

Neutral Citation Number: [2025] EWCA Civ 924

Case No: CA-2025-001040-A

IN THE COURT OF APPEAL (CIVIL DIVISION)

ON APPEAL FROM THE HIGH COURT OF JUSTICE, BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES, INTELLECTUAL PROPERTY LIST (Ch), PATENTS COURT

Royal Courts of Justice

Strand, London, WC2A 2LL

Date: 21 July 2025

**Before :**

LORD JUSTICE ARNOLD

LORD JUSTICE STUART-SMITH
and

LADY JUSTICE ANDREWS

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**Between :**

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|  | 1. **ASTRAZENECA AB**
2. **ASTRAZENECA UK LIMITED**
 | Applicants  |
|  | **- and -** |  |
|  | 1. **GENERICS (U.K.) LIMITED**
2. **TEVA PHARMACEUTICAL INDUSTRIES LIMITED AND TEVA UK LIMITED**
3. **GLENMARK PHARMACEUTICALS EUROPE LIMITED**
4. **SANDOZ LIMITED**
5. **BESTWAY PHARMACY NDC LIMITED**

 **- and -**  | Respondents |
|  | **SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE** | **Intervenor** |
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**Geoffrey Pritchard KC, Thomas Lunt and Dheemanth Vangimalla** (instructed by **Freshfields LLP**) for the **Applicants**

**Mark Vanhegan KC and Adam Gamsa** (instructed by **Taylor Wessing LLP**) for **Viatris**

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**James Abrahams KC** (instructed by **Powell Gilbert LLP)** for **Glenmark**

**Jeff Chapman KC and Simon Paul** (instructed by **Pinsent Masons LLP**) for **Sandoz and Bestway**

**Jonathan Moss** (instructed by the **Government Legal Department**) for the **Secretary of State for Health and Social Care**

Hearing date : 16 July 2025

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Approved Judgment

This judgment was handed down remotely at 10.30am on 21 July 2025 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

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**Lord Justice Arnold:**

Introduction

1. On 16 July 2025 this Court (Peter Jackson LJ, Stuart-Smith LJ and myself) handed down judgments ([2025] EWCA Civ 903) dismissing an appeal by the Defendant (“AstraZeneca”) against an order made by Dr Michael Tappin KC sitting as a Deputy High Court Judge revoking UK Supplementary Protection Certificates Nos. SPC/GB13/021 and SPC/GB14/050 (“the SPCs”) on the ground that the patent upon which they were based, European Patent (UK) No. 1 506 211 (“the Patent”), was invalid for the reasons given in his judgment dated 28 April 2025 ([2025] EWHC 1012 (Pat)). The claims of the Patent relate to a compound called dapagliflozin, marketed by AstraZeneca under the trade mark Forxiga, which is used to treat diabetes and other conditions. The Court refused AstraZeneca permission to appeal to the Supreme Court on the ground that there was no arguable point of law which would enable AstraZeneca to succeed on an appeal.
2. Before knowing those decisions, AstraZeneca (and its subsidiary AstraZeneca UK Ltd, which is a party to the infringement proceedings referred to below, but whose involvement I shall not mention again) had made a precautionary application for an interim injunction to restrain the Claimants (“Viatris”, “Teva” and “Glenmark”) and two other respondents (“Sandoz” and “Bestway”) from marketing generic dapagliflozin until the determination by the Supreme Court either of an appeal, or an application for permission to appeal, by AstraZeneca. In the light of the Court’s decisions, AstraZeneca concentrated its application on the second of those alternatives. Having heard argument on that application, the present constitution of the Court announced that the application would be refused, but nevertheless granted an interim injunction until 4pm on 30 July 2025, for reasons which were briefly outlined orally, but to be explained more fully in writing later. This judgment sets out my reasons for reaching that conclusion. It also explains why, in reaching that conclusion, we declined to hear full oral argument on adequacy of damages. Although the reasons can be stated reasonably succinctly, in the interests of transparency I shall explain the procedural background in a little detail.

