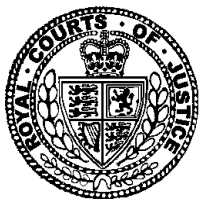

Neutral Citation Number: [2022] EWHC 189 (Pat)

Case No: HP-2015-000007

HC-2014-001795

HP-2014-000021

HP-2015-000049

HP-2020-000034

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

Rolls Building

7 Rolls Building

London EC4A 1NL

Date: 03/02/2022

Before :

MR JUSTICE ZACAROLI

- -

Between :

(1) DR REDDY'S LABORATORIES (UK) LIMITED

(2) SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE

(3) THE NHS COMMISSIONING BOARD (OPERATING AS NHS ENGLAND)

(4) THE WELSH MINISTERS

(5) THE DEPARTMENT OF HEALTH IN NORTHERN IRELAND

(6) THE REGIONAL HEALTH AND SOCIAL CARE BOARD (OPERATING AS

THE HEALTH AND SOCIAL CARE BOARD)

(7) THE SCOTTISH MINISTERS

(8-21) SCOTTISH HEALTH BOARDS

- and -

Inquiry

Clai

WARNER-LAMBERT COMPANY LLC **Inquiry**

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Brian Nicholson QC and Christopher Hall (instructed by **Mishcon de Reya LLP**) for the **First Inquiry Claimant**

Philip Moser QC, Brendan McGurk and Alice Hart (instructed by **The Government Legal Department**) for the **Second to Fifth Inquiry Defendants**

Douglas Campbell QC, Ligia Osepciu and Daniel Selmi (instructed by **RPC**) for the **Seventh to Twenty-first Inquiry Claimants**

Richard Boulton QC, Tim Austen, Tim Goldfarb and Thomas Lunt (instructed by **Kirkland & Ellis LLP**) for the **Inquiry Defendant**

Hearing dates: 11, 12 and 14 January 2022

Further written submissions received 28 January 2022

- -

Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

.....

Mr Justice Zacaroli:

1.
In June 2021 a trial took place in these proceedings of preliminary issues in claims by numerous parties (the "Inquiry Claimants") for compensation under cross-undertakings in damages given by the Inquiry Defendant ("Pfizer") in respect of various interlocutory injunctions or contractual undertakings, and for damages in respect of threats of infringement of patent proceedings (the "unjustifiable threats claim") pursuant to section 70(1) of the Patents Act 1977 (the "1977 Act").

2.
Specifically, that trial (the common assumptions trial, or "CAT") addressed what common assumptions of law were to be made in the Inquiry Claims when identifying the appropriate counterfactual(s) for the purposes of determining compensation and damages. In a judgment handed down on 30 July 2021 ([2021] EWHC 2182 (Ch), the "CAT Judgment") I determined that the appropriate counterfactual for each of the Inquiry Claims was one in which none of the orders, undertakings or threats which it turned out had been wrongly made would have been made. I also determined that findings of fact in each Inquiry Claim would be binding on all Inquiry Claimants.

3.
The background to these proceedings is set out more fully in the CAT Judgment, to which the reader is referred. I will adopt the abbreviations and definitions used in that judgment. As a result of settlements made since the CAT Judgment, the only remaining Inquiry Claimants are Dr Reddy's (a Skinny Label Generic, see §6 and §29(1) of the CAT Judgment), NHS EWNI and NHS Scotland.

4.
This judgment principally addresses applications by Pfizer to amend its pleading in each of the remaining Inquiry Claims. I will address these applications in the following order:

(1)
An application to amend Pfizer's defence to Dr Reddy's claim, to advance defences to the unjustifiable threats claim;

(2)
An application to amend Pfizer's defence to the NHS Parties' claim, so as to exclude any damage said to have arisen from the sale and supply of pregabalin products which would have been used for or attributable to the treatment of any condition covered by Claims 2, 5, 7, 8 and 9 of the Patent, collectively referred to as the inflammatory pain claims ("IPCs");

(3)
An application to amend Pfizer's defence to the claims of NHS EWNI and Dr Reddy's, so as to include an argument based on the construction of the NHS Guidance Order;

(4)
An application to amend Pfizer's defence to Dr Reddy's claim, so as to exclude from Dr Reddy's damages claim any damage arising from the supply of pregabalin used for the treatment of IPCs, either on grounds of illegality because such supply would constitute an infringement of the Patent or because it would be inequitable to allow Dr Reddy's claim to include such damage. Insofar as the claim is put on the latter basis, it already appeared in Pfizer's pleading, but Dr Reddy's made a late application during the course of the hearing to strike it out;

(5)
An application to amend Pfizer's defence to Dr Reddy's claim, so as to rely upon other communications it could have made in the counterfactual that would not have amounted to unjustifiable threats;

(6)
An application to amend Pfizer's defence to Dr Reddy's claim, to plead an alternative counterfactual case. At the hearing I announced my decision to allow this amendment in principle, subject to Pfizer producing a properly particularised pleading of its alternative case.

5.
Finally, I will address an application by Dr Reddy's to reformulate the directions for the remaining Inquiry Claims.

(1) Pfizer's application to amend as against Dr Reddy's to include a defence to the unjustifiable threats claim

6.
Pfizer seeks permission to amend to include a defence to the unjustifiable threats claim by Dr Reddy's pursuant to section 70(2A)(a) and (b) of the 1977 Act (as those provisions were in force in 2015).

7.
Section 70(2A)(a) provided that if the defendant (Pfizer) proves that the acts in respect of which proceedings were threatened constitute or would if done constitute an infringement of a patent, then the claimant is entitled to relief under s.70 "only if he shows that the patent alleged to be infringed is invalid in a relevant respect."

8.

