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

7 Rolls Building
Fetter Lane, London
EC4A 1NL

Date: 30th July 2021

Before:

MR JUSTICE ZACAROLI

Between:

(1) DR REDDY'S LABORATORIES (UK LIMITED) **(2) ACTAVIS GROUP PTC EHF** **(3) ACCORD-UK LIMITED** **(formerly Actavis UK Limited)** **(4) BALKANPHARMA DUPNITSA AD** **(a company registered under the laws of Bulgaria)** **(5) ACTAVIS INTERNATIONAL LIMITED** **(a company registered under the laws of Malta)** **(6) SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE** **(7) NHS ENGLAND** **(8) THE WELSH MINISTERS** **(9) THE DEPARTMENT OF HEALTH, SOCIAL SERVICES AND PUBLIC SAFETY FOR NORTHERN IRELAND** **(10) THE REGIONAL HEALTH AND SOCIAL CARE BOARD** **(11) THE SCOTTISH MINISTERS** **(12-25) THE SCOTTISH HEALTH BOARDS** **(26) RANBAXY (UK) LIMITED** **(27) SANDOZ GMBH** **(28) SANDOZ LIMITED** **(29) SANDOZ AG** **(30) HEXAL AG** **(31) TEVA UK LIMITED** **(32) PLIVA HRVATSKA D.O.O.** **(a company organised and existing under the laws of Croatia)** **(33) TEVA API INDIA PRIVATE LIMITED** **(a company organised and existing under the laws of India)** **(34) TEVA OPERATIONS POLAND SP Z.O.O.** **(a company organised and existing under the laws of Poland)** **(35) PLUS CHEMICALS, BRANCH OF TEVA PHARMACEUTICALS INTERNATIONAL GMBH** **(a company organised and existing under the laws of Switzerland)**	**Inquiry Claimants**

- and -

(1) WARNER-LAMBERT COMPANY LLC **(2) PFIZER LIMITED**	**Inquiry Defendants**

Brian Nicholson QC and Christopher Hall (instructed by **Mishcon de Reya LLP**) for Dr Reddy's

Andrew Lykiardopoulos QC and David Scannell QC (instructed **by Powell Gilbert LLP**) for Actavis and (instructed by **Pinsent Masons LLP**) for Teva

Philip Moser QC, Brendan McGurk and Alice Hart (instructed by **Government Legal Department**) for NHS England, Wales and Northern Ireland

Douglas Campbell QC and Ligia Osepciu (instructed by **Reynolds Porter Chamberlain LLP**) for NHS Scotland

Benet Brandreth QC (instructed by **HGF Law LLP**) for Ranbaxy

Richard Boulton QC, Charlotte May QC, Tim Goldfarb, Tim Austen and Thomas Lunt (instructed by **Kirkland & Ellis (International) LLP**) for the Warner-Lambert Company LLC and Pfizer Limited

Hearing dates: 14, 15, 16 and 17 June 2021

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APPROVED JUDGMENT

Covid-19 Protocol: This judgment is handed down remotely by circulation to the parties' representatives by email, release to BAILII and publication on the Courts and Tribunals Judiciary website. The date and time for hand-down is deemed to be NB 10:30 AM on 30th July 2021.

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MR JUSTICE ZACAROLI

Mr Justice Zacaroli:

Introduction

1. This is the trial of preliminary issues (ordered by Birss J on 18 December 2020) in claims by numerous parties (together the "Inquiry Claimants") for compensation under cross-undertakings in damages given in respect of various interlocutory injunctions or contractual undertakings, and for damages in respect of threats of infringement proceedings pursuant to section 70(1) of the Patents Act 1977.

2. It raises the question as to the appropriate assumptions to make when identifying the relevant counterfactual(s) for the purposes of determining such compensation and damages, where different parties have claims under different cross-undertakings and threats, given or made on different occasions, but relating to the same patent and where all parties operate in the same (largely finite) market.

Background

3. The background to this matter is fully explained in the judgment of the Supreme Court dated 14 November 2018 in *Warner-Lambert v Generics (UK) Ltd (t/a Mylan)* [2018] UKSC 56, and the judgment of Arnold J at first instance in the same case dated 10 September 2015 ([2015] EWHC 2548 (Pat)). I set out here only the background that is directly relevant to the preliminary issues.

4. The first inquiry defendant, Warner-Lambert Company LLC, was the registered proprietor of European Patent No. 0 641 330 for Isobutylgaba, of which pregabalin is a derivative, for the treatment of seizure disorders, notably epilepsy and general anxiety disorder ("GAD"). The second inquiry defendant, Pfizer Limited, was the holder of the relevant marketing authorisation for "Lyrica", the branded pregabalin medicine marketed in the UK. I will refer to the inquiry defendants together as "Pfizer". This patent expired in the United Kingdom on 17 May 2013.

5. Pfizer is also the proprietor of a second medical use European Patent (UK) No. 0 934 061 with claims in Swiss form (explained at paragraphs 2-3 of the Supreme Court judgment referred to above), directed exclusively to the use of pregabalin for treating pain (the "Patent"). The Patent had a priority date of 24 July 1996 and expired on 16 July 2017. Notwithstanding the fact that the Patent covered pain of various descriptions, Pfizer has only ever been authorised to market pregabalin for the treatment of neuropathic pain.

6. The Inquiry Claimants are predominantly pharmaceutical companies mainly engaged in marketing generic pharmaceutical products ("Generics"). Upon expiry of EP No. 0 641 330 and the subsequent expiry in July 2014 of data exclusivity for Lyrica, Generics were free to apply, broadly speaking, for a marketing authorisation for pregabalin for use in treating epilepsy and GAD. The parties have used the following terms to refer to different forms of marketing authorisation:

skinny label: marketing authorisation indicated for the treatment of epilepsy and GAD, but not neuropathic pain;

full label: marketing authorisation indicated for the treatment of epilepsy, GAD and neuropathic pain;

intermediate label: marketing authorisation indicated for the treatment of epilepsy, GAD and central neuropathic pain (but not peripheral neuropathic pain).

7. On 24 June 2014 Generics (UK) Limited, trading as Mylan, commenced revocation proceedings against the Patent. On 9 July 2014, the second to fifth Inquiry Claimants ("Actavis") applied for marketing authorisation for a full label pregabalin product. Actavis commenced its own revocation action against the Patent on 12 September 2014. On 30 September 2014, Actavis notified Pfizer of its intention to launch a skinny label pregabalin product. On 8 December 2014 Pfizer commenced infringement proceedings against Actavis in respect of its skinny label product. Over the period November 2014 to February 2015, Pfizer wrote to various parties (including the Pharmaceutical Services Negotiating Committee, superintendent pharmacies, clinical commissioning groups and the Department of Health) in terms which were subsequently held by Arnold J to constitute threats of patent proceedings within section 70(1) of the Patents Act 1977 (the "Threats").

Interlocutory orders and undertaking

8. The precise chronology of the various interlocutory orders and undertakings is of some importance to the parties' arguments, and I will therefore set it out in detail.

9. In early January 2015 Pfizer sought an injunction against Actavis. Although Actavis was lawfully entitled to sell pregabalin for the treatment of epilepsy and GAD (due to the expiry of EP No. 0 641 330 and the Patent only covering pain), it was nevertheless foreseeable (to Actavis' knowledge) that pharmacists would be likely to dispense generic pregabalin for the treatment of neuropathic pain. That was because (as explained in more detail by Arnold J in his judgment refusing to grant the injunction: [2015] EWHC 72 (Pat), at [28]-[29]) the great majority of prescriptions identify the drug prescribed by its generic name and do not indicate the condition for which the drug is prescribed, in which case the pharmacist is free to dispense either a branded drug or a generic one.

10. In refusing to grant the injunction, Arnold J concluded ([2015] EWHC 72 (Pat) at [112]) that mere knowledge on the part of Actavis that pharmacists would dispense its product for the treatment of neuropathic pain was insufficient for the purposes of section 60(1)(c) of the Patents Act 1977 (which makes it an infringement to keep, dispose of or offer to dispose of any product obtained directly by means of the claimed process). Accordingly, Pfizer's claim did not raise a serious question to be tried. At [73], however, he noted that the best solution to the problem was to try to ensure that prescribing doctors prescribed pregabalin for the treatment of pain by reference to the brand name Lyrica rather than by reference to the generic name pregabalin.

11. Actavis and the first Inquiry Claimant ("Dr Reddy's") launched skinny label products in February 2015.

12. Pfizer then applied for and was granted an order by Arnold J dated 26 February 2015 (the "NHS Guidance Order") which required the National Health Service Commissioning Board to distribute guidance to GP practices and community pharmacies. The guidance referred to the dispute between Pfizer and a number of generic suppliers regarding pregabalin and said:

> "1. Pregabalin should only be prescribed for the treatment of neuropathic pain under the brand name Lyrica (unless there are critical contra-indications or other special clinical needs e.g. a patient allergic to an excipient, branded product unavailable etc which apply to Lyrica, when you should not prescribe Lyrica or pregabalin).
>
> 2. When prescribing pregabalin for the treatment of neuropathic pain to patients you should (so far as reasonably possible):
>
> a) prescribe by reference to the brand name Lyrica; and
>
> b) write the prescription with only the brand name "Lyrica" and not the generic name pregabalin or any other generic brand.
>
> 3. When prescribing pregabalin for the treatment of anything other than pain, you should continue to prescribe by reference to the generic name pregabalin.
>
> 4. When dispensing pregabalin, if you have been told that it is for the treatment of pain, you should ensure, so far as reasonably possible, that only Lyrica, the branded form of pregabalin, is dispensed. However, when dispensing pregabalin for the treatment of anything other than pain, you are not restricted to dispensing Lyrica."

13. Under schedule 3 to the Order, Pfizer gave the following undertaking to the court:

> "If the Court later finds that this Order has caused loss to the Respondent, the Department of Health, the Actavis group of companies, the Teva group of companies or the Dr Reddy's group of companies, and decides that the Respondent, Department of Health, the Actavis group of companies, the Teva group of companies or Dr Reddy's Laboratories (UK) Limited should be compensated for that loss, the Applicant will comply with any order the Court may make."

14. Over the following months, a number of Generics launched skinny label products, including the thirty-first to thirty-fifth Inquiry Claimants ("Teva") and the twenty-seventh to thirtieth Inquiry Claimants ("Sandoz").

15. The trial of the various revocation proceedings and of Pfizer's infringement claim against Actavis was heard in July 2015 and Arnold J gave judgment on 10 September 2015: [2015] EWHC 2548 (Pat). He concluded that the following claims in the Patent were invalid for lack of sufficiency: claim 1 (relating to pain, generally); claim 3 (use according to claim 1 in respect of neuropathic pain); and various other claims limited to specific types of pain. He also declared that Pfizer had made unjustifiable threats of proceedings for patent infringement. The remaining claims of the Patent (including 10-12 covering treatment of certain types of peripheral neuropathic pain, and claims 2, 5, 7, 8 and 9 covering the treatment of inflammatory pain and certain types of inflammatory pain) were upheld.

16. Arnold J granted permission to appeal in respect of alleged errors of law or principle.

17. In the meantime, on 19 June 2015 Sandoz had obtained a marketing authorisation for a skinny label and a full label pregabalin product. It launched the former in June 2015, and the latter on 2 October 2015, following the hand-down of Arnold J's judgment.

