said that indicated their interest in generic empagliflozin. Mr Ooi says that representatives of Pinsent Masons and Taylor Wessing, who have in the past acted for one or more of those companies, observed the CMC before Mellor J and requested copies of BI's skeleton arguments and evidence. Mr Mitcheson informed me that a representative of Teva was attending the hearing before me. However, it is not possible to draw an inference from these facts that any of these companies has applied for a UK MA, or will be ready and willing to launch a generic empagliflozin product at risk in the UK in the next 14-15 months.

75. However, it is also not possible to draw the inference that they will not be, as DR suggested, based on the fact that they have not joined this litigation or notified BI of their intention to launch a product. It is quite possible that they are monitoring DR's conduct of this litigation, and the outcome of this application, before deciding whether to break cover. For example, as BI points out, Sandoz did not join the dapagliflozin litigation nor notify AZ of its intention to launch a generic dapagliflozin product, but nevertheless did so the day after my trial judgment was handed down in that case.

76. DR submitted that *"the effect of the decreasing empagliflozin market is that within ~6 months it will no longer be commercially attractive for third party generic entry"*. It said that that, *"coupled with the reality that it is likely to take several months to obtain a UK MA, means it will be commercially unattractive for any third party to enter the market 'at risk' before trial."*

77. As I have said, I regard DR's prediction about the speed and extent of the decline in the empagliflozin market as likely to be overstated. Further, as I have said, the market was worth £150M in 2024. Even if the market has declined significantly in about 6 months, I do not accept that that will not present a commercially attractive option for further generic competitors. In addition, I do not agree that it can be assumed that it will take any other generic company several months to obtain a UK MA – indeed they may well have applications in the pipeline. It is of course possible that some generic competitors will take a different view to DR about the risk of launching while EP552 is in force, but there is still a considerable period between the expiry of EP552 and judgment after trial.

78. For these reasons, it is not safe to assume, as DR suggested, that if no injunction is granted it would be the only generic supplier of empagliflozin in the UK until judgment after trial. It is entirely possible that it will be, but there is a real risk that it will not be and that other generics will enter the market, either before or after the expiry of EP552.

79. Mr Vanhegan referred to what Floyd LJ said in the first *Neurim v Mylan* judgment at [46] and submitted that it was necessary to conclude that further generic entry was likely rather than merely possible before it could be taken into account. I do not think Floyd LJ was laying down such a hard and fast rule. The context of Floyd LJ's comments were that the period in question was only four months, Teva was prevented from launching and the claimants' own evidence was that other generic companies were unlikely to enter the market before patent expiry.

80. Here, DR has agreed to a trial in October 2026 and then decided to launch its product now into a market which, while likely to decline, will still be attractive for generic pharmaceutical companies in the 14-15 months under consideration. In those circumstances I do not believe it can be right to ignore the risk of further generic entry just because it is not possible now to identify a company which has (or has applied for) a UK MA and is (or soon will be) ready to enter the market. Further, I do not believe that it is possible or useful to try to assess the percentage chances of each possible outcome; instead I think that the right approach is to consider the questions of whether each party will suffer irreparable harm on the basis of each hypothesis (further generic entry or not).

Serious issue to be tried

81. It was common ground that there was a serious issue to be tried on the validity of the SPC (though as I understood it there is no issue about whether it will be infringed if it is valid).

82. DR accepted that there was a serious issue to be tried about infringement of the crystalline form patent EP552 (indeed, as BI noted, it accepted that within two days of being asked whether it admitted that its product fell within the scope of protection of EP552). Mr Mitcheson went so far as to submit that in the absence of evidence from DR that its product did not infringe EP552 I should conclude that it does. However, there is no evidence from BI that the product does infringe EP552 (DR has not yet provided a sample) and so I reject that submission. DR has not yet put validity of EP552 in issue.

83. It was also common ground that there were serious issues to be tried as to the validity and the infringement of EP255.

84. Often the fact that there are a multitude of possible outcomes in a multi-patent case (so that some patents may be held valid and others invalid, and some infringed and others not) may not affect the range of possible commercial outcomes – it may well be that the overall result will either be that the product in issue can be freely marketed, or it cannot and damages will be payable on all sales made. However, in this case it occurred to me that it might be necessary to consider the scenario in which the SPC is invalid and EP255 is valid and has to some extent been infringed so as to render DR liable for damages. (For these purposes, the outcome on infringement and, if raised, validity of EP552 can be left to one side because there will in any event be at least a period, after 1 May 2026, when there is no protection from EP552.)