By its proposed amendment, Pfizer seeks to contend that to the extent that the actions, in relation to which the threats were made, consisted of pharmacists dispensing generic pregabalin (specifically "Alzain", Dr Reddy's branded generic pregabalin product) for treating conditions covered by the IPCs then those actions constituted an infringement of a patent which was, in the relevant sense, valid. The IPCs were held to be valid in the earlier proceedings involving Actavis (the "Actavis Proceedings") – see §9 to §25 of the CAT Judgment. Accordingly, Pfizer claims that Dr Reddy's is not entitled to the relief claimed. The acts of infringement are said to have been committed by pharmacists and to have consisted either in:

(1)
(contrary to 60(1)(c) of the 1977 Act) pharmacists dealing in Alzain, which was an infringing product because Dr Reddy's knew and intended that it would be used (among other things) for treating conditions covered by the IPCs; or

(2)
(contrary to section 60(1)(b) of the 1977 Act) the preparation of prescriptions by pharmacists (e.g. by attaching the relevant label to the outside of the box) for dispensing to patients, which constituted an infringement by pharmacists because such action would constitute using "the process" when they knew or a reasonable person would have known that it would be an infringement of the patent.

9.
Section 70(2A)(b) provided that if the defendant proves that the acts in respect of which proceedings were threatened constitute or would if done constitute an infringement of a patent, then even if the claimant shows that the patent is invalid in a relevant respect, he shall not be entitled to relief if the defendant proves that at the time of making the threats he did not know, and had no reason to suspect, that the patent was invalid in that respect. Pfizer seeks to rely on this in relation to threats made in respect of actions that would have constituted infringement of Claims 1 and 3 (i.e. the Claims which the Supreme Court has held to be invalid) if they had been valid.

10.
Dr Reddy's principal objection to these proposed amendments is that they are far too late, because the court has already granted Dr Reddy's the relief to which it is entitled under section 70 and these amendments are an attempt to go behind the court's existing orders and declarations. In the alternative, it contends that it is too late on case management grounds for Pfizer to be permitted to resile from its admission, in its defence in the Inquiry Claim, that the six threats of infringement proceedings upon which Dr Reddy's relies in the Inquiry Claim were unjustifiable threats.

11.
Dr Reddy's was originally sued by Pfizer for infringement in 2015. Pfizer pleaded that Dr Reddy's had infringed the Patent by disposing of, offering to dispose of, using, importing and/or keeping whether for disposal or otherwise a product obtained directly by means of a process as claimed "in at least claims 1 and 3 of the Patent". Dr Reddy's denied that the Patent was valid and denied infringement. It counterclaimed for loss and damage caused by unlawful threats of proceedings for patent infringement. The proceedings between Pfizer and Dr Reddy's were stayed at an early stage, pending the outcome of the Actavis Proceedings.

12.
Following the conclusion of the Actavis Proceedings, Dr Reddy's applied for a final order dismissing the infringement claim against it and for judgment on the threats. By his order of 16 March 2020, Birss J:

(1)
Recited the outcome of the Actavis Proceedings, including that Claims 1, 3, 4, 6, 10, 11, 12, 13 and 14 of the Patent had been determined to be invalid, and that Claims 2, 5, 7, 8 and 9 (i.e. the IPCs) had been determined to be valid;

(2)
Ordered that Pfizer's claim against Dr Reddy's be dismissed on the basis that Claims 1, 3, 4, 6, 10, 11, 12, 13 and 14 are invalid;

(3)
Ordered an inquiry as to damages, so as to quantify the damage suffered by Dr Reddy's pursuant to the cross-undertakings in the various interlocutory orders obtained by Pfizer and "by reason of [Pfizer's] unjustifiable threats of patent infringement proceedings"; and

(4)
Declared that Pfizer "has made unjustifiable threats of proceedings for patent infringement".

13.
Because the original proceedings between Pfizer and Dr Reddy's were stayed at an early stage, the precise threats on which Dr Reddy's relied had not been fully particularised (beyond reference to certain examples). In the Actavis Proceedings, however, there had been greater particularisation. Thus the threats which Arnold J declared (in his order of 16 October 2015) to have been unjustifiable threats of proceedings for patent infringement were identified in his judgment dated 10 September 2015. That part of Arnold J's order was subsequently set aside, and it is common ground that in the Actavis proceedings there was no final determination of the claim in relation to unjustifiable threats. In particular, Pfizer had been given permission to amend its defence in the Actavis Proceedings to include a defence under s.70(2A)(b) of the 1977 Act, but there was no determination of that issue.

14.
Shortly after Birss J's order of 16 March 2020, Dr Reddy's served its points of claim in the Inquiry Claim. At paragraph 1, Dr Reddy's pleaded the salient parts of Birss J's order of 16 March 2020. At paragraph 30, Dr Reddy's pleaded that Pfizer had made unjustified actionable threats of proceedings for patent infringement, identifying six communications from Pfizer to one or other body (the "Threats"), cross-referenced to the passage in Arnold J's judgment of 10 September 2015 where he had found those communications to constitute unjustifiable threats. In its defence in the Dr Reddy's Inquiry Claim, Pfizer admitted both paragraphs 1 and 30.

15.
Pfizer contends that Birss J's Order of 16 March 2020 does not preclude it contending either that the Threats were justified by reference to the IPCs, or that to the extent they were unjustified Pfizer did not know, and had no reason to suspect, that the Patent was invalid. In particular, it contends that the Order is not to be so construed because, in the Actavis Proceedings, the question whether the Threats were unjustifiable had not been resolved.

16.
I reject this contention. Birss J's Order of 16 March 2020 stands to be construed as between Pfizer and Dr Reddy's and in the context of the claims made by each of them against the other. Moreover, it is to be construed objectively. Mr Austen, who led the submissions on behalf of Pfizer in this regard, referred to evidence that Pfizer's understanding and intention was that the Order was intended merely to reflect what Arnold J had found. He accepted, however, that Pfizer's subjective intention is

not relevant to the construction of the Order. On an objective reading of the Order, for the reasons developed below, I consider that it constituted a final determination of Dr Reddy's entitlement to the relief referred to in section 70(3), at least in respect of the Threats, so as to preclude Pfizer from subsequently relying on the defences set out in section 70(2A).