18. Pfizer immediately sought, and obtained, interim relief in the form of orders of Birss J dated 3 October 2015 (without notice) and 5 October 2015 (on notice) and an order of Arnold J dated 17 November 2015 (following a full on notice hearing). These orders (the "Sandoz Orders") restrained Sandoz from launching its full label pregabalin product. They each contained a cross-undertaking in damages given by Pfizer. By Schedule 1 to the order of 17 November 2015 Pfizer gave the following undertaking:

> "If the Court later finds that this Order has caused loss to [Sandoz or any company in the Sandoz group], the Department of Health and/or the National Health Service Commissioning Board and decides that [Sandoz or any company in the Sandoz Group], the Department of Health and/or the National Health Service Commissioning Board should be compensated for that loss, [Pfizer] will comply with any order the Court may make."

19. In addition, by Schedule 2 to the order of 17 November 2018, Pfizer gave the following undertaking (insofar as relevant for present purposes):

> "If the Court later finds that the [NHS Guidance Order] has caused loss from 3 October 2015 onwards to [Sandoz or any company in the Sandoz group] … and decides that [Sandoz or any company in the Sandoz group] should be compensated for that loss from 3 October 2015 … [Pfizer] will comply with any Order the Court may make."

20. The twenty-sixth Inquiry Claimant ("Ranbaxy") had also obtained a marketing authorisation for a full label pregabalin product and, following Arnold J's decision at first instance, made advanced plans to bring the product to market. Pfizer sought, however, and obtained from Ranbaxy a contractual undertaking to Pfizer that it would not launch its full label pregabalin product in the UK

pending final determination of the proceedings relating to Actavis (the "Ranbaxy Undertaking"). In return, Pfizer gave a cross undertaking in damages in respect of loss caused by the Ranbaxy Undertaking. In the same agreement, Ranbaxy also became the beneficiary of a contractual cross-undertaking in relation to any loss caused by the NHS Guidance Order, but only with effect from 19 November 2015.

21. By a consent order of Mann J dated 31 January 2016, Dr Reddy's was ordered not to apply to vary its marketing authorisation so as to include indications for pain and/or neuropathic pain. Pfizer gave a cross-undertaking in damages to Dr Reddy's in respect of any loss caused by the order of 31 January 2016. Subsequently, on 30 March 2016, Dr Reddy's secured a new marketing authorisation for a full label pregabalin product. By a further consent order of Mann J dated 19 May 2016, Dr Reddy's was ordered not to offer for sale, sell or supply pregabalin under its full label marketing authorisation. Pfizer gave a cross-undertaking to Dr Reddy's in respect of any loss caused by the consent order of 19 May 2016. By a further consent order of Mann J dated 1 December 2016, the Order of 31 January 2016 was varied so that there was no constraint on Dr Reddy's applying to vary its marketing authorisation to include central and/or peripheral neuropathic pain, with the exception of certain specified types of pain. I will refer to these orders, together, as the "Dr Reddy's 2016 Orders".

22. In March 2016, Actavis obtained a separate intermediate label marketing authorisation that included the use of pregabalin for the treatment of central neuropathic pain. By a consent order of Rose J dated 23 May 2016, Actavis was ordered not to sell or supply a pregabalin product for the treatment of pain or neuropathic pain (the "Actavis Modified Label Order"). Pfizer provided a cross-undertaking in respect of any loss caused to Actavis or NHS EWNI by the Actavis Modified Label Order.

23. On 17 March 2016, Mann J ordered by consent a variation to the Sandoz Order of 17 November 2015 so as to add a further cross undertaking in damages in favour of the National Health Service of Scotland ("NHS Scotland"):

> "If the Court later finds that this Order [i.e. the Sandoz Order of 17 November 2015] has caused loss from 9 February 2016 to [NHS Scotland] and decides that [NHS Scotland] should be compensated for that loss from 9 February 2016, [Pfizer] will comply with any order the Court may make".

24. On 13 October 2016, the Court of Appeal upheld Arnold J's findings that claims 1 and 3 of the Patent were invalid.

25. On 14 November 2018, the Supreme Court delivered its judgment, in which it upheld the conclusion that claims 1 and 3 were invalid, but also concluded that claims 10, 11 and 12 were invalid.

The Preliminary Issues

26. By paragraph 1 of the Order of Birss J dated 18 December 2020 ("the Birss J CMC Order"), a trial was ordered of two preliminary issues:

> "(a) What are the appropriate counterfactual assumptions over the period from 8 July 2014 (expiry of Pfizer's data exclusivity) to present upon which to determine any damages payable to each of the Inquiry Claimants in the Inquiry Claims?
>
> (b) To what extent (if not already answered at (a)) are findings of fact binding as between different parties in these proceedings?"

27. Paragraph 2 of that order provided that an agreed list of possible counterfactual assumptions, based on that at Schedule B, was to be filed with the Court. The parties were left to seek to agree those assumptions. Schedule B, as finalised, contained the following possible counterfactual assumptions:

> "1. Is it correct to assess the counterfactual for each Inquiry Claim on the assumption that the same Threats, Relevant Orders and Undertakings were or were not made across all the Inquiry Claims?
>
> 2. Is it correct to assume, as a matter of law, in the counterfactual for each Inquiry Claim that none of the Threats, Relevant Orders and the Undertakings were made, and if not, which of the Threats, Relevant Orders and Undertakings should it be assumed would have been made in the counterfactual for each Inquiry Claim?
>
> 3. In determining the amount of damages (if any), is it appropriate to assess the Inquiry Claimants' loss on the assumption that any or all of the claims of the Patent were known by all to be invalid at all relevant times following expiry of Pfizer's data exclusivity on 8 July 2014?
>
> 4. Is it correct to assume, as a matter of law, that the Inquiry Defendant could not have restrained prescribers or dispensers from prescribing or dispensing pregabalin for pain and/or restrained generic manufacturers from launching full label products, and if so then (having regard to the chronology) from which date?
>
> 5. Is it correct to assume, as a matter of law, that the Inquiry Defendant could not have threatened any parties with patent infringement proceedings and if so then from which date?
>
> 6. Is it correct to assume, as a matter of law, that the Inquiry Defendant could not have restrained launch of full label products by Sandoz or other manufacturers and if so then from which date?"

28. Schedule B contained a proviso, however, that if, in order to address whether assumptions 4, 5 and/or 6 are appropriate, a dispute (or disputes) of fact has to be resolved, then whether the relevant assumption is appropriate will not be decided at this trial of preliminary issues.

The arguments of the parties in outline

29. The parties can conveniently be divided into four groups:

(1) Those Generics whose principal claim is to lost profits which would have been derived from sales of a skinny label product (the "**Skinny Label Generics**"). This group comprises Actavis and Teva, who were together represented by Mr Lykiardopoulos QC and Mr Scannell QC, and Dr Reddy's, represented separately by Dr Nicholson QC and Mr Hall;

(2) Those Generics whose principal claim is to alleged lost profits which would have been derived from sales of a full label product (the "**Full Label Generics**"). Following settlement of the claim by Sandoz, this now comprises only Ranbaxy, represented by Mr Brandreth QC;

(3) The entities that fall under the umbrella respectively of the National Health Service in England, Wales and Northern Ireland ("**NHS EWNI**"), represented by Mr Moser QC, Mr McGurk and Ms Hart, and NHS Scotland, represented by Mr Campbell QC and Ms Osepciu (together, the "**NHS Parties**"); and

(4) Pfizer, represented by Mr Boulton QC, Ms May QC, Mr Goldfarb, Mr Austen and Mr Lunt.

30. The essential position of these parties in relation to Assumptions 1 to 6 can be distilled into the following.

The Skinny Label Generics

31. The Skinny Label Generics' principal claim is based upon the cross-undertaking in the NHS Guidance Order and the Threats. As to Assumptions 1 and 2, they oppose the imposition of a single consistent counterfactual and contend that the appropriate counterfactual must be assessed separately for each Inquiry Claim.

32. Dr Reddy's primary contention is that, as a result of admissions Pfizer has made of its pleaded case, there is only one possible answer to the question raised by paragraph 1(a) of the Birss J CMC Order, and none of Assumptions 1 to 6 have any relevance to its Inquiry Claim. I will address this point separately at [156] to [164] below. Aside from this, Dr Reddy's largely adopts the submissions of Actavis/Teva.

33. In respect of their claims under the cross-undertaking in the NHS Guidance Order and under the Threats, the appropriate counterfactual contended for by the Skinny Label Generics is that neither the NHS Guidance Order nor the Threats were made, but all other orders and undertakings remained in place in the counterfactual world, as they did in the actual world.

34. Actavis has an alternative claim based on the Actavis Intermediate Label Order where it contends that the appropriate counterfactual is that the Actavis Intermediate Label Order was not made, and the Sandoz Orders were not made, but that the NHS Guidance Order and the Threats were made.

35. Dr Reddy's takes a slightly different position to Actavis on its alternative claim relating to the Dr Reddy's 2016 Orders. In light of the agreement on the pleadings as between it and Pfizer as to what would have happened in the counterfactual (see below at [156]), it recognises that it could suffer no loss by reason of the Dr Reddy's 2016 Orders. It maintains the alternative claim, *pro tem*, however, in case (contrary to the position currently agreed between it and Pfizer) its Inquiry Claim proceeds on the basis that full label products would, or might, have come on the market.

36. The Skinny Label Generics contend that the question raised by Assumption 3 should be answered in the negative: in the counterfactual world the validity of the Patent, and all claims under it, would have remained in dispute (as they did in the actual world) until after the judgment of the Supreme Court.

37. They also contend that the questions in Assumptions 4 to 6 should be answered in the negative, except that in relation to Assumption 4 (whether it is correct to assume as a matter of law that Pfizer could not have restrained prescribers or dispensers from prescribing or dispensing pregabalin for pain and/or restrained manufacturers from launching full label products), as regards the claims made under the Sandoz Orders, the Ranbaxy Undertaking and the Label Orders, Actavis/Teva accept that the answer is yes. That is because any claim under the Sandoz Orders must assume that they (the Sandoz Orders) were not made, and because when assuming what would have happened had the Ranbaxy Undertaking or Label Orders not been made, the only "realistic counterfactual" is one where the Sandoz Orders had also not been made.

The Full Label Generics

38. Ranbaxy's claim is based upon the cross-undertaking in the Ranbaxy Undertaking (which, as noted above, related both to the loss suffered by reason of the Ranbaxy Undertaking and extended the benefit of the NHS Guidance Order to Ranbaxy as from 19 November 2015).

39. It also opposes a single consistent counterfactual and contends that the appropriate counterfactual in relation to its claim is that the Ranbaxy Undertaking and the NHS Guidance Order did not exist. It would be content that all other orders (which effectively means the Sandoz Orders) remained in place, but it accepts in its pleaded case that the counterfactual world also did not include the Sandoz Orders, because it accepts that "there is no principled or factual reason why it alone would no longer have been subject to such interim measures".

40. Ranbaxy's position is largely aligned with that of the Skinny Label Generics in relation to Assumptions 4 to 6.

The NHS Parties

41. NHS EWNI's claim is based upon the NHS Guidance Order and the cross-undertaking in the Sandoz Orders. NHS Scotland's claim is based upon the Sandoz Orders, for loss arising from 9 February 2016.

42. The NHS Parties' primary case relates to Assumption 3: it is to be assumed that in the counterfactual world for all Inquiry Claimants it was known at all relevant times that all of the claims (or at least all of the relevant claims) of the Patent were invalid. All of the other parties oppose that proposition. They also contend that the questions raised by Assumptions 4 to 6 should be answered in the affirmative, largely because this flows from the answer to Assumption 3.

43. As to Assumptions 1 and 2, the NHS Parties contend that a single consistent counterfactual should be applied across all Inquiry Claims that *none* of the orders, undertakings or Threats was made.

Pfizer

44. Pfizer agrees with the NHS Parties to the following extent: there should be a single consistent counterfactual across all Inquiry Claims, in which none of the Threats, orders or undertakings were made.