85. I say EP255 "has to some extent been infringed so as to render DR liable for damages" because I have in mind that it is possible that a court will hold that some but not all supplies of DR's generic empagliflozin under its skinny label MA are infringements of the claims of EP255 that render DR liable to pay damages. BI's pleaded case of infringement advances various arguments for direct infringement, including outward presentation and both objective and subjective intention that more than a *de minimis* proportion of the product will be used for the claimed purposes, as well as an indirect infringement case. The requirements for infringement of purpose-limited product claims such as those of EP255 have not yet been established by the courts (indeed even the requirements for infringement of Swiss-form claims have been left uncertain by the judgments of the Supreme Court in the *Warner-Lambert* case) and there has been

debate about the scope of relief that should result when a product is in fact used for indications outside the scope of a medical use claim as well as ones within its scope.

86. As I say, it occurred to me that it might be necessary to examine this scenario and to consider whether it might lead to either party suffering irreparable harm, and I asked the parties to address me on that. Mr Vanhegan said that the scenario should not be considered because it involved getting into the merits, but I do not agree. It merely involves recognising that various outcomes of the litigation are possible, and identifying one as giving rise to a factor that should be taken into account when considering irreparable harm to one or both parties.

Would damages be an adequate remedy for BI?

87. DR submitted that BI's damages as a result of DR's presence on the market could be calculated on the basis that every sale of its generic empagliflozin products was a sale lost to BI, i.e. a 1:1 basis. It said that BI's damages were simply the product of DR's sales and BI's profit margin.

88. However, when I posed the scenario outlined in paragraphs 84-85 above, Mr Vanhegan said that he would not accept that DR had to pay damages for infringement of EP255 on all of its sales of empagliflozin. Further, it was clear from the evidence and discussion before me that there is going to be substantial argument about the proportion of empagliflozin patients to which the medical use in the claims of EP255 is relevant. Both parties referred to an October 2024 NICE epidemiological report. DR pointed out that it showed that only 8.4% of T2D patients had HF and Ms Oberte used that number to claim that only 0.63% of T2D patients had HF and were being prescribed empagliflozin. BI pointed out that the NICE report showed that 92% of T2D patients had HF or were at risk of HF and Mr Humbert said that Ms Oberte had not applied scaling factors correctly (including by double-counting). This illustrates, to my mind, that on one potential outcome of the litigation and view of the law it will be very hard to assess BI's damages.

89. DR said that if no other company were to launch a generic empagliflozin product, then, given the nature of its launch plans (see above), there was no real risk of BI reducing its list or actual prices. Mr Mitcheson did not suggest otherwise, so I shall proceed on that basis.

90. However, for the reasons I have explained above, in my judgment there is a real risk of further companies launching generic empagliflozin products before judgment after trial. Prof. Cookson explained that in such a situation he would expect the price of the generic products to spiral downwards within a few months, with the decrease in prices being faster and further the more generic competitors enter the market (though the effect would be greater if the generic competitors had full labels rather than skinny ones) and that BI would be forced to discount its prices to retain market share. Mr Potter did not dispute that (his report was prepared on the assumption that DR would be the only generic company on the market). Mr Vanhegan suggested that Prof. Cookson's evidence was that there would be no price spiral unless there were four or more competitors in the market. I do not read his evidence that way – I read it as saying that there is an inverse correlation between price and the number of generic entrants and that when there are four or more competitors the price spiral will be rapid.

91. Prof. Cookson also explained that while initially empagliflozin would remain in Category C of the Drug Tariff, multiple generic entry would be likely to lead to recategorisation into Category A or Category M. While the timing of such a recategorisation was uncertain, he pointed to the speed at which the DHSC had moved to recategorise dapagliflozin on multiple generic entry, given the size and value of that market. In my judgment, there is a substantial risk that, in the event of multiple generic entry, there will be a recategorisation of empagliflozin in the period before judgment after trial.

92. In the light of Ms Grieve's evidence, BI did not contend that there would be any resistance on the part of the DHSC to recategorisation of empagliflozin to Category C if it was successful at trial. Nor did it argue that there would be a loss of goodwill if it sought to increase its prices again. Rather, it contended that there would be a "budget shock" to the NHS if BI sought to raise its prices to current levels, which would lead to increased pressure for switching empagliflozin patients to dapagliflozin. Mr Humbert said that meant that in practice BI would not be able to restore its prices to current levels after trial.