Procedural background

1. Viatris, Teva and Glenmark brought claims for revocation of the SPCs on 9 October, 24 November and 21 December 2023 respectively. No application was made for expedition of the trial of these claims, and they were listed for trial in March 2025. The trial was heard by Dr Tappin KC between 10 and 20 March 2025, and judgment was reserved.
2. On 20 February 2025 Glenmark notified AstraZeneca that it had obtained a marketing authorisation for a generic dapagliflozin product and was prepared to launch that product “at risk” (i.e. to take the risk that AstraZeneca would bring proceedings for infringement of the SPCs and the consequences which that might entail) on 17 March 2025. On 6 March 2025 AstraZeneca applied for an interim injunction to restrain Glenmark from marketing dapagliflozin until the conclusion of the form of order hearing after the delivery of the judgment, and subsequently it commenced infringement proceedings. The first date on which it proved feasible for the judge to hear the application was 27 March 2025. Glenmark gave an undertaking not to market its product prior to the determination of the application in return for a cross-undertaking in damages from AstraZeneca. The judge refused the application for the reasons given in his judgment of 28 March 2025 ([2025] EWHC 748 (Pat)), but on 9 April 2025 this Court (Coulson LJ, Warby LJ and myself) allowed AstraZeneca’s appeal for the reasons given in judgments handed down on 16 April 2025 ([2025] EWCA Civ 480).
3. In the meantime it had become clear that Teva and Viatris were also preparing to launch generic dapagliflozin products. AstraZeneca commenced infringement proceedings against Teva and Viatris, and obtained undertakings from Teva and Viatris that they would not launch prior to judgment on the revocation claims, again subject to the usual cross-undertakings.
4. On 1 May 2025 AstraZeneca applied to Dr Tappin KC for permission to appeal against his decision to revoke the SPC, having already applied for an interim injunction to restrain Glenmark, Teva and Viatris from marketing dapagliflozin until the determination of the appeal on 29 April 2025. Dr Tappin KC subsequently granted AstraZeneca permission to appeal. The application for an interim injunction was adjourned, with undertakings being given in the meantime, and in due course came before HHJ Hacon sitting as a High Court Judge.
5. In the meantime Sandoz launched a generic dapagliflozin product immediately after the revocation judgment was handed down, and supplied 75,000 packs of it to Bestway, which Bestway started selling on 29 April 2025. On 30 April 2025 AstraZeneca applied for an interim injunction against Sandoz and Bestway, which led to Sandoz and Bestway giving similar undertakings to those which had been given by Glenmark, Teva and Viatris. Most of the product sold by Bestway was recalled.
6. By the time of the hearing before Judge Hacon, I had expedited the substantive appeal and it had been listed for hearing on 25 and 26 June 2025. On 28 May 2025 Judge Hacon granted the injunction sought by AstraZeneca against Glenmark, Teva, Viatris, Sandoz and Bestway until the determination of the appeal for the reasons given in his judgment of that date ([2025] EWHC 1339 (Pat)).
7. Glenmark, Teva, Viatris, Sandoz and Bestway all applied for permission to appeal against Judge Hacon’s order. On 13 June 2025 I refused all five applications to appeal on the grounds that the appeals had no real prospect of success and there was no other compelling reason to hear them (on the contrary, the imminence of the substantive appeal was a compelling reason not to hear the appeals unless they had a real prospect of success). I included the following direction in my order:

“The parties should discuss with each other their respective plans with respect to an application for permission to appeal to the Supreme Court, and an application for an injunction or stay of an injunction pending the determination of that application, in advance of the hearing on 25 and 26 June 2025, and should make enquiries with the Court of Appeal List Office as to when in July 2025 any such application could be heard. Preparations should be made to enable the Court to deal with any such application in an orderly fashion.”