17.
Section 70(1) of the 1977 Act entitles a person aggrieved by threats of infringement proceedings to apply for the relief referred to in section 70(3). That relief is: a declaration that the threats are unjustifiable; an injunction; and damages.

18.
By his order of 16 March 2020, Birss J granted the only relief referred to in section 70(3) which remained relevant (there being no continuing need for an injunction following expiry of the Patent). There can be no dispute so far as the declaration is concerned. That is the very relief identified in s. 70(3). It could only be made if the necessary pre-requisites for granting the declaration existed including, in particular, that Dr Reddy's had established an entitlement to it because the threats were unjustifiable.

19.
Mr Austen contended that the fact that Birss J ordered an inquiry as to damages does not preclude Pfizer from subsequently contending that no damages should be payable on the basis that the Threats were justifiable or that Pfizer did not know and had no reason to suspect that Claims 1 and 3 were invalid. I disagree. Birss J's Order was that there be an inquiry as to damages suffered by Dr Reddy's "by reason of … the unjustifiable threats". The Order also required Pfizer to pay all sums found to be due on the taking of the inquiry. The premise of the order for an inquiry, and for payment of the sums found due on taking the inquiry, is that there had been unjustifiable threats, and that the only question to be resolved on the inquiry was the extent, if at all, that Dr Reddy's had suffered loss and damage as a result.

20.
Mr Austen sought to draw a distinction between the defences under sub-paragraphs (a) and (b) of section 70(2A). While sub-paragraph (a) concerns a justification for the threats, sub-paragraph (b) does not, as it simply provides Pfizer with a defence, assuming unjustified threats were made, if it did not know, and did not have reason to suspect, that the Patent was invalid. For present purposes, I do not think this distinction assists Pfizer. Each of the sub-paragraphs provides circumstances in which an aggrieved person would not be entitled to the relief referred to in section 70(3). To allow Pfizer now to run either defence, therefore, would be contrary to Birss J's Order of 16 March 2020 which has already granted the relief referred to in section 70(3), and which is premised on Dr Reddy's being entitled to that relief.

21.
Mr Austen also submitted that Birss J's order cannot have the effect for which Dr Reddy's contends, because the declaration did not identify which threats were unjustifiable. It is true that the order is not clear in this respect. I do not think, however, that this matters. Pfizer did not object to the Order at the time on that basis. Both parties were aware of the threats that were, at least principally, in issue, being those identified as threats to bring proceedings for patent infringement in Arnold J's judgment of 10 September 2015. The fact that the parties had these threats, at least, in mind is corroborated by the fact that it was those threats that were shortly afterwards pleaded as the Threats by Dr Reddy's, and admitted as such by Pfizer.

22.
Moreover, the defences which Pfizer now seeks to advance do not depend on the precise identification of the threats. On the contrary, if (as Pfizer contends) the action at which the threats were directed constituted infringement of the IPCs or if, to the extent it would have constituted infringement of Claims 1 and 3, Pfizer neither knew or had reason to believe that Claims 1 and 3 were invalid, then that would provide an answer to each and any of the Threats and any other threats that might have been in contemplation.

23.
During the course of the hearing, I asked Mr Austen whether Pfizer's contentions on this aspect related only to the correct interpretation and effect of the Order of 16 March 2020, or whether there was any fall-back argument. In written submissions filed on 28 January 2022, Pfizer repeated the contentions that I have already dealt with and did not make any additional arguments. In those written submissions, however, it was suggested that a passage in the transcript of the hearing before Birss J on 16 March 2020 supports its contentions as to the scope and effect of the Order.

24.
The relevant passage concerned Dr Reddy's request that the Order include further declarations as to the infringement of the Patent. Birss J refused to make such declarations. As I read the transcript, however, Birss J's concern was that it was not appropriate to make declarations of infringement where there was no actual legal right any more, relying on continued uncertainty in the market, in the absence of any evidence as to such continued uncertainty. I do not find anything in that passage which affects the scope and effect of the Order, so far as may be relevant to Pfizer's attempt to advance new defences to the unjustifiable threats claim.

25.
For these reasons, I conclude that Pfizer's application to amend should, in this respect, be refused.

(2) Pfizer's application for permission to amend its defence against the NHS Parties to include a new argument based upon the IPCs

26.
As against NHS Scotland, Pfizer seeks permission to amend its defence to include the following:

"53A. Warner-Lambert contends that, to the extent any damage is said to have arisen from sale and supply pregabalin products which would have been used for or attributable to the treatment of any condition covered by the Inflammatory Pain Claims, such damage should be excluded from the final calculation of quantum."

27.
Draft particulars are provided, as follows;

"It would be unjust and inequitable for NHS Scotland to recover any damages arising from the supply and sale of pregabalin products which would have been used to treat one or more of the conditions covered by the Inflammatory Pain Claims, held valid by the Court. This is so, regardless of whether such use in the counterfactual would have infringed the Inflammatory Pain Claims or not."

28.
A materially similar application to amend is made in respect of the defence to the claim of NHS EWNI at paragraph 83(eb) of Pfizer's draft amended points of defence and to the defence of the claim of Dr

Reddy's at paragraph 53B(b) of Pfizer's draft amended points of defence. These draft pleadings contain additional particulars relating to the NHS Guidance Order, which I address separately below.

29.
As the particulars pleaded in relation to NHS Scotland make clear, this claim is not dependent on establishing any infringement of the IPCs. It is, however, dependent on the IPCs being valid (as held in the Actavis Proceedings).

30.
The juridical basis of this alleged defence is said to be that, because the IPCs were at all material times valid, Pfizer was therefore entitled to a monopoly over the use of pregabalin for the treatment of conditions covered by the IPCs, irrespective of whether Pfizer could establish a cause of action for infringement against any person. Mr Austen relied in this respect on Arnold J in Warner Lambert v Sandoz [2016] EWHC 3317, at [80], where he noted that:

"Warner-Lambert is entitled to the benefit of the monopoly conferred by the IPCs even if it is not in a position to allege infringement of those claims…"

31.
He pointed by analogy to the distinction in contract law between the contractual bargain and the secondary obligation to pay damages for breach of contract. I do not find this analogy helpful. A patent is a creature of statute, and the consequences of the grant of a patent are contained within the statute. For example, section 60(1) identifies the only circumstances which constitute infringement of a patent.