93. Ms Grieve agreed with Prof. Cookson's evidence that the greater the price difference between dapagliflozin and empagliflozin, the greater was the incentive for the NHS to encourage switching from empagliflozin to dapagliflozin. Mr Lomas pointed out that the SSHSC had power to find the money needed to address a cost increase (which, as Ms Grieve explained, would be managed by NHS England). But he was careful not to give the impression that the existence of that power meant that it would be exercised. He said that it might well be that the NHS sought to engage in a negotiation.

94. Therefore I conclude that, if empagliflozin is recategorised, there is a substantial risk that it will in practice be impossible for BI to return its prices to current levels. That will have long-term implications and it will not be possible to calculate with any degree of confidence the damage that will have been caused to BI, as that will involve projecting a market (which is likely to be still in flux) several years into the future.

95. BI also contended that the fact that DR's empagliflozin products are to be marketed under a skinny label may well affect the prescribing behaviour of clinicians, either driving them away from empagliflozin towards dapagliflozin or encouraging prescription of Jardiance by brand name, if a patient has or is at risk of developing HF and/or CKD.

96. If the skinny label of DR's empagliflozin would encourage clinicians to prescribe Jardiance by brand name for such patients, then that would not result in irreparable harm to BI – quite the opposite. The argument depends on clinicians prescribing dapagliflozin rather than empagliflozin because of DR's skinny label.

97. BI advanced essentially two reasons why that could happen. First, it was said that clinicians could be concerned about off-label use if they wrote a prescription for empagliflozin knowing that DR's label was a skinny one (and it was said that prescribing software might alert prescribers to that fact). Secondly, it was said that patients with (or at risk of developing) HF and/or CKD who had been told about the cardiorenal protective properties of empagliflozin might be concerned if they received a medicine in which the patient information leaflet did not mention HF or CKD indications.

98. There was extensive evidence on this argument, including from DR's pharmacists and BI's clinicians. However, the support for the argument even amongst BI's clinicians was not strong. Dr McConnell said that only astute patients would even notice the difference in the labels, and that she may not have noticed unless it had been drawn to her attention. Dr Lamba said that he would not switch a patient to dapagliflozin as a result of the skinny label on DR's product. Dr Colvin said he would be concerned about off-label prescribing, but also said that he would be unlikely to know about the skinny label unless it had been drawn to his attention.

99. Further, the premise on which the clinicians gave their evidence was that the dapagliflozin products on the market all had full labels. That was critical to the argument, because if that was not the case, any concern on the part of the clinician or patient about DR's skinny label would not be alleviated by writing a prescription for dapagliflozin.

100. Ms Oberte's evidence was that Glenmark and Amarox both had skinny label MAs for dapagliflozin. There was no evidence that Amarox has dapagliflozin products on the market in the UK. Glenmark does, but there was a dispute in the evidence as to whether its product was being marketed under a skinny label or not (it also had a full label MA). Ms Oberte asserted that there had been skinny label dapagliflozin products on the market in the UK since the start of August 2025. Mr Humbert responded by saying it would not make sense for Glenmark to be selling under a skinny label when its competitors were selling under a full label, and that he had checked with some of BI's pharmacy partners *"who have indicated that they do not have the option to order a skinny label of Glenmark's product"*.

101. DR's riposte was to produce an IPD Analytics report of 22 August 2025 which stated that *"most generic dapagliflozin products in the UK are indicated for all three indications, whereas at least one competitor in the UK (Glenmark) markets its generic dapagliflozin for T2DM only."* Further, Ms Oberte noted that Mr Humbert had not explained the circumstances of the pharmacy partners he referred to. Also, she pointed out that Glenmark had a good reason for selling under a skinny label, namely the forthcoming grant of AZ's patent for the use of dapagliflozin for CKD without T2D. Further, her evidence, based on information from Mr Curley, was that two of the existing suppliers of generic dapagliflozin had applied to vary their MAs to remove the CKD indication.

102. Overall, I was not persuaded that there was any real substance to this argument. Doing the best I can on the evidence before me, it appears likely that there is, or soon will be, generic dapagliflozin on the market under a skinny label. If there are concerns amongst clinicians about off-label use or amongst patients about the absence of indications from the patient information leaflet, that will not be solved by prescribing dapagliflozin.