1. This led to 16 July 2025 being identified as a date by which the substantive judgments on the appeal should be available and which would be convenient for the hearing of any such application, and to a timetable for the filing of evidence being directed. On 25 June 2025 AstraZeneca filed an application notice for the relief described in paragraph 2 above. Glenmark, Teva and Viatris subsequently notified AstraZeneca that, if the appeal were to be allowed, they would not seek a stay of a final injunction pending an appeal to, or application for permission to appeal to, the Supreme Court.
2. On 3 July 2025 I granted the Secretary of State for Health and Social Care (“the SSHSC”) permission to intervene in the application and to file evidence 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 SSHSC is neutral with respect to AstraZeneca’s application, but is concerned that, in paragraphs 24 and 73 of my judgment of 16 April 2025, this Court misunderstood the position of the National Health Service with respect to price rises by patentees (and SPC holders). It is not appropriate to comment on that concern, but it is nevertheless worth recording, because it is often misunderstood, an important point made by Ms Grieve, which is that “the NHS is not a body; it is a service, in the provision of which many different public bodies have different roles, often circumscribed by statute”. NHS England is, at present, one of these bodies, but there are many others. The SSHSC also has an interest as a beneficiary of the various cross-undertakings given by AstraZeneca.
3. In the run-up to the hearing on 16 July 2025, Sandoz and Bestway pointed out that there was a potential jurisdictional problem in that, although they were respondents to AstraZeneca’s application dated 25 June 2025, they were not parties to the revocation proceedings and hence would not be parties to any application by AstraZeneca for permission to appeal to the Supreme Court. This problem was resolved partly by Sandoz and Bestway helpfully undertaking to be bound by the outcome of the application against Glenmark, Teva and Viatris and partly by my granting Sandoz and Bestway permission to intervene if and to the extent necessary. At the hearing Glenmark, Teva, Viatris, Sandoz and Bestway presented a united front in opposing AstraZeneca’s application.
4. It should be appreciated that Glenmark, Teva, Viatris and Sandoz are not the only generic pharmaceutical companies interested in the dapagliflozin market. 12 other companies currently hold marketing authorisations for generic dapagliflozin products, 11 of which are for dapagliflozin monotherapy. It is not known how close any of them may be to launching dapagliflozin products, but all have given undertakings or assurances to AstraZeneca not to launch for so long as Glenmark, Teva, Viatris, Sandoz and Bestway are enjoined. The reason for all this interest is not hard to discern. Dapagliflozin is currently AstraZeneca’s biggest-selling product in the UK. The current sales volume is around 1 million packs per month, worth over £400 million per annum, and sales are increasing.
5. It will be understood that, as at 16 July 2025, the status quo was that, by virtue of the interim injunctions and undertakings previously granted or given, AstraZeneca retained its monopoly of the dapagliflozin market in the UK. Although Glenmark, Teva, Viatris and Sandoz were all ready to launch generic dapagliflozin products, they had been prevented from doing so.
6. The final point to note is that the evidence filed by both sides for the purposes of the present application was predicated upon the assumptions that: (i) determination by the Supreme Court of an application by AstraZeneca for permission to appeal would take between three and six months from 16 July 2025; and (ii) if permission were granted, determination of the appeal would take between 15 and 23 months from 16 July 2025.

Applicable principles

1. Although this Court has dismissed AstraZeneca’s appeal, there is no dispute that it retains jurisdiction, as a court of equity, to grant an injunction where it is just and convenient to do so, including an interim injunction until the determination of an appeal by AstraZeneca to the Supreme Court, or, failing that, an application by AstraZeneca to the Supreme Court for permission to appeal, or, failing that, an application by AstraZeneca to the Supreme Court for an interim injunction pending the determination of its application for permission to appeal.
2. Although we are concerned with a prospective appeal from this Court to the Supreme Court, I consider that the applicable principles mirror those which apply to an appeal from the High Court to this Court. The fundamental principle is that the court should, as far as possible, “so arrange matters that, [if and] when the appeal comes to be heard, the appellate court may be able to do justice between the parties”: *Minnesota Mining and Manufacturing Co v Johnson & Johnson Ltd* [1976] RPC 671 at 676 (Buckley LJ, my interpolation).
3. In *Novartis AG v Hospira UK Ltd* [2013] EWCA Civ 583, [2014] 1 WLR 1264, Floyd LJ said at [41]:

“I would summarise the principles which apply to the grant of an interim injunction pending appeal where the claimant has lost at first instance as follows. (1) The court must be satisfied that the appeal has a real prospect of success. (2) If the court is satisfied that there is a real prospect of success on appeal, it will not usually be useful to attempt to form a view as to how much stronger the prospects of appeal are, or to attempt to give weight to that view in assessing the balance of convenience. (3) It does not follow automatically from the fact that an interim injunction has or would have been granted pre-trial that an injunction pending appeal should be granted. The court must assess all the relevant circumstances following judgment, including the period of time before any appeal is likely to be heard and the balance of hardship to each party if an injunction is refused or granted. (4) The grant of an injunction is not limited to the case where its refusal would render an appeal nugatory. Such a case merely represents the extreme end of a spectrum of possible factual situations in which the injustice to one side is balanced against the injustice to the other. (5) As in the case of the stay of a permanent injunction which would otherwise be granted to a successful claimant, the court should endeavour to arrange matters so that the Court of Appeal is best able to do justice between the parties once the appeal has been heard.”

1. Although Floyd LJ did not say so in this paragraph, it can be seen from his reasoning in the rest of his judgment, and from the cases to which he referred, that, in considering “the balance of hardship” in cases of this kind, the court should normally adopt the approach set out by Lord Diplock in *American Cyanamid Co v Ethicon Ltd* [1975] AC 396 at 407G-409D. I discussed this, and its application to cases concerning pharmaceutical patents, in my judgment of 16 April 2025 at [18]-[36].