45. In common with all other parties, however, Pfizer disagrees with the NHS Parties on Assumption 3. As to Assumptions 4 to 6, Pfizer broadly contends that either these raise issues of fact and law (despite the wording of the Assumptions) and thus cannot be resolved at this trial, or should in any event be answered in the negative.

Legal principles

46. While the parties were unable to point to an authority directly in point on the issues raised for determination in this preliminary issues trial, there was much common ground as to the principles to be applied, in general, to the assessment of compensation under a cross-undertaking in damages, as set out in the following paragraphs.

47. Compensation is to be assessed on the same basis as that upon which damages for breach of contract would be assessed if the undertaking had been a contract between the claimant and the defendant, under which the claimant promised not to prevent the defendant from doing that which the order restrained it from doing, but with such logical and sensible adjustments as are required by the fact that the court is not in fact awarding damages for breach of contract: *Abbey Forwarding Ltd v Hone (No.3)* [2014] EWCA Civ 711, per McCombe LJ at [63], approving the obiter comments of Lord Diplock in *F. Hoffmann-La Roche & Co. AG v Secretary of State for Trade and Industry* [1975] AC 295, 361. McCombe LJ added:

> "It is compensating for loss for which the defendant "should be compensated" (to apply the words of the undertaking). Labels such as "common law damages" and "equitable compensation"

> are not, to my mind, useful. The court is compensating for loss caused by the injunction which was wrongly granted. It will usually do so applying the useful rules as to remoteness derived from the law of contract, but because there is in truth no contract there has to be room for exceptions."

48. At [62] of *Abbey Forwarding v Hone*, McCombe LJ rejected the suggestion (made by Arnold J in *Lilly Icos LLC v 8PM Chemists Ltd* [2010] FSR 95 at [40]) that the correct approach to assessing compensation under a cross-undertaking is that adopted by equity when awarding compensation for breach of fiduciary duty. Nevertheless, at [47], he confirmed that the jurisdiction is equitable in origin and nature, endorsing the following statement of Aickin J in *Air Express Ltd v Ansett Transport Industries (Operations) Pty Ltd* (1979) 146 CLR 249:

> "In a proceeding of an equitable nature it is generally proper to adopt a view which is just and equitable, or fair and reasonable, in all the circumstances rather than to apply a rigid rule. However the view that the damages should be those which flow directly from the injunction and which could have been foreseen when the injunction is granted, is one which will be just and equitable in the circumstances of most cases…"

49. Only the parties identified in the order as beneficiaries of the cross-undertaking are entitled to sue upon it: *SmithKline Beecham PLC v Apotex Europe Ltd* [2007] FSR 6, per Jacob LJ at [86].

50. In *Les Laboratoires Servier v Apotex Inc* [2008] EWHC 2347, Norris J (having set out the principles to be applied in quantifying compensation in that case, at [5]) said (at [9]) that the court ought not to take too cautious an approach to assessing compensation, where the party who 'wrongly' obtained an injunction did so on the basis that quantifying its own loss if the injunction was refused would have been more difficult than quantifying the loss suffered by the other party if the injunction turned out to be wrongly granted. He concluded that a principle of "liberal assessment" (applied by Lord Wilberforce to the assessment of damages for patent infringement in *General Tire & Rubber Co Ltd v Firestone Tyre & Rubber Co Ltd* [1975] 1 WLR 89, at p.824E) was equally applicable in the present context. This passage was endorsed by Kitchin LJ in *AstraZeneca AB v KRKA dd Novo Mesto* [2015] EWCA Civ 484, at [16].

51. It is important to distinguish between losses caused by the order itself, and losses caused by the existence of the underlying litigation. Only the former are recoverable under the cross-undertaking: *Lilly Icos* (above), at [27], where Arnold J again quoted the High Court of Australia in *Air Express*, in which (for example) Gibbs CJ said (at pp.312-313):

> "…it is perfectly clear, and it appears from the words of the undertaking themselves, that the only damage to which a defendant is entitled are those which he has sustained by reason of the grant of the injunction. The generally accepted view is that the damages must be confined to loss which is the natural

> consequence of the injunction under the circumstances of which the party obtaining the injunction has notice … In a number of authorities the court has distinguished between loss which was caused by the injunction and loss which arose from the litigation…"

52. Although at one point Mr Moser submitted that I ought not to follow in certain respects the approach adopted in Australia, I understood him to be doing so in order to meet an argument which in fact none of the other parties advanced. Certainly I did not understand him to contend that the passage from *Air Express* quoted in the last paragraph did not represent the position in England. It would be difficult to do so, given its express endorsement by Arnold J in *Lilly Icos*.

53. There is no relevant distinction to be drawn between loss flowing from the existence of the litigation and loss flowing from the existence of the Patent, in circumstances where Pfizer sought in the litigation to uphold the validity of the Patent. Both are excluded by the principle that the only loss recoverable is that which flows from the order.

54. This was (albeit apparently without the point being disputed) implicit in, for example, the approach to the quantification of compensation for breach of a cross-undertaking by Norris J in *Servier* (above). In that case, an injunction had been granted to Servier (the holder of the relevant patent in respect of a drug known as perindopril) restraining Apotex (a manufacturer or generic drugs) from selling perindopril. At trial, the patent was held to be invalid. In assessing the circumstances that would have existed, had the injunction not been made, Norris J analysed the prospects of other generics entering the market against the background that they would have been doing so in circumstances where the validity of the patent was yet to be determined, and thus "at risk". That is inconsistent with the suggestion that the market was at all relevant times taken to know that the patent was invalid.

55. It was also common ground between the parties that damages for the statutory tort in respect of the Threats are assessed on the usual tortious basis: the sum of money which will put the injured party in the same position as he would have been in if he had not sustained the wrong (see, for example, *General Tire & Rubber Co Ltd v Firestone Tyre & Rubber Co Ltd* [1975] 1 WLR 819, at p.824 per Lord Wilberforce). Save for one point relating to the NHS Parties' implied contract theory (which I address below), it was not suggested by any party that the different basis of assessing damages had any impact on the questions raised by this preliminary issues trial.

56. Similarly, it was not suggested that any different analysis – so far as the questions raised by this preliminary issue trial are concerned – is required in relation to the damages flowing from the cross-undertaking given in respect of a contractual undertaking given instead of an order (as in the case of Ranbaxy).

57. This trial of preliminary issues proceeds on the basis that there are, at least potentially, two stages in an inquiry as to damages pursuant to a cross undertaking. Stage 1 involves identifying the hypothetical counterfactual assumptions to be made if the relevant order, undertaking or threat had not been

made. Stage 2 then involves identifying the facts (on the usual standard of proof) which would have occurred upon the basis of those counterfactual assumptions. This trial of preliminary issues is concerned only with stage 1.

58. All parties were agreed that the one element of the actual world that must always be removed in constructing the counterfactual is the very order, undertaking or Threat which turns out to have been wrongly made and is alleged to have caused loss. As I have already noted, the Skinny and Full Label Generics' case is that this is the *only* element that must be removed – as a matter of law – in creating the counterfactual, whereas Pfizer and the NHS Parties contend that other elements must as a matter of law also be removed in constructing the counterfactual.

59. I will address Assumption 3 first, which is the NHS Parties' primary case, as this is the counterfactual assumption that involves the most significant departure from the actual world.

Assumption 3: Assumed knowledge of invalidity?

60. In my judgment, the NHS Parties' contention that it should be assumed that everyone knew at all material times that the Patent was invalid is to be rejected for the simple reason that it contravenes the principle that compensation is limited to that which flows from the 'wrongful' order, undertaking or threat (see [49] above). Assumption 3 would confuse, for example, the consequences flowing from the order with the consequences flowing from the existence of the Patent and the subject matter of the litigation.

61. In particular, if the NHS Parties' claim for compensation under the NHS Guidance Order were to be assessed on the assumption that everybody knew that the Patent was invalid, that would be tantamount to awarding compensation *for* the existence of the Patent and Pfizer's defence of it in the litigation, as illustrated by the following:

    (1) Leaving aside the question of any other of the orders, undertakings and Threats, if the NHS Guidance Order had not been made, then the decision for each Generic, in determining whether to bring its product to market, would have been made in the context of uncertainty over the validity of the Patent. Risk averse Generics would have been more likely to refrain from doing so, and prices would be less likely to have fallen (and the NHS Parties' damages would be less);

    (2) If, however, it is to be assumed that everyone knew the Patent was invalid, then there would have been nothing to stop Generics bringing their products to market, and prices would likely have fallen quickly. The NHS Parties' damages would thus be much greater and practically indistinguishable from damages caused by the existence of the Patent itself.

62. Although a party who seeks and obtains an interlocutory injunction which later turns out to be wrongly granted is not a "wrongdoer" (see, for example, *SmithKline Beecham plc v Apotex Europe Ltd* [2006] EWCA Civ 658, per Jacob LJ at [25]), the injunction is nevertheless treated as having been wrongly made.

It is to cater for that possibility that the price of obtaining such an injunction is a cross-undertaking in damages. Neither the application for the grant of the Patent nor the bringing (or defending) of proceedings so as to uphold the validity of the Patent is treated as wrongful in the same sense, and there is no requirement to provide a cross-undertaking in damages in either case. Accordingly, the loss flowing from the wrongly made order (supported by the cross-undertaking) must be distinguished from loss caused by the Patent or the subject matter of the litigation (which is not so supported).

63. Although the point does not appear to have been the subject of argument, I consider that the assumption made in assessing compensation in the *Servier* case (above) – that those considering launching their own generic product would have been doing so in circumstances that risked infringing the patent – was correct.

64. The NHS Parties advanced a number of arguments against this conclusion.

65. First, Mr Moser on behalf of NHS EWNI contended that the cross-undertaking in the NHS Guidance Order is to be treated as a contract between Pfizer and NHS EWNI, in which Pfizer promised not to prevent NHS EWNI from doing that which they were restrained from doing by the terms of the order. That deemed contract contained implied terms that Pfizer "would not" have done various things, including: it would not have required NHS EWNI to issue the guidance; it would not have been permitted to make relevant threats against any NHS body, pharmacies or Generics; it would not have required Generics only to supply full label pregabalin in such proportion as was required to meet prescriptions for indications other than neuropathic pain; and it would not have taken steps against third parties, including Generics, in order to stop the prescribing and dispensing of generic pregabalin.

66. Recognising, tacitly at least, that it would be difficult to satisfy the contractual test for implication of terms, Mr Moser submitted that these terms were not to be implied as a matter of strict contract law, but pursuant to a broad principle of equity that if a loss was foreseeable at the time of the NHS Guidance Order it is encompassed within a claim under the cross-undertaking. He submitted that the purpose of the NHS Guidance Order was to protect Pfizer by preventing Generics bringing a full label product to market, so the promise which is deemed to exist by reason of the cross-undertaking includes the implied term that Pfizer would not do anything to prevent Generics bringing their full label products to market.