103. BI's final heads of irreparable harm related to the impact that it was said that generic entry would have on jobs, its product pipeline and its partnership programmes. Mr Humbert said that it would not be possible to retain all its existing staff engaged in the supply of Jardiance in the UK for the next 15 months unless BI retained exclusivity in the empagliflozin market. He said that loss of talented and experienced staff would have knock-on effects, including diminished capacity to support patients and healthcare providers, loss of staff who would be needed to support supplies of Jardiance if BI was successful at trial, and reduced ability to support its planned launch of its vicadrostat-

empagliflozin combination product. Finally, he said that BI would be forced to seriously consider its investments in NHS partnerships and would be likely to cancel at least some of them, because it would not be commercially viable to bear the costs of clinician education and training, improvement of patient pathways and management of testing and diagnosis in circumstances where a significant proportion of the investment would be for the benefit of generic empagliflozin suppliers. Cancellation of such programmes, he said, would be to the detriment of patients.

104. Ms Oberte said that BI would probably have to consider staffing levels in any event given the competition from generic dapagliflozin and pointed out that vicadrostat was currently in phase III trials and might never be approved, so it was too early to make plans for launch of a combination product. She did not comment on the likelihood of partnership programmes being cancelled. Mr Humbert responded by saying that BI was indeed considering redundancies in the light of the genericisation of the dapagliflozin market but not at the level that would be required if there was generic entry to the empagliflozin market, and that BI had indeed been planning for the potential launch of the combination product.

105. Mr Vanhegan referred me to what was said about similar kinds of arguments in the first *Neurim v Mylan* case. In particular Floyd LJ said at [37] that such arguments should be examined with a critical eye, and went on to reject them at [48]-[49]. However, each case must turn on the facts and the evidence, and in *Neurim v Mylan* a key factor was that the period of generic competition being considered was only four months, compared to the two years of remaining protection. If the investments in that case were justified by the remaining protection, it was hard to see why they would cease to be justified by loss of exclusivity (to a single generic) for a period of four months. Further, the claimants had the funds needed to continue the investment over the period of four months.

106. No doubt inspired by that latter point, Mr Vanhegan pointed out that BI had ample funds to continue employing staff and funding programmes. That is no doubt true, but that does not mean that it makes commercial sense for a company to spend its money in that way, especially when it is faced with a period of 14-15 months of generic competition. As Mr Humbert said: *"The rationale is that the revenues generated by Jardiance allow these projects to continue, so, where revenues are uncertain, it is not commercially viable to continue expensive projects and investment in a market that is no longer served by Jardiance"*. While I have considered it critically, I am not able to reject Mr Humbert's evidence, though in my judgment the likelihood of BI having to make redundancies and cancel partnership programmes is less if DR is the only generic competitor (given the nature of its plans, to which Mr Humbert was not privy) than if there is multiple generic entry. But in either case it may be difficult to determine the extent to which such steps were the result of competition from generic empagliflozin competition rather than generic dapagliflozin.

107. Overall, for these reasons, I cannot conclude that damages would be an adequate remedy for BI if it turns out that the injunction sought should have been granted.

Would damages be an adequate remedy for DR?

108. DR submitted that, if injuncted, it would not be possible to use its sales after judgment as a proxy for its sales in the period from now until judgment, because by then the

market would be very different. I agree with that.

109. However, as I have said, DR did not suggest that it had any intention of trying to achieve a greater market share than that identified by Ms Oberte, or of decreasing its price relative to the price of Jardiance, at any point between now and judgment after trial. Conversely, as I have said, BI did not suggest that DR was likely to have any difficulty in achieving the market share it proposed, within the stated time frame, with a price in the range which Ms Oberte had given, at least in the absence of further generic competition.

110. That means that it should be possible to quantify the lost sales of DR reasonably accurately, at least in the absence of generic competition. After trial the size of the empagliflozin market over the period to judgment will be known, as will the price of Jardiance. DR's actual proposed price and its expected market share (with which BI did not take issue) can be applied to those figures. I should record that my view as to the balance of the risk of injustice has been arrived at on that basis.

111. However, in the event that the SPC is held to be invalid and EP255 to be valid then (at least for the period from 1 May 2026 when EP552 expires) it is possible that the court will conclude that, while sales under DR's skinny label would infringe EP255 to some extent, an injunction preventing DR from selling any generic empagliflozin was too broad given the scope of protection of EP255. For similar reasons to those given when considering the opposite side of the coin in 87 above, it will be very difficult to assess the magnitude of the damage suffered by DR as a result.