32.
It is common ground that (as explained by Arnold J in his judgment at [2015] EWHC 72 (Pat), at [28]-[29]) the great majority of drug prescriptions identify the drug prescribed by its generic name and do not indicate the condition for which the drug is prescribed, in which case pharmacists are free to dispense either a branded drug or a generic one. It is also common ground that, while neither Pfizer nor anyone else had authorisation to market pregabalin for use in treating any of the conditions covered by the IPCs, it is highly likely that some amount of pregabalin was dispensed by pharmacists to some people for the treatment of those conditions. Pfizer contends that such use represented at least 13.8% of the market for pregabalin.

33.
Pfizer contends that, notwithstanding such use of pregabalin was neither an infringement of its Patent nor wrongful for any other reason, it would be "unjust and inequitable to require Pfizer to pay compensation based on an allegation that it would have been deprived of its legitimate monopoly arising from IPC to a greater extent in the counterfactual world than it was in the actual world". Mr Austen referred in support to the equitable basis for recovery of compensation under a cross-undertaking, as explained by McCombe LJ in Abbey Forwarding Ltd v Hone (No 3) [2015] Ch 309, at [63]:

"The law as to recoverability of loss suffered by reason of a cross-undertaking is as stated by Lord Diplock in his dictum in the Hoffmann-La-Roche case, but with this caveat. Logical and sensible adjustments may well be required, simply because the court is not awarding damages for breach of contract. It is compensating for loss for which the defendant "should be compensated" (to apply the words of the undertaking)."

34.
Mr Austen also accepted that the quantification of damages is best described as an art not a science, and is subject to the point to which I referred in §50 of the CAT Judgment:

"In Les Laboratoires Servier v Apotex Inc [2009] FSR 3, Norris J (having set out the principles to be applied in quantifying compensation in that case, at para 5) said (at para 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 819, 824E) was equally applicable in the present context. This passage was endorsed by Kitchin LJ in AstraZeneca AB v KRKA dd Novo Mesto (2015) 145 BMLR 188 at para 16."

35.
The NHS Parties' claim to have suffered loss is premised on the contention that, but for the Orders, Threats and Undertakings, there would have been an earlier entrance into the market by full label (and skinny label) products leading to an earlier fall in the price of generic pregabalin and its recategorization, so that the price at which the NHS Parties reimbursed pharmacists would have been significantly reduced. It is common ground that the amount pharmacists pay for generic drugs is the same irrespective of the purpose for which they are dispensed.

36.
Mr Austen made it clear that this argument is not one as to what the counterfactual world would have looked like, or even what either pharmacists or the NHS Parties should have done in the counterfactual world. Instead, the argument is purely one of law: that the amount of damages recoverable by the NHS Parties should be reduced or discounted to the extent that it claims damages referable to lost generic sales in a part of the market over which Pfizer was entitled to a monopoly.

37.
In my judgment, this argument has no realistic prospect of success and the amendment should be refused on that basis. The basis of my conclusions in the CAT Judgment was that compensation should be calculated on the basis of what would have happened in a counterfactual world where the relevant Orders, Threats and Undertakings were removed, but which otherwise reflected the real world.

38.
It is common ground that in the real world, a certain proportion of generic pregabalin was dispensed "off-label" for the treatment of conditions covered by the IPCs, that (at least for the purposes of this argument) there was nothing wrongful in that, and that there was nothing Pfizer could have done to prevent it. Pfizer could not, for example, have encouraged pharmacists to use Lyrica, rather than generic pregabalin, when dispensing pregabalin off-label for treatment of inflammatory pain (as it lacked the relevant market authorisation).

39.
Further, as I made clear in rejecting the NHS Parties' arguments on this point in the CAT Judgment, the counterfactual includes the fact that Pfizer asserted a claim to the Patent (in particular Claims 1 and 3) notwithstanding that it later turned out to be invalid. In other words, the counterfactual world did not include an assumption that the relevant Claims in the Patent were known at all times to be invalid.

40.
The practical consequence is that in the counterfactual world the proportion of Lyrica that was prescribed and dispensed for treating neuropathic pain (covered by Claims 1 and 3) would likely have been increased by the mere existence of Pfizer's Patent, since (at best) other manufacturers of pregabalin could not be sure that the Patent would later be held to be invalid. In other words, its share of the market in the counterfactual world as in the real world is calculated on a basis which includes the fact that it claimed a monopoly to which it was never entitled.

41.
There is no greater inequity in my judgment in the NHS Parties' loss occasioned by the wrongful Orders, Undertakings and Threats being assessed by reference to a counterfactual in which sales of Lyrica are decreased because pharmacists would have dispensed at least some generic pregabalin, lawfully and off-label, to treat a condition that was covered by the IPCs, than there is in the NHS Parties' loss being assessed by reference to a counterfactual in which sales of Lyrica are increased as a result of Pfizer claiming a monopoly (in respect of Claims 1 and 3) to which it was in fact never entitled.

42.
That conclusion best reflects the notion that the quantification of loss is an art not a science and is consistent with the liberal approach to assessment of compensation, as indicated by Norris J in Servier.

(3) Pfizer's application to amend as against NHS EWNI and Dr Reddy's to include an argument based on the construction of the NHS Guidance Order.