67. Mr Moser pointed, in particular, to [73] of the judgment of Arnold J dated 21 January 2015 (refusing the injunction sought by Pfizer against Actavis). Having noted that a variety of Generics had plans to bring a generic pregabalin product to market authorised only for epilepsy and GAD, he identified the "best solution" as one which ensured that doctors prescribed pregabalin for the treatment of pain solely by reference to the brand name Lyrica. In his judgment dated 2 March 2015, on granting the NHS Guidance Order, Arnold J noted, at [21] that the guidance "may well have the result that [pharmacists] are required to dispense Lyrica rather than generic pregabalin for treating pain, thus making

a lower profit on such dispensing, but that consequence is justified by the existence of the Patent (assuming it is valid)." At [22], he noted that the only other alternative open to Pfizer was to pursue its application for interim relief against the Generics. At [28] and [30], in deciding that the benefit of the cross-undertaking should be extended to Teva, Arnold J accepted the argument of Teva's counsel that:

> "…the effect of the order was intended to be, and was likely to be, that prescribers prescribed pregabalin for treating pain by reference to the brand name Lyrica rather than the generic name pregabalin. If prescribers did so, then pharmacists would be obliged to dispense Lyrica rather than generic pregabalin for treating pain. If it turned out that the Patent was invalid, however, then Teva should not have been prevented from making sales of generic pregabalin which pharmacists would otherwise have dispensed for the treatment of pain whether or not Teva would infringe the Patent if it was valid by selling the product under a skinny label."

68. Thus, even though it does not appear to have been envisaged at that time that any Generic was planning to bring a full label product to market, and nothing in the NHS Guidance Order prevented a Generic from doing so, it would nevertheless have the practical effect of limiting that product's access to the market. It is acknowledged that it would not have precluded access to the market for such a product altogether, because the NHS Guidance Order would not be 100% effective in achieving its aim.

69. The problem with NHS EWNI's implied term argument is that it overstates the contractual basis of a claim under a cross-undertaking. In the *Hoffmann-La Roche* case (upon which McCombe LJ relied in *Abbey Forwarding v Hone (No.3)* (above)), Lord Diplock merely said that the assessment of damages under a cross-undertaking is made "upon the same basis" as that upon which damages for breach of contract would be assessed. McCombe LJ himself, in the passage quoted above at [47], merely said that the court would usually assess damages "applying the useful rules as to remoteness derived from the law of contract", albeit that because there was no contract in fact there would be exceptions.

70. The implied contract approach does not in any event work in the case of the NHS Guidance Order, which did not restrain any party from doing anything. Instead, it positively requires the NHS to give guidance. In determining what loss flows from that order, resort to an implied promise by Pfizer not to do something does not make sense; instead, all that is required is to posit that the guidance had not been given.

71. I accept that the context in which the NHS Guidance Order was made is highly relevant to the question as to what loss was reasonably foreseeable at the time. It is entirely plausible – based on the passages in Arnold J's judgments to which Mr Moser referred – that it was foreseeable that the NHS Guidance Order would prevent Generics from accessing the market with full label products. That, however, is a question of fact, and not for determination at this trial. I do not

see any basis to elevate this, as a matter of law, to an implied term that Pfizer would not prevent others from doing that which it was foreseeable the NHS Guidance Order might prevent. Moreover, it is a non sequitur to go from this to the assertion that the assessment of damages must proceed on the assumption that everyone knew the Patent was invalid.

72. The argument based on implied terms in the deemed contract can also have no application to the assessment of damages in respect of the Threats, where the analogy with contractual damages is irrelevant.

73. Second, the NHS Parties contend that it is necessary to assume that everyone knew at all material times that the Patent was invalid because of the operation of the hindsight principle, as established by the House of Lords in *Bwllfa and Merthyr Dare Steam Collieries (1891) Ltd v Pontypridd Waterwork Co* [1903] AC 426. That case concerned the amount of compensation that should be paid (pursuant to the Waterworks Clauses Act 1847) by the owner of land to the owner of coal seams under that land, in return for the owner of the coal seam being required to leave the coal unworked. There were delays in the commencement of arbitration proceedings to determine this question. In the intervening period the price of coal had risen. The House of Lords held that the evidence of the increased price in coal was admissible in the arbitration. The relevant question was what the owners of the coal seam would have made out of the coal during the time it would have taken them to get it. For that purpose it was permissible to rely on what had actually happened to the price of coal in the intervening period, as Lord Macnaghten vividly explained at p.431:

> "If the question goes to arbitration, the arbitrator's duty is to determine the amount of compensation payable. In order to enable him to come to a just and true conclusion it is his duty, I think, to avail himself of all information at hand at the time of making his award which may be laid before him. Why should he listen to conjecture on a matter which has become an accomplished fact? Why should he guess when he can calculate? With the light before him, why should he shut his eyes and grope in the dark?"

74. I reject this contention of the NHS Parties. The hindsight principle is concerned with quantification of a liability which is dependent upon some contingency. If, at the date the court considers the issue the contingency has occurred, then it may base its conclusion on what has actually occurred, rather than trying to estimate as at some earlier date the likelihood of it occurring: see, for example, *Re Annacott Holdings Ltd* [2013] EWCA Civ 119, per Arden LJ at 19(ii).

75. The question as to the appropriate counterfactual involves no valuation issue, and certainly no question of valuing a liability subject to a contingency. The question is an aspect of causation: what elements of the actual world should be taken to exist (or not exist) in the counterfactual world? It is true that hindsight is involved in the limited sense referred to by Lewison J in *Smithkline Beecham plc v Apotex Europe Ltd* [2005] EWHC 1655 (Ch), at [44]: "with the benefit of hindsight and after investigation of all the facts, the court at trial may decide

that the claimant (in whose favour the injunction was granted) is not entitled to the relief claimed". That, however, does not mandate using hindsight to ascribe knowledge to market participants during the period in which loss is to be calculated which they never had.

76. Indeed, a proper application of the hindsight principle would actually *require* account to be taken of the fact that nobody knew whether the Patent was valid or not until the issue was finally resolved by the Supreme Court, since that remained the state of affairs during the whole of that period. As Mr Brandreth submitted, the hindsight principle is concerned with the knowledge the court should have, as to events which have happened since the date as at which the liability is to be valued, not the knowledge to be ascribed to those in the market during the intervening period.

77. Mr Moser referred to *Lilly Icos v 8PM* (above) in which Arnold J concluded (at [40]) that the correct approach to assessment of damages for breach of a cross-undertaking was that adopted by equity when awarding compensation for breach of fiduciary duty, "namely to consider the position with the benefit of hindsight". It was that part of Arnold J's decision, however, which the Court of Appeal in *Abbey Forwarding* (above) disapproved. In any event, nothing in Arnold J's judgment in *Lilly Icos* supports the view that it is necessary, in applying hindsight, to assume that everyone knew at all times that the relevant patent was invalid. At [243], in actually applying hindsight, he did so for the purpose of evaluating the impact on the quantum of damages of the contingency that events (such as the business ceasing) might occur after the date of the injunction. He held that for that purpose the court should rely on what has actually happened (e.g. the business in fact continued).

78. Third, the NHS Parties rely upon *Virgin Atlantic Airways Ltd v Premium Aircraft Interiors UK Ltd* [2013] UKSC 46. In that case, the Court of Appeal had determined that the respondent's patent was valid but, before the assessment of damages for infringement took place, the European Patent Office ("EPO") amended the patent so as to remove, with effect from the date of the grant, all the claims found in the English courts to have been infringed. The respondent contended that it was still entitled to damages for infringement, contending that the English court's determination that the patent was valid was *res judicata*, and the appellant could not rely on the EPO's subsequent, retrospective, decision.

79. The Supreme Court held that while the principle of *res judicata* barred an infringer from relying on arguments relating to validity or infringement which had been determined in the English proceedings, it did not prevent the assertion on the inquiry as to damages that the patent had, as a matter of fact, been revoked or amended.

80. In agreement with, in particular, Mr Lykiardopoulos, I consider that the *Virgin Atlantic Airways* case provides no assistance to the NHS Parties. It was concerned with an inquiry as to damages *caused by infringement* and the subsequent, but retrospective, amendment of the patent cut off the analysis at the beginning. It has no application to the present case, where the question is what loss flowed from the grant of an interlocutory injunction.

81. Mr Moser's reliance on the approach taken in competition law cases is inapposite for a similar reason. The question in such cases (e.g. *Société Technique Minière v Maschinenbau Ulm* [1966] ECR 235, at [249]-[250]) is what damage was caused by the agreement in dispute, for which purpose it is necessary to construct a counterfactual which excludes that agreement. A similar approach would be warranted if the question here was what loss was caused by the existence of the Patent but, for reasons I have set out above, that is not the question.

82. Similarly, the NHS Parties' contention is not advanced by the deeming provision in Article 68 of the European Patent Convention (that the effect of revocation of a European Patent is that it shall be deemed not to have had, from the outset, the effects specified in Articles 64 and 67). The fact that the Patent may be deemed to have been invalid from the outset does not in my judgment require the conclusion that in assessing what loss flowed from a wrongly granted interlocutory injunction the market should be assumed to have known at all material times that the Patent was invalid.

83. For those reasons, in my view, Assumption 3 should be answered in the negative.

Assumptions 1 & 2: A consistent counterfactual that all/none of the other orders were made

84. The main point of dispute between Pfizer and the NHS Parties, on the one hand, and the Generics, on the other hand, is whether in considering the appropriate counterfactual for any one of the Inquiry Claims all other orders, undertakings and Threats should be assumed to have remained in place, or whether they should be assumed not to have been made. The answer to the linked question, whether the same counterfactual assumptions should apply across all Inquiry Claims, is likely to follow logically from the answer to that first question.

85. It is common ground that there is no English authority directly in point. Each party accordingly argued by a combination of first principles, by analogy with other situations or by reference to the one Australian case in which the point was considered: the decision of Jagot J in the Federal Court of Australia in *Sigma Pharmaceuticals (Australia) PTY Ltd v Wyeth* [2018] FCA 1556 ("*Sigma*").

86. As I have noted, all parties were agreed that the starting point for assessing loss caused by a particular order, undertaking or threat is that such order, undertaking or threat was not made.

87. A preliminary question which emerged during the course of the hearing was what is the precise nature of the assumption that an order was not made. Three possibilities were canvassed: (1) the order was refused by the court; (2) the order was applied for but not pursued before the court; and (3) the order was not sought in the first place.

88. In fact, the first of those possibilities gives rise to a number of sub-questions: is it to be assumed that the order was refused because the court concluded there was no good arguable case that the Patent was invalid, or because there was no good arguable case that the defendant had infringed the Patent, or some other reason? The NHS Parties contended that, if their primary case that the Patent was known to be invalid was wrong, then it should be assumed that the order was refused, alternatively that the application was made but not pursued, alternatively that the application was not made. On these alternatives, they contended that some form of knowledge that the Patent was invalid would have arisen, but on a "sliding scale".

89. This question arose in *Sigma*. In that case, Wyeth obtained a series of interlocutory injunctions against Sigma, Alphapharm and Generic Health (the "*Sigma* Generics") preventing those companies from launching a generic version of venlafaxine, in respect of which Wyeth held a number of patents, including a method patent. Wyeth provided a cross-undertaking in respect of each injunction. The *Sigma* Generics challenged the validity of Wyeth's method patent, which was rejected by Jagot J. However, on appeal, that decision was overturned by the Full Court. Special leave to appeal was subsequently refused. Each of Sigma, Alphapharm and Generic Health sought enforcement by the court of the cross-undertakings given by Wyeth for the damage they suffered as a result of the "wrongly" made injunctions.

90. Jagot J rejected the first possibility (that it should be assumed in the alternative the application for an injunction had been refused by the court) because it would in practice run foul of the principle that compensation must be based on loss caused by the order, and not by the litigation. At [362] she said:

> "…the notion that it is to be assumed contrary to the fact that the interlocutory injunction was refused let alone that it was refused on the ground that founded the Full Court's orders is irreconcilable with the repeated emphasis in Air Express on the requirement that any compensation relate to the effect of the interlocutory orders, not the litigation. To assume otherwise would effectively remove the majority of the risk which the method patent presented to the generics. If the analysis proceeds on that basis, the inevitable tendency would be to compensate the generics for the existence of the method patent and the litigation which is impermissible."