112. Moreover, if there is further generic competition (and I have concluded that there is a real risk that there will be) matters become more complex. DR did not say that it would not adjust its price if (contrary to its position about what would happen) further generic empagliflozin products came onto the market. Nor did BI accept that DR would obtain (or retain) the market share it anticipated in such circumstances. It will be very difficult to ascertain with any confidence what sales DR would have made, at what price, in such circumstances.

113. Further, unless there are further generic companies ready to launch a product imminently in the UK (which seems unlikely given that the only company with a UK MA at present is Medreich), if DR is injuncted it will lose its first mover advantage in the generic empagliflozin market. It will be denied the opportunity to build up relationships with traders in its targeted distribution channels and it will be very difficult to assess the value of that lost opportunity.

114. For these reasons, I am not able to conclude that damages under the cross-undertaking would be an adequate remedy for DR if it turns out that the injunction sought should not have been granted.

Balance of the risk of injustice

115. For the reasons I have explained above, I cannot say that damages will be an adequate remedy for either party. Moreover, this is not a case in which the size or likelihood of the unquantifiable harm, or the uncertainties involved in assessing it, can be seen to be greater for one party than the other. Just looking at those factors does not allow me to

identify which course is likely to cause the least irremediable prejudice and is more likely to produce a just result.

116. However, the *status quo* favours the grant of an injunction. I also have in mind what Arnold LJ said in *Dapa II CA* at [26], quoted above, namely that *"it is proper for a court to take into account, when considering the balance of the risk of injustice and deciding to preserve the status quo, that the generic company could have "cleared the path" for its launch by bringing proceedings for revocation of the patent sufficiently far in advance."*

117. In the present case, despite the huge amount of evidence, there is almost no evidence from DR to explain its conduct of this litigation. To recap, DR first wrote to BI on 22 March 2024 alleging invalidity of EP131, the SPC and EP255. In April 2024 BI stated that it would not launch generic empagliflozin in the UK until it had an MA and relevant marketing exclusivity periods had expired. Marketing exclusivity was due to expire in May 2025 and DR appears to have timed its MA applications accordingly, with the MAs being granted the same month. However, there is nothing in DR's conduct of this litigation or its statements about its plans to suggest that it ever intended to launch a product on expiry of marketing exclusivity.

118. The claim form was issued on 9 October 2024 and served on 6 February 2025. BI's Defence was filed on 24 March 2025, an application for a CMC was issued on 12 May 2025 and the CMC was fixed by consent for 24 July 2025. DR did not seek a trial listing in advance of the CMC nor did it apply for expedition. In April 2025 DR proposed a split trial, with the trial of EP131 and the SPC earlier than that of EP255 (a possibility which BI raised in its Defence). However, BI rejected that proposal (albeit not finally until June 2025) and DR ultimately agreed on 17 July 2025 to a trial of all issues in October 2026. Mr Vanhegan said that it did so because BI's solicitors were saying that there was a realistic prospect that the Supreme Court would grant permission to appeal in the dapagliflozin case. Maybe that was so, despite the Court of Appeal's explanation at the hearing on 16 July of why permission to appeal was being refused (and the Supreme Court's refusal of permission to appeal in the apixaban case), but equally there was a realistic prospect that it would refuse permission. Finally, as I have mentioned above, on 21 July 2025 DR said that its launch plans for its generic empagliflozin product were still being discussed.

119. In his third statement (his first for the purpose of this application) Mr Ooi set out the chronology which I have outlined above. He said that the timeline of the litigation was leisurely and suggested that DR had either not decided whether to launch a generic empagliflozin product in the UK or that any launch plans were some way into the future. Otherwise, he said, he would have expected DR to have commenced proceedings sooner, progressed them more expeditiously and have fought for an earlier trial date. As Mr Mitcheson observed, if DR had moved with expedition from March 2024 it would have been possible to have had a trial by now. Mr Ooi also drew attention to the fact that DR had not challenged the validity of EP552 (despite the fact that it accepts that there is a serious issue to be tried regarding its infringement) and said that suggested that DR had not planned to launch a generic empagliflozin product until after the expiry of EP552 in May 2026.

120. There was no real attempt in DR's evidence to grapple with these points. Mr Curley points to without prejudice discussions taking place between October 2024 and January

2025. But that can only explain the delay in serving the claim form, and in any event the decision to issue proceedings but not serve them is a commercial and/or litigation decision (perhaps in the hope of obtaining a favourable settlement without alerting other generic companies).