43.
As against NHS EWNI and Dr Reddy's, the particulars in support of its proposed new argument based on the IPCs include the following:

"(iii) Further or alternatively, the Guidance found at Schedule 1 to the NHS Guidance Order provides that:

"1. Pregabalin should only be prescribed for the treatment of neuropathic pain under the brand name Lyrica® (unless there are clinical contra-indications or other special clinical needs e.g. patient allergic to an excipient, brand product unavailable etc which apply to Lyrica®, when you should not prescribe Lyrica® or pregabalin)"

(iv) In the circumstances, the Guidance applied only to the prescribing of pregabalin for neuropathic pain and not to the prescribing of pregabalin (off-label) for inflammatory pain. In the premises, the counterfactual scenario absent the NHS Guidance Order is limited to the change, if any, in the prescribing of pregabalin for neuropathic pain and may not take into account any damages said to have been made as a result of any prescriptions for any of the conditions covered by the Inflammatory Pain Claims which are not properly part of the counterfactual in this regard."

44.
Mr Austen submitted that this was intended to raise a point solely as to foreseeability of the loss that might be occasioned by the NHS Guidance Order: loss that arose because the use of pregabalin for inflammatory pain was not foreseeable because the order referred only to neuropathic pain. Such an argument, if pleaded, would seem to me unobjectionable. It raises a question of fact, and does not give rise to any of the arguments as to validity, infringement, or inequity to which many of the other

proposed amendments give rise. That is not, however, how I read the proposed additional paragraph in the draft pleading. Those paragraphs appear to contain an argument that the counterfactual scenario is to be limited – as a matter of law – to the change in the prescribing of pregabalin for neuropathic pain; and the exclusion of damages resulting from prescriptions for conditions covered by the IPCs is because they are "not properly part of the counterfactual in this regard". That appears to be a repeat of, or variation on, the argument that to allow such damages would be inequitable in the face of Pfizer's monopoly.

45.
As drafted, therefore, I will refuse the application to amend to include paragraphs 83(eb). It is nevertheless open to Pfizer to seek permission to amend to include the proposition which Mr Austen said was intended to be pleaded, namely one based on foreseeability of loss as a purely factual matter.

(4) Pfizer's application to amend so as to exclude from Dr Reddy's damages claim any damage arising from the supply of pregabalin used for the treatment of IPCs, either on the ground that such supply would constitute an infringement of the Patent or because it would be inequitable to allow Dr Reddy's claim to include such damage.

46.
The principal aim of this proposed amendment is to preclude Dr Reddy's from recovering damages for sales of Alzain on the basis that the actions of pharmacists in dispensing Alzain would have constituted an infringement of the IPCs.

47.
Pfizer contends, in short, as follows:

(1)
The illegality doctrine, the rationale for which is that it would be contrary to public interest to enforce a claim if to do so would be harmful to the integrity of the legal system (Patel v Mirza [2017] AC 467, per Lord Toulson at [120]), is equally applicable to prevent an inquiry claimant recovering a particular part of the damages claimed.

(2)
To allow Dr Reddy's to recover damages for lost sales, where those sales would have constituted an infringement of Pfizer's patent would undermine the underlying purpose of a grant of a patent and the right to a corresponding monopoly.

(3)
The dispensing by pharmacists of Alzain for the treatment of conditions covered by the IPCs is an infringement of the Patent (in respect of the IPCs) for the reasons I have outlined above in relation to the unjustifiable threats.

48.
Much of the argument against this cause of action was led by Mr Campbell QC for NHS Scotland, although (as I have noted above) as against NHS Scotland, Pfizer does not pursue any argument which depends on establishing the infringement of the Patent. Aside from the point that it is too late to run the argument (which I address below), Mr Campbell said that there are four fundamental problems with it.

49.

First, Mr Campbell contended that it is precluded by s.60(5)(c) of the 1977 Act, because the acts of pharmacists said to amount to infringement consist of "the extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consists of dealing with a medicine so prepared". Insofar as Pfizer allege infringement under s.60(1)(c), which is based on the disposal or use of a product obtained directly by means of the process (where, as here, the invention is a process), then it is not obvious, on the face of it, to see how the dispensing of Alzain could be said to be the "extemporaneous preparation … of a medicine…" within s.60(5)(c). At the very least, Pfizer has a realistic prospect of success in defeating NHS Scotland's argument on this point, such that it would be wrong to disallow the amendment on this ground.

50.
So far as Pfizer's claim based on infringement under s.60(1)(b) is concerned, its argument is significantly weaker. The relevant Claims in the Patent said to be infringed are sub-sets of Claim 1, which is defined as the use of pregabalin "for the preparation of a pharmaceutical composition for treating pain". It is not obvious to see how the prescription of Alzain off-label to treat inflammatory pain (or the affixing of a label to the medicine box for that purpose) constitutes the preparation of a pharmaceutical composition. If it does, however, then there would appear to be a strong case for concluding that it also constituted the extemporaneous preparation of a medicine, so as to be excluded under s.60(5)(c). I received very little argument on this point, however. I was told there is no authority on the meaning of s.60(5)(c), and I was cited no authority in support of Pfizer's argument that such conduct would be an infringement within s.60(1)(b). These are novel points of law which I consider ought not to be decided on an amendment application, but should be determined in light of the particular facts in any given case.

51.
Second, Mr Campbell says that Pfizer's claim opens up all of the same policy issues which were considered by the Supreme Court in the Actavis Proceedings. That may be so, and may indicate the hurdles Pfizer's claim would face, but does not establish that the claim has no realistic prospect of success. His third point related solely to the position of the NHS but, as I have already noted, Pfizer does not advance any claim against the NHS Parties dependent on establishing infringement. His fourth point related to the claim being raised too late.

52.
Dr Nicholson for Dr Reddy's did not advance any additional arguments as to the merits of the claim, in itself. No point was taken by either NHS Scotland or Dr Reddy's as to the merits of the contention that, if the off-label supply of Alzain by pharmacists constituted infringement of the IPCs, then it was arguable that the damages otherwise recoverable by Dr Reddy's should be reduced by application of the illegality doctrine. I proceed, therefore, on the basis that the argument that Pfizer wishes to introduce by this amendment has a realistic prospect of success.

53.
Dr Nicholson's main objection (supported by Mr Campbell in this respect) was that bringing these claims at this late stage would constitute an abuse of process.