Application to the present case

1. In my judgment AstraZeneca’s application for an interim injunction pending the determination of an appeal to the Supreme Court should be refused because an appeal has no real prospect of success, and its application for an interim injunction pending the determination of an application to the Supreme Court for permission to appeal should be refused because that application has no real prospect of success. As stated above, there is no arguable point of law that would enable AstraZeneca to succeed on an appeal. Even if AstraZeneca were able to persuade the Supreme Court that the correct standard for plausibility is the “*ab initio* implausibility” standard, that would not avail AstraZeneca because the Patent does not satisfy even that standard. Furthermore, arbitrary selection is an independent objection to the validity of the Patent. Dr Tappin KC held that the Patent was invalid for that reason applying established principles, and this Court has affirmed that decision.
2. Because there is no real prospect of success, which in this context equates to there being no serious issue to be tried for the purposes of the *American Cyanamid* approach, it is not necessary to consider the rival arguments on adequacy of damages or on the overall balance of the risk of injustice.
3. Although I would refuse AstraZeneca’s application for the reasons given in paragraph 20 above, that is not the end of the matter. This Court must allow for the possibility that we are mistaken in our assessment of AstraZeneca’s prospects of success, and in particular its prospects of success in obtaining permission to appeal from the Supreme Court. In my judgment it is just and convenient to grant AstraZeneca an interim injunction for a period of 14 days to enable AstraZeneca to make an urgent application to the Supreme Court. Not only is the Supreme Court best placed to determine whether AstraZeneca’s application for permission to appeal has a real prospect of success, but also the Supreme Court alone has power to decide whether expedition of the application is warranted, and if so what measure of expedition should be applied.
4. Glenmark, Teva, Viatris, Sandoz and Bestway argued that no interim injunction should be granted, even for so short a period as 14 days, because: (i) damages would be an adequate remedy for AstraZeneca; (ii) even if they would not, damages would be an even less adequate remedy for Glenmark, Teva, Viatris, Sandoz and Bestway; and (iii) the overall balance of the risk of injustice favoured refusal of an injunction.
5. We declined to hear full oral argument on points (i) and (ii). My reasons for taking that course are as follows. First, none of the evidence (or, consequentially, the arguments in the parties’ skeleton arguments) addressed this time period. Glenmark, Teva, Viatris, Sandoz and Bestway argued that this necessarily meant that AstraZeneca must fail, because it had failed to address this possibility in its evidence. I disagree, because the blind spot was common to all parties. Furthermore, it is doubtful that it would realistically have been possible for the parties to produce robust evidence as to the likely effects of the grant or refusal of an injunction for such a short period of time.
6. Secondly, and perhaps more importantly, I do not consider that it is appropriate for this Court to undertake the exercise urged upon it by Glenmark, Teva, Viatris, Sandoz and Bestway in any event. In granting an injunction for 14 days, this Court is doing no more than preserving the status quo for a short further period in order to enable the Supreme Court to make whatever order it deems just and convenient. As at 9 April 2025 this Court, and as at 28 May 2025 Judge Hacon, considered that the balance of the risk of injustice favoured the grant of interim injunctions. It can be seen from both judgments that an important factor was preservation of the status quo. If the hearing of the substantive appeal had been listed only seven days later than it was, and if the preparation of the judgments following that hearing had taken only seven days longer than it did, the injunction granted by Judge Hacon would have run for 14 days longer than it in fact did. In these circumstances the decision to grant AstraZeneca an injunction for a further 14 days cannot require the determination of highly contested issues as to adequacy of damages, particularly in circumstances where the evidence is insufficiently granular to enable any realistic assessment to be made of whether the effects contended for on either side will manifest themselves over so short a period. Accordingly, the overriding consideration must be to hold the ring by preserving the status quo for a further 14 days to enable the Supreme Court to make whatever order it considers just and convenient.
7. As for point (iii), Glenmark, Teva, Viatris, Sandoz and Bestway relied upon the relative merits of the parties’ cases, and in particular the fact that AstraZeneca has lost twice, as being decisive if the balance of the risk of injustice was otherwise even. It can be seen from my reasoning in paragraph 20 that I agree that this Court’s assessment of the merits of AstraZeneca’s intended application to the Supreme Court for permission to appeal leads to the conclusion that no interim injunction should be granted pending the determination of that application. As explained in paragraph 22 above, however, we must allow for the possibility that our assessment is mistaken. Thus our view of the merits cannot be a bar to the grant of an interim injunction for 14 days if that is otherwise appropriate.

**Lord Justice Stuart-Smith:**

1. I agree.

**Lady Justice Andrews:**

1. I also agree.