91. While this decision is not binding on me, I find this reasoning persuasive. I have already concluded that the principle that compensation under a cross-undertaking is limited to compensating for loss that flows from the order is clearly established in English law. As Mr Moser's submissions implied, the only relevance in distinguishing between the three alternatives is because the more that is assumed about how and why the relevant order was not made, the greater knowledge might be imputed to everyone in the market as to the validity or otherwise of the Patent. In the most extreme case, for example, where it is to be assumed that the court refused to make the order because it concluded that there was no arguable case that the Patent was valid, then other Generics would

have known that there was no real impediment to launching their own products. That in my view, however, reveals the fallacy in assuming anything more than that the order was not made: it prevents the loss flowing from the fact that the order was made from being isolated from other causes of loss.

92. In many cases, there is unlikely to be any real distinction between the second and third alternatives. In *Sigma*, however, Jagot J was required to decide between them, in circumstances where there was a delay between an injunction being applied for and it being granted. She concluded that the appropriate assumption was that the application had been made, but had not been pursued on the date the order was actually made. That was in response to an argument by Sigma that its conduct prior to the injunction being granted, but in anticipation of it, would not have occurred but for the injunctions and so should be disregarded in the counterfactual. She dismissed that argument for the same reason that damages under the cross-undertaking must flow from the existence of the order. Neither the issuing of an application nor a threat to seek an injunction is supported by a cross-undertaking in damages, and any action taken by Sigma in response cannot be said to have been a consequence of the later order. Accordingly, she concluded that everything that occurred in the actual world, up until the order was made, should be included in the counterfactual, such that "the only thing that is removed from the analysis is the grant of the interlocutory injunction" (see [359] to [360]).

93. Again, I find this reasoning persuasive. The task of the court is to isolate the consequences of the relevant order, undertaking or threat from all other matters. Accordingly, in the case of an order, the counterfactual should depart from the actual at the last possible moment before the order was made, because that preserves the causal history for which Pfizer is not liable. (This is not to say that, in a particular case, a party is precluded from contending as a matter of fact that actions it took in anticipation of an order being made were caused by the order: see *Lilly Icos* (above), per Arnold J at [192].)

The parties' submissions in more detail

94. Pfizer (supported by the NHS Parties as their alternative case) contends that it is necessary to assume the single counterfactual across all the Inquiry Claims that none of the orders, undertakings or Threats were made, both as a matter of principle and as a matter of practicality.

95. The argument based on principle has two prongs: first, damages are compensatory, so that no Inquiry Claimant may recover more than the loss actually suffered by them; and, second, the assessment must be fair and just in accordance with equitable principles (relying on, among other things, the passage in *Abbey Forwarding* referred to at [48] above). In circumstances where there is a finite market and the actions of each Generic impact on all other Generics, if claims are assessed on the basis of inconsistent counterfactuals, one or more of the parties would be overcompensated and Pfizer would be overburdened.

96. Mr Boulton submitted that the framing of a counterfactual is an analytical tool, for the purpose of establishing loss. In this case, although there are different claims made by different parties, the single issue is what loss has been caused by the (plural) orders, undertakings and Threats. That is because the loss that arises in this case is essentially the same sort of loss: what share of the finite market would each Generic who would have entered the market have acquired.

97. He further submitted that a single counterfactual was required in order to comply with the requirements of (1) "realism" and (2) the purpose for which the counterfactual is constructed. Separate and inconsistent counterfactuals would be unrealistic because they could not all have happened, and they would not lead to an accurate assessment of loss (being the purpose of the counterfactual), but would lead to overcompensation.

98. Pfizer relies on *Sigma* where, at [231] to [232], Jagot J posed the question whether it was necessary or appropriate, when considering the position of one party, had the injunction against it not been made, to disregard the grant of an injunction against other parties, and answered it in the affirmative "…as otherwise it is not practically possible to construct consistent hypotheses of what would or might have occurred in any given case."

99. So far as practicalities are concerned, Pfizer contends that the integrity of the court's processes and the fair administration of justice require that where possible the court should avoid giving irreconcilable judgments on what are essentially the same facts.

100. Mr Lykiardopoulos, for Actavis/Teva, took the lead in opposing this aspect of Pfizer's case. His core submission was that in considering the but-for element of the counterfactual, the only thing to be removed from the actual world *as a matter of law* is the specific order, undertaking or Threat to which the cross-undertaking relates. On Actavis/Teva's principal case, therefore, which arises under the cross-undertaking in the NHS Guidance Order and under the Threats, the only assumption in constructing the counterfactual is that the NHS Guidance Order and the Threats were not made. To do otherwise would be to confuse the loss flowing from the relevant order, undertaking or Threat with loss flowing from the subject matter of the litigation.

101. Whether anything else which actually happened is to be 'removed' from the counterfactual world is a question of fact. He accepted that where it was unrealistic (as a matter of fact) to assume that a particular order or undertaking (which was actually made) would have been made in the counterfactual, then it should also be removed. He submitted that applying this test:

    (1) In considering Actavis' alternative case – based on the Actavis Modified Label Order – the assessment of loss caused by the cross-undertaking should proceed on the assumption that the Actavis Modified Label Order *and* the Sandoz Orders were not made. That is because if the Sandoz Orders had not been made, it is unrealistic to suggest that anyone would have been injuncted, or given undertakings, preventing them from bringing intermediate label products to market;

(2) Any claim by Ranbaxy under the Ranbaxy Undertaking must similarly proceed on the basis that neither the Ranbaxy Undertaking nor the Sandoz Orders had been made, because it is unrealistic to think that Ranbaxy would ever have given their undertakings if the Sandoz Orders had not be made; but

(3) In contrast, it is not unrealistic that, had the NHS Guidance Order and the Threats not been made, the Sandoz Orders would have been made. Accordingly, it would be wrong to remove the Sandoz Orders from the counterfactual to be constructed on Actavis/Teva's primary case based on the cross-undertaking in the NHS Guidance Order and the Threats.

102. Mr Lykiardopoulos stressed that different counterfactuals are required, because of the essential difference between the claims under the NHS Guidance Order (which are framed by reference to the restriction on the products supplied by Skinny Label Generics being used for anything other than epilepsy and GAD) and the claims under the Sandoz Orders and the Ranbaxy Undertakings (which are framed by reference to the restrictions on Full Label Generics). Thus, the essential difference between (1) and (2) in paragraph [101] above, on the one hand, and (3), on the other hand, is that – in contrast to the Sandoz Orders – the NHS Guidance Order was not designed to, and did not, stop anyone from launching a full label product but was only intended to bring about a change in prescribing practice.

103. This conclusion was supported, he submitted, by the propositions, first, that compensation is limited to that which flows from the specific order to which the cross-undertaking related (or the specific Threat under which damages were sought) and, second, that changes should be made from the actual world only to the minimum extent necessary. To remove all orders from the counterfactual would wrongly stray into awarding compensation based on the litigation itself and the invalidity of the Patent.

104. Mr Lykiardopoulos agreed with Mr Boulton that the framing of the appropriate counterfactual is simply a tool for assessing the loss that flows from a wrongfully made interlocutory injunction. He fundamentally disagreed, however, with the way in which that tool was to be applied. Contrary to Mr Boulton's submission that there needs to be one counterfactual because there is in substance here only one type of loss caused by the (plural) orders, undertakings and Threats, Mr Lykiardopoulos submitted the loss caused by each order, undertaking or Threat must be considered separately: to remove anything except the relevant order, undertaking or Threat – as a matter of law – from the counterfactual would *prevent* the court from assessing the loss which flowed from that relevant order, undertaking or Threat. As he put it in argument, in assessing loss caused by the NHS Guidance Order:

> "…if you remove the Sandoz injunction, it is no longer assessing loss caused by the NHS Guidance Order and threats; it is assessing loss by the NHS Guidance Order, threats and the Sandoz injunction…"

105. For similar reasons, while Mr Lykiardopoulos did not dispute that damages must be compensatory, he submitted that the compensatory principle *required* there to be different counterfactuals for the NHS Guidance Order and Threats (on the one hand) and the Sandoz Orders and Ranbaxy Undertaking (on the other), and *required* that in considering loss caused by the former, only the NHS Guidance Order and Threats should be removed from the counterfactual. The compensatory principle focused solely on the extent to which each Inquiry Claimant was properly compensated for the loss they suffered, and was not concerned with whether Pfizer would end up paying more to the Inquiry Claimants as a whole than the total loss that could have been suffered in any single counterfactual. That was the price Pfizer would be required to pay for having obtained multiple orders and undertakings against or from a variety of Generics.

106. There may be arguments as to whether – as a matter of fact – the Sandoz Orders would have been made, had there been no NHS Guidance Order, but it is the Skinny Label Generics' claim that it would still have been made. Mr Lykiardopoulos submitted that to remove – as a matter of law – the Sandoz Orders from the counterfactual in relation to the inquiry under the NHS Guidance Order would prevent the Skinny Label Generics from advancing that argument at stage 2.

107. The parties cited a number of authorities which they contended supported (mostly by analogy) their respective contentions. Ultimately, these were of limited assistance in answering the central question raised by this trial of preliminary issues. I address each of the principal cases relied on in turn.

Sigma

108. *Sigma*, on the face of it, directly supports the conclusion that there should be a single counterfactual, in which all of the relevant orders, undertakings and threats are removed. That is, as I have noted above, precisely what Jagot J did. Mr Moser relied in particular on the following passages from her judgment:

(1) At [193], having noted the inter-relationship between the claims of the inquiry claimants, and that the assessment of the degree of probability that one would have sought and obtained a "PBS" listing of their products (under a scheme pursuant to which pharmaceutical products available to be dispensed to patients at a Commonwealth-subsidised price are listed), and when, necessarily affected what other inquiry claimants would have done, said this:

> "I made clear to the parties that compensation could not be assessed on the basis of inconsistent hypotheses. There could be disputes about the construction of the applicable hypotheses but, once constructed, the hypotheses must be consistent across all claims. Otherwise no determination of compensation could be just, at least not to Wyeth. To give an example, the generics and the manufacturers/suppliers did not agree about hypothetical supply prices. Because the claims of the manufacturers/suppliers

> depend on the generics, there cannot be inconsistent hypothesised supply prices between them."

(2) She returned to this point, at [231] to [232]:

> "231. …Is it necessary or appropriate to disregard the grant of Sigma interlocutory injunction when considering Alphapharm's position had the Alphapharm interlocutory injunction not been granted? And is it necessary or appropriate to disregard the grant of Sigma and Alphapharm interlocutory injunctions when considering Generic Health position had the Generic Health interlocutory injunction not been granted?
>
> 232. In my view, these two questions must be answered yes, as otherwise it is not practically possible to construct consistent hypotheses of what would or might have occurred in any case. For example, if when considering Sigma's position it is taken that Sigma would not be subject to the Sigma interlocutory injunction but when considering Alphapharm's position it is taken that Sigma was subject to an interlocutory injunction, then the inevitable consequence is that the hypothesised market for Alphapharm is distorted from the outset. The hypothesised market on this latter approach would contain only Alphapharm when, in fact, it is known that Sigma was and would have been the first to market."

109. In considering the weight to place on the views of Jagot J in this respect, however, it is important to note two things. First (as she noted at [233]), the parties all assumed that this was the correct approach, so there was no contrary argument. Second, each of the interlocutory injunctions in that case contained a cross-undertaking in favour of (1) the person against whom the injunction was granted and (2) any third party affected by the order. Each of the inquiry claimants had a claim, therefore, under each of the orders. In those circumstances, it is difficult to see any basis on which a separate counterfactual should have been constructed for the claims under the separate orders.