54.
In his order of 16 March 2020, Birss J dismissed Pfizer's claim against Dr Reddy's for infringement of the Patent, on the basis that Claims 1, 3, 4, 6, 10, 11, 12, 13 and 14 were invalid. In its original pleading, Pfizer had contended that Alzain infringed the Patent because it was for treating the

conditions claimed in “at least” Claims 1 and 3. Although the IPCs might be said to be encompassed within “at least” Claims 1 and 3, I do not think that the Order of 16 March 2020 can be read as actually dismissing a claim made by Pfizer that Dr Reddy’s had infringed the IPCs. Pfizer had not pleaded facts amounting to an alleged infringement of the IPCs.

55.
Accordingly, in order to preclude Pfizer now advancing a claim that Dr Reddy’s infringed the IPCs, Dr Reddy’s contends that it would be an abuse of process, either on the basis of the principle in Henderson v Henderson (1843) 3 Hare 100, or on the basis that it amounts to a collateral attack on the Order of Birss J of 16 March 2020.

56.
The principle in Henderson v Henderson is well known: it may be an abuse of process for a party to bring a claim which it could and should have brought in earlier proceedings. I was not referred to any authority for that proposition, but no issue was taken by Mr Austen with that formulation of the principle.

57.
For the following reasons, I conclude that Pfizer could and should have advanced a claim for infringement of the IPCs within its original claim against Dr Reddy’s, or at least within that claim by the time it consented to the dismissal of its infringement claim.

58.
First, while the facts as to Dr Reddy’s knowledge and intentions, relating to an infringement of the IPCs, are different from those relating to an infringement of Claims 1 and 3, it is not suggested that the basis upon which Pfizer now contends that Dr Reddy’s infringed the IPCs could not have been pleaded prior to March 2020.

59.
Second, the fact that a proportion of generic pregabalin had been dispensed by pharmacists off-label for the treatment of inflammatory pain was already known to Pfizer, it having been alleged within the Actavis Proceedings.

60.
Third, the Order of 16 March 2020 marked the end of the liability stage of the action and the commencement of the quantum stage. That is clear from the fact that the Order dismissed without reservation Pfizer’s claim for infringement against Dr Reddy’s, and from the recital which referred to Pfizer having made an interim payment on account of Dr Reddy’s costs of the “liability phase of the action”.

61.
Fourth, although Pfizer now seeks to rely on an infringement claim merely as a means of reducing the damages payable in the quantum phase of the action, such a claim, if it works at all, would have entitled Pfizer to damages in the same way as the infringement claim it had already brought.

62.
Fifth, the fact that Pfizer did not advance a claim for infringement of the IPCs has significant practical consequences. The new infringement claim will involve a substantial trial (both of issues concerning infringement and issues concerning validity) with a strong likelihood of one, or possibly two, appeals.

Aside from the question of abuse of process, I consider that this justifies refusing the amendment at this stage on case management grounds.

63.
As to validity, the recitals to the Order of 16 March 2020 referred to the fact that the IPCs had been held to be valid. Pfizer contends that this – at least potentially (depending on the nature of the argument Dr Reddy's might seek to run) – precludes Dr Reddy's from challenging the validity of the IPCs. If Pfizer is correct, then that in itself demonstrates significant prejudice to Dr Reddy's if Pfizer's amendment is permitted. Aside from that, although the IPCs were held to be valid in the Actavis Proceedings that was, at least in part (as to sufficiency) as a result of a concession by Actavis and it is common ground that Dr Reddy's is not for that reason precluded from bringing its own revocation action. It would appear that it would have to do so by a separate revocation action, because none of the other circumstances (in which validity can be challenged) in section 74 of the 1977 Act apply. Pfizer points out that the basis on which Dr Reddy's would do so has not been explained, and that no reason has been suggested why Dr Reddy's would succeed where Actavis either failed, or chose not to pursue its case. Nevertheless, Dr Reddy's has stated in terms that it would apply to revoke the Patent in respect of the IPCs. That action would be far from straightforward.

64.
In any event, the new claim undoubtedly depends on Pfizer being able to establish infringement. That would involve disputed questions of fact as to the actions and intentions of Dr Reddy's and (potentially at least) pharmacists, and a question of law as to the correct approach to establishing liability of a manufacturer for infringement of a secondary medical use patent. That was an issue that took up a considerable amount of time in the Actavis Proceedings, and was one on which the Supreme Court was ultimately split. Since the Supreme Court's decision on the point was obiter, the point has the potential to be appealed yet again to the highest level. Mr Austen suggested that it might be possible to expedite the trial, and to pursue any appeal by way of leap-frog to the Supreme Court. Whether it would be appropriate to expedite a trial, at the expense of other litigants, in order to enable Pfizer to run a point which could have been run during the liability phase of the action is far from clear. Nor is it clear that this would be an appropriate case for a leap-frog appeal. On any view, the validity and infringement issues raised by the proposed amendment will between them require a number of days in court at first instance, and a strong likelihood of one or more appeals.

65.
There has been a considerable amount of water under the bridge since the order of Birss J of 16 March 2020. Once all potential inquiry claimants had been identified, and they had exchanged pleadings, in December 2020 Birss J fashioned a bespoke three-stage procedure for managing together, and determining, the multiple inquiry claims. Common issues of law, and fact, were identified and the first have been resolved at the CAT. As a result of my decision to refashion the directions going forward (see section (7) below) the second stage is to be merged with the third, with a trial of all remaining issues to be listed not before October 2023. It would at the very least be a significant diversion to introduce into the Inquiry Claims at this stage an issue, as between Dr Reddy's and Pfizer, of liability issues that were litigated at length in the Actavis Proceedings over three years between 2015 and 2018.