121. Ms Oberte, having referred to the end of the dapagliflozin litigation on 31 July 2025 and the genericisation of the market, says that DR *"has been following this case and the impact of it on the market very closely. Our strategy with respect to empagliflozin has been led by these developments."* She adds that *"bearing in mind that many of our competitors were focussed on launching generic forms of dapagliflozin at the beginning of August 2025"* DR *"decided to take what might be considered a counterintuitive business move and focus instead on empagliflozin"*. It is not clear from this evidence what DR's intentions were with respect to empagliflozin prior to the start of August 2025. However, in the absence of any direct response to the challenge laid down by Mr Ooi, based on DR's conduct of this litigation I can only infer that Mr Ooi's assessment is correct and until at least August 2025 DR had not intended to launch its generic empagliflozin products in the UK until at least after expiry of EP552 on 1 May 2026 and probably not until after judgment at a trial on the SPC and EP255.

122. It seems clear that DR has been closely following the progress of the dapagliflozin litigation and that it was the dapagliflozin market becoming generic at the start of August 2025 that has prompted its change of position. However, that does not mean that what Arnold LJ said in *Dapa II CA* at [26] ceases to apply – indeed in that case Glenmark had also changed its plans as regards timing of its launch.

123. Further, what remains unexplained is why DR appears to have failed to prepare for the possibility of the dapagliflozin market becoming generic and adapted its litigation strategy accordingly. It must have been apparent to DR from the outset that if the dapagliflozin revocation claims succeeded, the dapagliflozin market would become generic. It was known in early 2024 that the trial in the dapagliflozin case would be heard in March 2025 and it was entirely possible that an appeal could be determined by the Court of Appeal before the end of 2025 even if it was not expedited. By the end of March 2025 it was known that Glenmark wished to launch a generic dapagliflozin product and it was therefore likely that, regardless of the outcome of AZ's application for interim injunctive relief and of the trial, an appeal against my trial judgment would be expedited. By the end of April 2025 my judgment finding the dapagliflozin SPC invalid was available and in May the appeal was expedited to be heard in late June. It must have been increasingly apparent to DR that there was a real prospect of the dapagliflozin market becoming generic and that that could happen rapidly. Yet it did not fight for an early trial date, even of the validity of the SPC.

124. Mr Mitcheson reminded me that EP552 provided BI with a basis to seek an interim injunction until 1 May 2026 and invited to me to consider what the reaction of the court would have been to a move by DR to come onto the market for the last six months of the life of EP552 without having even issued a claim for its revocation. That is a fair forensic point, but the question facing me is a different one, namely whether I should injunct DR until the form of order hearing following the trial in October 2026.

125. DR relied on the observation by Roth J in *Novartis v Teva* [2022] EWHC 959 (Ch) at [79] that, just as the failure by a generic to clear the way counts in favour of the grant of an interim injunction, so too *"conduct by a patentee by way of repeated divisional*

filings and amendments to prolong the patenting process with the consequence that generics cannot effectively seek to clear the way is relevant as a factor against the grant of interim relief." Mr Vanhegan said that BI had a "patent thicket" which made clearing the way a "practical impossibility", and in particular he complained about BI's failure to alert DR as to the potential significance of EP552, which he said BI had a "moral obligation" to do.

126. I do not agree that this case is anything like the situation which Roth J had in mind (though it may be possible to clear the way in a case like that by use of the *Arrow* declaration jurisdiction). Nor do I agree that the onus was on BI to alert DR about the potential relevance of EP552. First, DR said in its first letter to BI in March 2024 that it was aware of other BI patents relating to empagliflozin and as then advised took no position in relation to them. Indeed, Mr Ooi points out that DR challenged the Canadian equivalent of EP552. Secondly, DR was in a better position than BI to know what crystalline form of empagliflozin was in the products which it intended to launch in the UK. As to the "practical impossibility" of clearing the "patent thicket", I do not know whether any of BI's other patents are relevant to DR's plans, but in any event it has plainly decided that it is worth seeking to clear the SPC and EP255 out of the way, but not to challenge those other patents.

127. Overall, I conclude that the preservation of the *status quo* coupled with DR's failure to take effective steps to clear the way mean that the injunction sought by BI should be granted. DR should not be allowed to rely on a foreseeable change in the empagliflozin market caused by genericisation of the dapagliflozin market to justify a change in its plans to the detriment of BI.