110. Mr Lykiardopoulos relied on *Sigma* for the opposite proposition that in constructing the counterfactual the court should *not* exclude other orders on the basis that they were wrongly made. That was because Jagot J held that, although other interlocutory orders made on the same wrong basis as that which gave rise to the claim under a cross-undertaking were to be excluded from the counterfactual, the *final* injunction that had been made (as it turned out, also wrongly) in that case was *not* excluded. That, however, was because the interlocutory injunctions, the existence of which gave rise to the claim for damages under the cross-undertaking were discharged on the grant of the final injunction. Accordingly, no loss was caused by the interlocutory injunctions from that date. The final injunction was not accompanied by a cross-undertaking in damages, so did not give rise to a separate claim for loss although it was wrongly made. At [1221] she said:

> "I have accepted that the final injunctions on 8 November 2010 must represent the date from which no compensation is payable. Those final injunctions, of course, were also wrongly granted but Wyeth's undertakings did not extend to any effect of the final injunctions (and nor logically could they do so given the principles which found the requirement to give the usual undertaking as to damages as the price of interlocutory orders). Unfair as it no doubt appears to the claimants, losses sustained as a result of a wrongly granted final injunction must lie where they fall."

111. Accordingly, I consider that nothing in this conclusion, or the reasons for it, provides support for removing from the counterfactual other interlocutory orders wrongly made on the same basis during the period in which damages fall to be assessed under the cross-undertaking in the first order.

Mastercard litigation

112. Actavis/Teva and Pfizer each relied, for differing purposes, on certain passages from the linked decisions of the Court of Justice of the European Union ("CJEU") in *Mastercard v European Commission* [2014] 5 CMLR 23 and the Court of Appeal in *Sainsbury's Supermarkets Ltd v Mastercard Incorporated* [2018] EWCA Civ 1536.

113. These decisions arose out of factually, legally and procedurally complex litigation concerning payment card schemes operated by Mastercard and Visa. The essential issue was whether a multilateral interchange fee ("MIF") charged by Mastercard's payment card scheme was prohibited by Article 101 of the Treaty on the Functioning of the European Union. That gave rise to the question whether the MIF was justified as an 'ancillary restraint' on the basis that it was objectively necessary. For that it was necessary to inquire whether the scheme would be impossible to carry out in the absence of the restriction in question.

114. Actavis/Teva rely upon the decision of the CJEU for the proposition that where multiple issues arise in the same proceedings, it may be appropriate to construct different counterfactuals for different issues. At [108] the CJEU said that in considering the appropriate counterfactual hypothesis (for determining whether the scheme would be impossible without the MIFs) "…it is important that that hypothesis is appropriate to the issue it is supposed to clarify and that the assumption on which it is based is not unrealistic."

115. That is an uncontroversial proposition which I did not understand Pfizer to contest. I do not think, however, that it provides any assistance in this case. In *Mastercard*, one issue was (as I have noted above) whether the scheme would be impossible to carry out in the absence of the MIFs, and the second issue was as to the anti-competitive effect of the MIFs. The fact that it is necessary to construct different counterfactuals for those conceptually different questions says nothing about whether separate counterfactuals are required for the claims of different Inquiry Claimants under different orders, undertakings or Threats in this case. Indeed it begs the question whether (as Actavis/Teva contend) the

questions arising under the different orders and undertakings are conceptually different or (as Pfizer contend) they are conceptually linked.

116. In their skeleton, Actavis/Teva also rely on the CJEU in *Mastercard* for the proposition that the counterfactual hypothesis must be "realistic" (see, again, [108] of the decision, quoted above). As I have noted above, Actavis/Teva use the word "realistic" in this case to refer to the factors that are built into the counterfactual world at stage 2, as a matter of fact. They use the word in the sense of "likely": for example, is it likely that, had the NHS Guidance Order not been made, Sandoz would have sought to bring a full label product to market and/or would have been restrained from doing so? Again, I do not see anything controversial in that proposition, but it is irrelevant to the question I need to determine at stage 1.

117. For its part, however, Pfizer contends that it is open to the court, at stage 1 (i.e. as a matter of law, not merely in the sense of whether something was "likely") to conclude that a particular element should be excluded from the counterfactual on the grounds that it is not sufficiently realistic. In the subsequent *Mastercard* proceedings before the Court of Appeal in England, one of the issues was whether, in evaluating the question whether the scheme would be impossible to carry out in the absence of the MIFs, this should be done on the basis of a counterfactual that the rival scheme would be able to continue to impose (unlawful) MIFs. This was known as the "death spiral" issue because, if the counterfactual assumed a rival scheme that could continue to set high MIFs, the scheme under scrutiny would be likely to lose most or all of its business to the rival scheme.

118. The Court of Appeal rejected the argument for two reasons. First, at [202], in reliance on [108] of the decision of the CJEU quoted above: where the schemes were engaged in the same business, using the same model, and were fierce competitors, it was unrealistic to assume that if one scheme was prohibited from setting default MIFs, the other would remain unconstrained. Second, at [204] to [208], finding (contrary to the conclusion of Popplewell J) that the Visa and Mastercard schemes were materially identical, the Court of Appeal nevertheless endorsed Popplewell J's conclusion that "it should not be open to one unlawful scheme to save itself by arguing that it otherwise would face elimination by reason of competition from the other scheme, which is itself unlawful."

119. The context in *Mastercard* was very different. This makes it difficult to read the conclusions reached in it across to the circumstances of this case. As to the conclusion that to assume that other schemes remained unconstrained was "unrealistic", there was no discussion as to whether that was a conclusion of law, or one based on the facts, but it appears to have been the latter. As to the second point, there is something inherently unattractive (as the way in which it was put by the Court of Appeal reveals) in the argument that an unlawful anti-competitive scheme can be saved from an adverse finding by reliance on the fact that the competition was itself unlawful in the same manner. In this case, however, it is Pfizer, as the "wrongdoer" which is seeking to rely on the fact that other orders or undertakings were wrongfully obtained or procured by it as a reason for excluding them from the counterfactual. That is not to say that the

fact they were wrongfully obtained is *not* a good reason for excluding them, but just that *Mastercard* does not provide a sufficient explanation for their exclusion.

Marex Financial Ltd v Sevilleja

120. Pfizer relied, in support of its proposition that a defendant ought not to be liable to pay compensatory damages that exceed the amount of loss caused by the matters for which it is liable, on the decision of the Supreme Court in *Marex Financial Ltd v Sevilleja* [2020] UKSC 31.

121. In that case, the Supreme Court concluded there is no justification for a "reflective loss" principle in the law of damages; although, it held that there are grounds for a more limited principle of company law that shareholders cannot bring an action to make good a diminution in the value of their shareholding, or in dividends received, which flowed from loss suffered by the company, for the recovery of which the company had a cause of action.

122. Mr Boulton referred me first to the judgment of Lord Reed at [3] to [4]. Lord Reed was there discussing the problem that A and B have concurrent claims against C in respect of losses which are interrelated, such that payment by C to one of them will have the practical effect of remedying the loss suffered by the other. He said that the principle that double recovery should be avoided does not prevent a claimant from bringing proceedings for the recovery of his loss, but the court would have to consider procedural mechanisms so as to avoid double recovery in the situations where the issue was properly before it.

123. Mr Boulton also referred me to [155], where Lord Sales said that "as a matter of basic justice, the defendant ought not to be liable twice for the same loss" and to [161], where he said that in such a case the court could take steps to manage the coincidence of claims by procedural means.

124. I do not find either of these passages to be of assistance. This is not a case involving the kind of double recovery referred to by Lord Reed. Nor is it a case where Pfizer is sought to be made liable twice (or more) for the same loss. Those parts of the judgments in the Supreme Court which refer to the court taking steps to manage, by procedural means, the risks that arise where there is potential double recovery are relevant only in showing that *if* the compensatory principle might be breached in the context of the multiple Inquiry Claims in this case, then the court has powers to prevent that happening (for example, managing cases together so that findings of fact in one case are binding in another). That says nothing, however, about whether there is such a risk in this case.

Lilly Icos

125. The NHS Parties relied on the approach adopted by Arnold J in *Lilly Icos*. In that case, four different claimants obtained an interlocutory injunction against the same defendant. The injunctions turned out to be wrongly granted (for reasons which applied equally to each of the claimants). The issue Arnold J had to decide was whether the defendant's loss was caused by only one, or all four,

of the injunctions. He concluded that all four of the injunctions had caused the defendant's loss (see [191]). It is true that he posed and answered the question (at [193] to [206]): what would have happened if there had been no injunctions? There does not appear, however, to have been any argument as to whether the appropriate counterfactual, for the purposes of each of the inquiry claims, was that the other injunctions either were, or were not, made. There is nothing, therefore, in the reasoning of Arnold J which casts light on the problem that arises in this case.

Secretary of State for Transport v Curzon Park Limited

126. *Secretary of State for Transport v Curzon Park Limited* [2021] EWCA Civ 651 was concerned with the assessment of compensation for the compulsory purchase of land. By the Land Compensation Act 1961, compensation is assessed on the basis of a hypothetical sale in the open market, but with certain counterfactual assumptions. In particular, by section 14(3) and (4), where there is a *prospect* of planning permission being granted on the relevant land or other land and where that prospect amounts to a reasonable expectation, the reasonable expectation is to be transformed into a certainty.

127. Mr Lykiardopoulos relied on certain passages in the judgment of Lewison LJ, referring to a fundamental principle of valuation (the "reality principle", said to be much the same thing as the "principle of equivalence") which requires the valuation to take place against the background of the real world, except in so far as specified hypotheses (whether statutory or contractual) otherwise require: see [40] to [43].

128. He also relied on the case for the conclusion that fair compensation required that the owner of the land should be paid the value of the land *to him* notwithstanding that other owners of contiguous land had similar claims and that, in aggregate, the amount paid to all of them was more than would have been achieved in the real world: see [64] to [67]. There were four contiguous sites that had been compulsorily acquired. The Secretary of State sought to limit the amount of compensation payable to the owner of each site by reference to the fact that, in the real world, although each owner would have had a reasonable expectation of the grant of planning permission on its land, only one of them could actually have achieved that. The Court of Appeal rejected that argument, notwithstanding that the cumulative amount of compensation payable went beyond that which would have been achieved in the real world. At [67], Lewison LJ said:

> "In the real world, if all four landowners had sold their land at the respective valuation dates without having first applied for planning permission, the market would no doubt have valued each parcel on the basis of hope value. It would be necessary for a purchaser to assess the likelihood of planning permission being granted for that particular parcel of land. The price paid would have reflected that assessment. In the real world more than one landowner could have had a reasonable expectation of the grant of planning permission for rationed development, even though

> only one of them would have actually achieved that. But what section 14 of the LCA does is to convert a reasonable expectation of planning permission into a certainty. It is not surprising that converting four reasonable expectations of planning permission into four certainties may have the cumulative effect of increasing the overall compensation payable to a level beyond that which would have been achieved in the real world. That, to my mind, is a clear encroachment on or modification of the principle of equivalence (as Mr King accepted), to which the courts are bound to give effect."

129. I do not think this case supports the arguments of the Skinny and Full Label Generics. The context (valuation according to a statutory scheme) is far removed from that of the present case (compensation for a breach of cross-undertaking under a jurisdiction founded in equity). Moreover, the "real world" analysis would have required the relationship between the planning applications of the four owners to have been taken into consideration in assessing the likelihood of an owner obtaining planning permission in calculating compensation payable to it. The departure from the real world was mandated by the statutory assumption that a reasonable expectation of planning permission was converted into a certainty. It was that which resulted in increasing the cumulative compensation above that which could have been achieved in the real world. There is no equivalent statutory assumption to be made in this case.