66.
The additional costs burden on Dr Reddy's would also be very substantial. Dr Nicholson said (on instructions and without waiving privilege) that, Dr Reddy's having deliberately stayed out of the validity/infringement proceedings concerning Actavis, if it had been faced with a re-run of those

points as against it, at the point that it was deciding whether to pursue its own claim for damages, it would have thought long and hard before doing so. I accept, as Mr Austen submitted, that there is no evidence to support that contention. It is nevertheless an objectively obvious fact that the shape of the potential proceedings being contemplated by Dr Reddy's in March 2020 would have been fundamentally different if the issues of validity of the IPCs and infringement had to be litigated. It is a fair inference that that would have been, at least, an important consideration in its decision to purse its damages claim at that time.

67.
Mr Austen submitted that these additional costs must be seen in the context of the high value of the proposed amendment to the defence. In the Actavis Proceedings, Pfizer had provided evidence to the effect that off-label prescription of pregabalin for the treatment of conditions covered by the IPCs amounted to 13.8% of the overall market. Mr Austen's submission, that 13.8% of the claimed damages was itself a very high number was, however, directed at the NHS Parties' claims which, at their highest as pleaded, are in the region of £600 million. That is a false reference point, however, given that this argument does not affect the NHS Parties' claims. Dr Reddy's claim is much lower in amount (pleaded as £34.6 million), such that even assuming that the proportion of Alzain prescribed off-label for the treatment of conditions covered by the IPCs could be established to be 13.8%, the sum in issue is in the region of £4.8 million. According to Mr Campbell, the costs incurred in the Actavis Proceedings were in the region of £10 million for one side alone (the figure was not disputed by Mr Austen). It is a fair inference that the costs of running the proposed amended defence against Dr Reddy's would at least be close to the amount at stake.

68.
I accept that Pfizer would be prejudiced if the amendment is not allowed, because it will be shut out from arguing that Dr Reddy's damages caused by the Threats and Orders and Undertakings ought to be reduced so as to exclude from the counterfactual sale of pregabalin which would have been dispensed by pharmacists for the purpose of treating conditions covered by the IPCs. Prejudice of this nature arises in many cases where an amendment to plead an additional cause of action is refused. I cannot make any assumptions as to the strength of the case that Pfizer would be prevented from advancing, beyond noting that it is a far from straightforward case, particularly taking into account that the claim for infringement against Actavis failed at all levels, including (albeit obiter) in the Supreme Court, whichever was the correct legal basis of the claim.

69.
In all the circumstances of the case, however, I consider that the prejudice to Pfizer is insufficient to prevent the conclusion that Pfizer could and should have brought a claim that Dr Reddy's infringed the Patent in respect of the IPCs during the liability phase of the proceedings and that it is an abuse of process to do so at this stage of the Inquiry Claim against Dr Reddy's. Similarly, on case management grounds, Pfizer ought not to be permitted to amend at this stage. The point made by Norris J in Les Laboratoires Servier v Apotex Inc (above, at [33]) is apposite here, where the new claim would add considerably to Inquiry Claims that are already envisaged to require a 25 day trial (on top of the CAT) and more than three and a half years to resolve.

70.
Accordingly, I will refuse permission for this amendment to Pfizer' defence. I address below, in section (8), Dr Reddy's application to strike out that part of the existing defence which raises the same argument as that raised against the NHS Parties and addressed in section (2) above.

(5) Pfizer's application to amend so as to rely on other communications it could have made in the counterfactual that would not have amounted to unjustifiable threats

71.
Pfizer seeks permission to plead that it:

"would have taken steps to diminish any benefits and/or increase the risks to 'generic players' seeking to supply a pregabalin product in the UK including … (a) … further communicated its belief that Lyrica should be prescribed by brand for the treatment of pain to, among others, such 'generic players', prescribers, dispensers, the makers of clinical software system [and many others]; (b) … informed 'generic players' threatening to use and/or using in the UK the process covered by … the Patent … of its intention to assert the Patent … Warner-Lambert could and/or would likely and/or would have sought an injunction…"

72.
Dr Reddy's objects to this amendment on the basis that it seeks to introduce into the counterfactual further threats of precisely the sort which have been declared to be unlawful, which (for the reasons I have set out above) Pfizer cannot now challenge.

73.
Mr Austen accepted, however, that: (1) the proposed amendment is not intended to introduce into the counterfactual any communication which would amount to an unlawful threat within the meaning of s. 70(1); (2) in other words, Pfizer does not seek to rely on a communication which "threatens another person with proceedings for infringement of a patent", other than such a threat that would be excluded by subsections 70(4) and (5) of the 1977 Act; (3) if any of the communications which Pfizer proposes to introduce would amount to such threats then Pfizer cannot rely on them as forming part of the counterfactual; and (4) the proposed amendment does not therefore depend on establishing either that the Patent was valid or that there was any infringement of it.

74.
In those circumstances, and taking into account the fact that communications of this sort, which were not held to be unlawful threats by Arnold J, existed in the real world (and are not excluded from the counterfactual world by any part of the CAT Judgment), I consider that the amendment should in principle be permitted. It is not sufficient, however, for Pfizer to plead that it would have made such communications without specifying precisely what communications it would have made. Without that precision it is impossible to know whether it would have amounted to an unlawful threat within s.70, and thus be excluded from the counterfactual for that reason alone. It would also be very difficult to determine the likelihood of it having made such communication at all, and its potential impact on the market, without such precision. Accordingly, before I reach a final decision on whether to allow this amendment, Pfizer should provide particulars of the communications which it says it would have made.

(6) Pfizer's application to amend to plead an alternative counterfactual against Dr Reddy's

75.
At the hearing I determined that Pfizer should have permission in principle to plead an alternative case against Dr Reddy's, but that it should provide particulars of that alternative case. Those particulars should identify the paragraphs in the NHS Parties' pleadings which Pfizer contends it would rely upon (in the event that the NHS Parties' case as pleaded in those paragraphs succeeded). In addition, to the extent that this would not already be clear from its cross-referring to the

paragraphs in the NHS Parties' pleading, Pfizer must plead what it contends the impact would be, if the claim advanced in the relevant paragraphs succeeds, on Dr Reddy's claim for damages.