Discussion

130. In the absence of authority directly on point, I approach the question which lies at the heart of Assumptions 1 and 2 from first principles.

131. While there is an attractive simplicity in the argument that the only fact occurring in the real world that is to be removed as a matter of law as part of the but-for part of the damages inquiry is the very order, undertaking or Threat upon which the Inquiry Claim is based, I do not think that it is correct in the circumstances of this case. Instead, I conclude that it is necessary when assessing the loss caused by any one order, undertaking or Threat which it turns out was wrongly made, to assume the removal from the counterfactual of the other orders, undertakings or Threats which it also turns out were – for the same reason – wrongly made.

132. The particular circumstance of this case that drives that conclusion is the fact that the market for pregabalin is a finite one, where demand is dictated only by patient need.

133. For each Inquiry Claimant, the question as to what loss it suffered as a result of the relevant order (or undertaking or threat) is answered by the share of the market that it would have enjoyed but for the distortion to the market caused by that wrongfully made order.

134. Because the market is a finite one, the answer to that question in turn depends upon the market share that would have been obtained by each other Generic that would have participated in the market. (This was characterised as a "zero sum game". Dr Nicholson objected to that characterisation, but on the mistaken understanding that it was said to be a zero sum game between the Inquiry Claimants. As I have noted here, however, it is a zero sum game as between all participants in the market.)

135. The question, essentially, is what would have been the outcome, for each supplier of pregabalin, of the competition between all such suppliers of pregabalin but for the market-distorting order that was wrongly made.

136. To assess the outcome of that competition by reference to a counterfactual where the market was nevertheless distorted by one or more other orders that were wrongly made for precisely the same reason as the order which gives rise to the particular Inquiry Claim would in my view be wrong in principle.

137. Put another way, because the market share that one market participant would have achieved cannot be identified without identifying the market share that each other market player would have achieved, it is only by creating a counterfactual world in which the playing field between market participants is levelled in this way that the respective shares which each participant would have achieved can fairly be assessed.

138. This reflects the principle (endorsed by McCombe LJ in *Abbey Forwarding*) that in assessing compensation under a cross-undertaking in damages, the court should adopt a view which is fair and reasonable. It is a relevant factor, in support of this conclusion, that the contrary approach, advocated by the Skinny Label Generics and the Full Label Generics would, to varying degrees, result in Pfizer being required to pay more in aggregate by way of compensation to all Inquiry Claimants than the total loss that could possibly have been caused in any single counterfactual world.

139. The simplest illustration of this is provided by combining the different counterfactuals contended for by Skinny Label Generics and the Full Label Generics. If the appropriate counterfactual is, as the Skinny Label Generics contend, that the orders and undertakings restricting Generics from bringing full label products to market remained in place, then the Skinny Label Generics would between them have shared 100% of the available market for Generics. It follows that *any* claim for loss by the Full Label Generics – which is necessarily premised on them having had, in the counterfactual, at least some share of the available market for Generics – would result in the multiple counterfactuals in aggregate assuming a total market share of more than 100% of the actual available market.

140. Similarly, if the NHS Parties are entitled to claim on the basis that the price for pregabalin would have collapsed from an early date, but the Generics are entitled to claim on the basis that the price would have remained high throughout, Pfizer would be required to pay a total amount of compensation which exceeded the amount that could possibly have been suffered by all Inquiry Claimants in aggregate in any single actual or counterfactual world.

141. It is not an answer to this to say that damages should be assessed liberally (per Norris J in *Servier*, see above at [50]). Norris J was there concerned with the extent to which the court should subject an Inquiry Claimant's evidence to "over eager" scrutiny. That does not preclude the court rejecting a basis of assessment which could not reflect any single reality.

142. The contrary approach also produces distinctions that are difficult to justify. Had the court restrained Generics A, B, C and D from launching generic products by way of a single order against them all, it could not sensibly be suggested that in considering the claim of Generic A under the cross-undertaking in damages contained in that order, it should be assumed that the order as against B, C and D remained in place.

143. I can see no principled distinction between that case and a case where separate orders were obtained against Generics A, B, C and D on different occasions (a circumstance driven simply by the fact that the Generics threatened to take action at different times).

144. Although Mr Lykiardopoulos did not suggest that – in such a case – the counterfactual world in relation to the claim of Generic A would be one in which the orders against B, C and D remained in place, that was because he accepted that it would – as a matter of fact at stage 2 of the inquiry – be sufficiently unlikely that they would have done so. I consider, however, that the possibility of the other orders remaining in place is to be excluded as a matter of assumption at stage 1, in the same way that an order made at the same time as against all four Generics should be wholly removed from the counterfactual in each of the Inquiry Claims by A, B, C and D.

145. Similarly, where the same Inquiry Claimant is the beneficiary of a cross-undertaking under two or more different orders, it would be absurd for its Inquiry Claim under one of the orders to proceed on the basis that the other order would have stayed in place. That is important here, where there is considerable interconnection between the orders. For example: Actavis and Dr Reddy's are beneficiaries of the cross-undertakings in the NHS Guidance Order and (respectively) the Actavis Modified Label Order and the Dr Reddy's 2016 Orders; NHS EWNI is a beneficiary of the cross-undertakings in the NHS Guidance Order and the Sandoz Orders; Sandoz (although no longer a party to these proceedings, having settled its claim) is a beneficiary of the Sandoz Orders and the NHS Guidance Order; and, as a result of the cross-undertakings in the Ranbaxy Undertaking, Ranbaxy is entitled to compensation for both the Ranbaxy Undertaking and the NHS Guidance Order having been wrongly granted.

146. This level of interconnection between the orders supports the view that the orders, undertakings and Threats should stand or fall together in the counterfactual world. They were all aspects of Pfizer's attempt to maintain its monopoly over the supply of pregabalin for treating neuropathic pain. Each attempt to do so turned out to be "wrongful" (in the sense used above) for the same reason – that Pfizer was not entitled to the monopoly it claimed. In assessing the loss caused by those attempts, or any one of them, to each Inquiry

Claimant, therefore, each of its wrongful attempts to enforce the same monopoly should be removed from the counterfactual.

147. Mr Lykiardopoulos' contentions in opposition to this conclusion (summarised above) can be distilled into the following four points: (1) it confuses loss caused by the subject matter of the litigation and loss caused by the individual orders; (2) it *prevents* Actavis/Teva's loss from the NHS Guidance Order being assessed; (3) different counterfactuals are required because of the different nature of the claims made by Skinny Label Generics and Full Label Generics; and (4) the fact that Pfizer may end up paying more in aggregate in damages than could be suffered in any single counterfactual world was simply the fair price that it had to pay for having prevented numerous Generics from accessing the market.

148. As to the first point, I disagree that to assume the other orders, undertakings and Threats were not made is tantamount to assessing loss by reference to the existence of the Patent or the subject matter of the litigation. To do so leaves in place in the counterfactual world both the Patent and the litigation, and says nothing about the knowledge of market participants as to the validity of the Patent. The actions of all Generics would therefore have been tempered (as they were in the real world) by the risk of infringing the Patent. There is no sense, therefore, in which the assumption would result in damages being assessed by reference to loss caused by the Patent or the litigation.

149. I also reject Mr Lykiardopoulos' objection that this would prevent the loss *actually suffered* by Actavis/Teva from being assessed. His argument was that to remove, for example, the Sandoz Orders from the counterfactual world would mean that the court was assessing the loss caused to Actavis/Teva by the NHS Guidance Order and Threats *and* the Sandoz Orders (when it should be assessing merely the loss caused by the NHS Guidance Order and the Threats). The argument, however, begs the question as to how loss is to be calculated in the first place: it assumes (contrary to the conclusion I have reached above) that in order to assess the loss flowing from each order (for example) it is correct that only *that* order is to be excluded from the counterfactual.

150. Further, I do not accept that the difference in the nature of the claims made, as between the NHS Guidance Order on the one hand and the Sandoz Orders, the Ranbaxy Undertaking, the Dr Reddy's 2016 Orders and the Actavis Modified Label Order on the other hand, requires separate counterfactuals. The suggested distinction (see [102] above) is that the NHS Guidance Order was focused solely on skinny label products, and was not designed to (and did not) stop anyone from launching a full label product, whereas the Sandoz Orders (etc) were focused either on full label products or intermediate label products.

151. While it is true that the precise claims arising under the cross-undertaking in the NHS Guidance Order are as a result different, I do not think that the difference is such as to undermine the conclusion that all of the orders, undertakings and Threats should be removed from the counterfactual, based as it is on the fact that they all share the fact that they were attempts by Pfizer to protect its monopoly in the use of pregabalin for the treatment of neuropathic pain. At the

time of the NHS Guidance Order, there was no perceived threat from Generics seeking to enter the market with a full label product, so the order was targeted at generic pregabalin being dispensed inadvertently for treatment of neuropathic pain. As I have noted at [68] above, it would nevertheless have had the effect of precluding a Generic, who did bring a full label product to market, from effectively accessing the market.

152. Moreover, the premise of my conclusion that it is necessary to assume none of the relevant orders, undertakings or Threats was made – that the loss occasioned to each Inquiry Claimant is dependent upon the actions of all other participants in the market – is equally true in respect of claims arising as a result of the NHS Guidance Order as it is in relation to the other orders and undertakings. The fact that some Generics were only planning to supply skinny label products, whereas others were planning to supply full label products would be reflected in the calculation of market share each would have obtained in the absence of the relevant orders, undertakings and Threats, but it does not alter the fact that the actions of each Generic impacted on the likely market share of all others. It was not suggested, for example, that there are two distinct markets: supply of pregabalin for treatment of epilepsy and GAD, and supply of pregabalin for treatment of neuropathic pain. That is reflected in the fact that full label products are supplied for the treatment of all those conditions, and that the appearance of full label products on the market would have affected the extent to which the Skinny Label Generics' products would have been prescribed or dispensed for epilepsy and GAD.

153. Mr Lykiardopoulos' fourth objection relates in part to the compensatory principle. I agree with him to this extent: the narrow principle that no Inquiry Claimant should receive more compensation than the damage actually suffered by it does not assist Pfizer or the NHS Parties. Their argument in this respect begs the same question (what *is* the actual measure of the loss) as the argument of Actavis/Teva which I have rejected at [149] above. Nevertheless, as I have noted above, there is support for the conclusion in the broader principle that, as an equitable remedy, the assessment of damages should be just and equitable and that, in this regard, it is appropriate to take into account that adopting separate counterfactuals for different groups of Inquiry Claims would result in greater damages being payable by Pfizer than could have been suffered in any single counterfactual world.

154. For the same reasons, I reject the contention (made in Mr Lykiardopoulos' fourth point and supported, in particular, by Mr Brandreth) that this overburdening of Pfizer is justified because it obtained an individual advantage every time it obtained an order or Threat, or received an undertaking, designed to protect the monopoly to which it claimed to be entitled.

155. I have reached the above conclusion without reliance on the arguments based on practicalities advanced by Pfizer (and supported by the NHS Parties). In any event, the preliminary issue raised by paragraph 1(a) of the Birss J CMC Order raises legal issues, and the answer to those issues ought not, generally speaking, be determined by which outcome would lead to a simpler process.

Dr Reddy's primary case

156. Dr Nicholson contended that the debate over Assumptions 1 to 6 is irrelevant to Dr Reddy's case, because its detailed pleading as to what would have happened in the absence of the NHS Guidance Orders and Threats has been admitted by Pfizer. That pleading does not need to, and does not, address which other orders, undertakings and Threats would have existed in the counterfactual, because it particularises the facts that Dr Reddy's says would have occurred but for the NHS Guidance Orders and Threats: Generics with skinny label products would have come to the market at the same time that they did in the actual world; no full label products would have been brought to market while the Patent remained in force; and pregabalin would have remained in Category C until shortly after the expiry of the Patent.