76.
In brief, the reasons for permitting that amendment are as follows. Since at least the CAT Judgment, it has been the case that findings of fact in one Inquiry Claim are to be binding on all Inquiry Claimants. Although it is true that there has never been an order that the Inquiry Claimants should cross-plead to each other's statement of case, each party's pleading was ordered to be served on all other parties, so that all parties were aware of the findings of fact that could be made in other Inquiry Claims.

77.
In my view it was obvious, at least by the time of the CAT, that Pfizer would wish to rely upon findings adverse to it in one Inquiry Claim, as against other Inquiry Claimants, where that was necessary to avoid the damages which it was required to pay being calculated on the basis of inconsistent findings of fact, leading to it having to pay more damages in aggregate to the Inquiry Claimants than could ever have been suffered in one consistent counterfactual. The need to avoid such a conclusion was a significant aspect of Pfizer's arguments at the CAT, and formed a significant part of my reasoning in the CAT Judgment.

78.
I accept Dr Nicholson's point that just because a fact is found, as between Pfizer and the NHS Parties, that does not necessarily have an impact as between Pfizer and Dr Reddy's unless it is pleaded to do so, as between them. It would not do so, in particular, if it was contrary to a fact that was pleaded and admitted as between Pfizer and Dr Reddy's. That is why it is essential – notwithstanding the CAT Judgment – that if Pfizer wishes to rely on any different counterfactual as against Dr Reddy's to the one that is the subject of its primary defence to Dr Reddy's claim, then it must be pleaded in the alternative. I also accept Dr Nicholson's point that it is not sufficient for Pfizer to plead merely that it will rely as against Dr Reddy's on whatever findings of fact are made in another Inquiry Claim.

79.
Now that the only remaining Inquiry Claimants are the NHS Parties (whose claims are closely aligned with each other) and Dr Reddy's, Pfizer's alternative case against Dr Reddy's can be summarised quite simply as reflecting such part of the NHS Parties' case that succeeds as against Pfizer.

80.
I take on board Dr Nicholson's argument that Pfizer should by now have pleaded its alternative case in the way I have just indicated, and that it ought not to be given a further opportunity to do so. I also take on board, however, the fact (as I have already noted) that the substance of Pfizer's intended alternative claim has always been clear (i.e. to reflect adverse findings made in other Inquiry Claims) and that its failure to have done this already appears to reflect a misunderstanding of my comments on previous occasions as to what is required by way of pleading. Dr Nicholson also accepted that the force of his complaint in this respect is diminished if (as I have ordered) the CIT is replaced with a single trial of all remaining issues.

(7) Dr Reddy's application that its claim be determined separately, or to reshape the remaining directions in the Inquiry Claims.

81.

As I have noted, I made an order at the hearing vacating the CIT, and directing that all remaining issues in the Inquiry Claims be determined at a single further trial. That was, in summary, for the following reasons.

82.
Following settlement of all other Inquiry Claims, the shape of these proceedings is very different to that which they had in December 2020 when Birss J ordered a three-stage trial process for determining the Inquiry Claims. Insofar as there are “common issues”, they are now common as between – in essence – two rival groups of Inquiry Claimants, being the NHS Parties on the one hand and Dr Reddy’s on the other.

83.
The CIT was intended to determine, among other things: the monthly proportions of pregabalin that would have been dispensed over the claim period, whether as generic pregabalin or Lyrica; the proportion that each generic manufacturer would have had of that market; the monthly price pharmacists would have paid for generic pregabalin and Lyrica; and the price at which the NHS would have reimbursed pharmacists.

84.
Aside from issues relating to mitigation and the potential reduction in the NHS Parties case as a result of a Pharmaceutical Pricing Regulation Scheme and the Pharmacy Margin Scheme, once the CIT issues are determined, any remaining issues as to quantum ought to be readily resolved. In particular, once the monthly volume that would have been supplied by each generic and the price that pharmacists would have paid are known, the remaining task ought to be mostly, if not wholly, mechanical.

85.
In addition, I consider that by focussing the parties’ attention on issues of quantum at an earlier stage, the prospects of settlement being reached between Pfizer and the remaining Inquiry Claimants is much increased.

(8) Dr Reddy’s application to strike out aspects of Pfizer’s pleaded case

86.
I have concluded above that Pfizer’s argument, that the damages claimed by any Inquiry Claimant should be reduced on the basis that it would be inequitable for those damages to include amounts referable to off-label prescriptions of generic pregabalin for the treatment of conditions covered by the IPCs, has insufficient prospects of success to permit Pfizer to amend its defence as against the NHS Parties. It logically follows that to the extent that the same argument is advanced in Pfizer’s existing pleading as against Dr Reddy’s, it should be struck out.

87.
Dr Reddy’s had not – until mid-way through the trial – applied to strike out the existing plea. Dr Nicholson explained on instruction that the reason for this was that Actavis (which was playing a full part in these proceedings until the week before the hearing) had made such an application, and Dr Reddy’s intended to hang on Actavis’ coat-tails in this respect.

88.
The precise paragraphs of Pfizer’s pleading which Dr Reddy’s sought to strike out were not the subject of any discussion in court during the first and second days of the hearing, which were the only

days that Mr Austen (who took the lead on this issue for Pfizer) was available. It was only on the third day that the Court's attention was drawn to the specific paragraphs. It was then apparent that Dr Reddy's application was too broad-ranging and that the effect of striking out particular passages in Pfizer's pleading – on the basis that they referred to the IPCs – could well have the effect of striking out aspects of Pfizer's defence which were not dependent on the argument I have found has insufficient merit. Dr Nicholson accepted that there was a risk of "unintended consequences" because of the breadth of the claim to strike-out as formulated in the application notice produced during the course of the hearing. I agree.

89.
In those circumstances, I do not accede to Dr Reddy's application to strike out any part of Pfizer's pleading at this stage. That does not preclude Dr Reddy's from formulating a properly defined strike-out application, reflecting the limited conclusion I have reached in the course of refusing Pfizer's application to amend as against the NHS Parties. Given that conclusion, it is to be hoped that this issue can be resolved by agreement.