157. He contended that in view of those admissions there was only one possible answer to the question posed by paragraph 1(a) of the Birss J CMC Order, namely that the appropriate counterfactual assumptions upon which to determine Dr Reddy's Inquiry Claim are the detailed facts pleaded by Dr Reddy's and admitted by Pfizer.

158. He contended that since this is the trial of that question, although Pfizer has reserved its position as to possible amendments to its pleading, it is simply too late for it to make any amendments. Moreover, the court's role is to adjudicate on the issues identified by the parties, so it cannot reach any conclusion other than that which is permitted on the parties' pleadings: *Al-Medinni v Mars UK Ltd* [2005] EWCA Civ 1041 (where the Court of Appeal found that the trial judge had erred in deciding a personal injury case on the basis of a theory as to the facts which neither side had presented).

159. Mr Boulton made four points in response: (1) the pleaded matters which Pfizer had admitted were all concerned with stage 2 of the inquiry, whereas the preliminary issue relates only to stage 1; (2) parties are not bound by their pleading at trial; (3) even if parties are bound by their pleadings in a bilateral case, that does not apply in multi-party proceedings; and (4) if the previous points are wrong, then Pfizer would seek to amend its case post-judgment.

160. The short answer, in my judgment, to Dr Reddy's point is that it is based on a misreading of the Birss J CMC Order. That ordered the trial of a *preliminary* issue as to what, if any, assumptions should be made as a matter of law at stage 1 (i.e. the "but for" stage) of the Inquiry Claims and whether the same assumptions should be made across all Inquiry Claims. Moreover, although paragraph 1(a) of the Birss J CMC Order asks an apparently open-ended question ("what are the appropriate counterfactual assumptions…?") the correct reading of paragraph 2 and Schedule B is that Schedule B contains a closed list of "the possible" counterfactuals under consideration. I note that the parties mostly agreed the terms of Schedule B, but to the extent that it could not be agreed, the differences were resolved by Birss J on the papers. Even though, therefore, if paragraph 1(a) of the Order was read in isolation, it might be said that it was to be answered by Dr Reddy's pleaded case, that is not how I interpret the Birss J CMC order as a whole.

161. Although Dr Nicholson is correct to say that the distinction between stage 1 and stage 2 is purely a matter of analytical convenience, and that the single question is what loss was caused by the relevant order, undertaking or Threat, nevertheless that distinction is implicit in the questions raised by this trial of preliminary issues. Those questions focus solely on the assumptions to be made, if any, as a matter of law in constructing the counterfactual and do not involve reaching a determination on any of the facts which flow from those assumptions.

162. Dr Nicholson is also correct to say that Pfizer's admission of Dr Reddy's case as to what the counterfactual world would have looked like enables stage 1 to be bypassed altogether as between Pfizer and Dr Reddy's. It is important to note, however, that Pfizer has pleaded (as against all Inquiry Claimants) on the basis that there is a single counterfactual assumption at stage 1 across all Inquiry Claims that none of the other orders, undertakings or Threats were made. It perceives, on the basis of the information currently known to it and of that single and consistent counterfactual assumption, its interests best lie in admitting Dr Reddy's case as to the assumptions to be made at stage 2 of the inquiry.

163. If, therefore, Pfizer's case as to the appropriate assumptions at stage 1 is not accepted, then it would be difficult to see why Pfizer would be prohibited from amending its pleading against any or all of the Inquiry Claimants. I do not accept, therefore, Dr Nicholson's contention that as this is "the trial" it is now too late for Pfizer to amend its pleading. This is not the trial of any of the factual questions that might flow from the assumptions to be made at stage 1.

164. In these circumstances, the principle to be derived from the *Al Medinni* case is irrelevant. In particular, my conclusion that there should as a matter of law be a single counterfactual assumption across all Inquiry Claims that none of the other orders, undertakings or Threats was made is one which falls squarely within the parameters of the cases advanced by the respective parties. I do not need to address, therefore, Mr Boulton's contention that the approach in *Al Medinni* does not apply where the question in issue is a mixed one of fact and law, or that it does not apply in a multi-party case. I merely make it clear (as this was a point of some importance to the parties) that there can be no basis for either Pfizer or any of the other Inquiry Claimants being bound, as between them, by any agreement (whether as to fact or as to the facts to be assumed in the counterfactual) between Pfizer and Dr Reddy's, even though this could lead to the court making findings, as between Pfizer and an Inquiry Claimant, that are inconsistent with the facts, or assumed facts, agreed by Pfizer with Dr Reddy's.

Assumptions 4 to 6

165. Assumptions 4 to 6 were introduced by the NHS Parties. In NHS EWNI's skeleton it is first contended that they should be answered in the positive because that flows from the answer to Assumptions 1 and 2: if there is a single counterfactual across all Inquiry Claims that none of the orders, undertakings or threats were made, then it follows that in the counterfactual Pfizer *would* not have done any of the things referred to in Assumptions 4 to 6. This contention,

however, crucially mis-states the language of Assumptions 4 to 6, which is whether Pfizer *could* have done those things. Whether it would have done so is a question of fact, and for that reason alone is not for determination within this preliminary issue trial.

166. NHS EWNI's second contention is that the positive answer for which they contend flows from its contention on Assumption 3: all of the actions covered by Assumptions 4 to 6 would have been inconsistent with the implied promises contained in the cross-undertakings. Since I have rejected the case under Assumption 3 based on implied promise, it follows that I also reject this argument of the NHS Parties.

167. There being no other reason advanced for constraining the scope of the Inquiry Claims by reference to Assumptions 4 to 6, I conclude that they should be answered in the negative.

Inflammatory pain

168. A further issue that was raised during the hearing relates to the fact that the claims in the Patent relating to inflammatory pain have been held to be valid. This fact has not featured substantively in any of the proceedings to date because neither Pfizer nor any Generic has obtained a marketing authorisation for pregabalin in connection with treatment of inflammatory pain.

169. Pfizer, in its main skeleton argument, commented that irrespective of its main arguments (which I have accepted) as to why Assumption 3 was answered in the negative, that it in any event ignored the fact that the claims in the Patent relating to the treatment of inflammatory pain were ultimately upheld as valid. Further, in dealing with Assumptions 4 and 6, Pfizer commented that it could, as a matter of law, have relied upon the inflammatory pain claims to obtain an injunction, albeit it might have been estopped from doing so (recognising that both issues raise questions of fact and were thus not suitable for determination at this trial of preliminary issues). Finally, in dealing with Assumption 5, Pfizer commented that any threat made in respect of the inflammatory pain claims, prior to the expiry of the Patent, could have been justified. These points also reflected Pfizer's points of defence, for example, in respect of NHS EWNI's claim. In view of my conclusions on Assumptions 3 to 6, it was unnecessary to consider these additional points made by Pfizer.

170. These passages in Pfizer's skeleton prompted vehement objection from the other parties. In a written note from NHS EWNI, four reasons were advanced why Pfizer could not run an argument to the effect that it could or would have sought interim relief to protect the inflammatory pain claims in the Patent: (1) it is logically incoherent for Pfizer to contend in the context of Inquiry Claims based on 'wrongful' orders, undertakings and Threats that it could have *rightfully* obtained the same or similar orders on the basis of the inflammatory pain claims in the Patent; (2) Pfizer had not sought to assert infringement of the inflammatory pain claims in the Actavis proceedings and it would be an abuse of process to attempt to do so now; (3) Pfizer has failed to articulate an arguable case on infringement of the inflammatory pain claims; and (4) although Arnold J's order following the trial in the Actavis proceedings declares the

inflammatory pain claims to be valid, there was no argument on the point (it having had no practical significance given that Actavis was not alleged to have infringed those claims) and in any event none of the other Inquiry Claimants would be prevented from challenging the validity of the inflammatory pain claims.

171. NHS Scotland and Ranbaxy advanced similar objections during the hearing.

172. Pfizer's position, developed in argument by Ms May, was (as foreshadowed in the passing references to this point in its main skeleton argument) that the other parties' objections raise questions of fact which cannot be determined at this preliminary issues trial. Further, insofar as it was contended that Pfizer had no arguable answer to the objections, so that this was in effect a strike-out application of certain aspects of its pleading, no such application had been made and Pfizer was not in a position to deal substantively with such an application.

173. In my judgment, despite the persuasive submissions advanced, in writing, on behalf of the NHS EWNI and, orally, by Mr Brandreth and Mr Campbell, the submissions of Ms May in this respect are to be preferred. It is telling, in this regard, that Actavis/Teva did not support the position taken by the NHS Parties and Ranbaxy. That is not because they accept that Pfizer can place any reliance on them (they strongly dispute that they can), but because they accept that it is not something which is for determination at this preliminary issues trial. In correspondence between Actavis/Teva and Pfizer, a further issue had been proposed (by Pfizer) for inclusion in the preliminary issues trial, as to whether damages could not be claimed in respect of products covered by the inflammatory pain claims, but it had been agreed that the issue would be removed from those to be determined at this trial.

174. Even without that exchange, it is clear that the issues raised by the NHS Parties' and Ranbaxy's objections to Pfizer's ability to rely in any way upon the inflammatory pain claims in the Patent are not matters that fall to be determined at this preliminary issue trial. Moreover, particularly in light of the exchange with Actavis, I consider it would not be fair to Pfizer to require it to respond substantively, in effect, to a strike out application notwithstanding no such application has been made.

Conclusions on preliminary issue 1(a)

175. For the above reasons, I conclude that the answer to the preliminary issue in paragraph 1(a) of the Birss J CMC Order is that it is appropriate to assume as a matter of law, in assessing the counterfactual for each Inquiry Claim, that none of the orders, undertakings or Threats were made.

176. The answer to each of the Assumptions in Schedule B is therefore:

(1) It is correct to assess the counterfactual for each Inquiry Claim on the assumption that the same Threats, orders and undertakings were not made across all Inquiry Claims;

(2) It is correct to assume as a matter of law, in the counterfactual for each Inquiry Claim that none of the Threats, orders or undertakings were made;

(3) The answer to each of the questions raised by Assumptions 3 to 6 is "no".

Preliminary issue 1(b)

177. Preliminary issue 1(b) raises essentially a case management issue. In my judgment, particularly given my conclusion that the same counterfactual assumptions are to be made at stage 1, the Inquiry Claims should be case managed on the basis that findings of fact will be binding on each of the parties to them.

178. Where every Inquiry Claimant's claim depends upon what share it would have had of the overall market, there is little practical sense in a procedure where the respective market shares of all participants in that market are assessed on the basis of different findings of fact as between Pfizer and each Inquiry Claimant.

179. It is true, as Dr Nicholson contended, that each Inquiry Claim is technically a separate claim and that it is possible for each of them to be tried as separate actions (in which case, it is entirely conceivable that different conclusions might be arrived at on issues of fact that are common as between the different Claims). That, however, does not mean that the court should permit each Inquiry Claim to proceed as a separate action.

180. Given the commonality of issues as between the Inquiry Claims, considerations of cost, fairness (to each Inquiry Claimant and to Pfizer) and efficient use of court time and resources all point in favour of common issues being determined on a common basis, with all affected parties being entitled to participate.

181. As I have already noted, that does not preclude Pfizer reaching an agreement with one or other Inquiry Claimant that, for the purposes of the compensation payable to that party, certain facts or assumed facts should be agreed. But any such agreement will be irrelevant as between Pfizer and any other Inquiry Claimant.

182. The precise manner in which the Inquiry Claims will need to be case managed hereafter will be considered at a further CMC.