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Case No: CA-2022-000735

**IN THE COURT OF APPEAL (CIVIL DIVISION)**  
**ON APPEAL FROM THE HIGH COURT OF JUSTICE, BUSINESS AND PROPERTY**  
**COURTS OF ENGLAND AND WALES, INTELLECTUAL PROPERTY LIST (ChD),**  
**PATENTS COURT**

**Mr Justice Zacaroli**  
**[2022] EWHC 189 (Pat)**

Royal Courts of Justice  
Strand, London, WC2A 2LL

Date: 1 February 2023

**Before :**

**LORD JUSTICE MALES**  
**LORD JUSTICE ARNOLD**  
and  
**LORD JUSTICE NUGEE**

**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 -  
WARNER-LAMBERT COMPANY LLC

**Inquiry**  
**Claimants/**  
**Respondents**

**Inquiry**  
**Defendant/**  
**Appellant**

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**Richard Boulton KC and Tim Austen (instructed by Kirkland & Ellis International LLP)**  
**for the Appellant**  
**Brian Nicholson KC and Christopher Hall (instructed by Mishcon de Reya LLP) for the**  
**First Respondent**

**Douglas Campbell KC and Daniel Selmi** (instructed by **RPC**) for the **Seventh to Twenty-first Respondents**

Hearing dates : 17-18 January 2023

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**Approved Judgment**

*This judgment was handed down by the Court remotely by circulation to the parties' representatives by email and release to The National Archives. The date and time for hand-down is deemed to be 10:30 on 2 February 2023.*

## **Lord Justice Arnold:**

### Introduction

1. This is an appeal by the Inquiry Defendant (“Warner-Lambert”) against an order of Zacaroli J dated 24 March 2022 in so far as it refused Warner-Lambert permission to make two amendments to its Points of Defence to claims by the Inquiry Claimants for orders that Warner-Lambert compensate the Inquiry Claimants for losses that the Inquiry Claimants allege they have sustained by reason of interim orders made by the Patents Court pursuant to cross-undertakings given to the Court by Warner-Lambert when those orders were made.
2. The judge granted Warner-Lambert permission to appeal with respect to its application to make the second amendment, but refused Warner-Lambert permission to appeal in relation to the first amendment. I granted Warner-Lambert permission to appeal with respect to the first amendment, whereupon the First Inquiry Claimant (“Dr Reddy’s”) served a respondent’s notice seeking to uphold the decision on additional or alternative grounds. During the hearing of the appeal Warner-Lambert twice applied for permission to amend its grounds of appeal and Dr Reddy’s applied for permission to amend its respondent’s notice. I would grant these applications, which were largely unopposed, and accordingly I shall address all the grounds relied upon by the parties.

### Background

3. The background to the present appeal is of considerable complexity. It arises out of four sets of proceedings concerning European Patent (UK) No. 0 934 061 (“the Patent”): the first two between Warner-Lambert and Pfizer Ltd (“Pfizer”) on the one hand and Generics (UK) Ltd trading as Mylan (“Mylan”) and Actavis Group PTC ehf and related companies (collectively “Actavis”) on the other hand; the third between Warner-Lambert and Sandoz GmbH and Sandoz Ltd (collectively “Sandoz”); and the fourth between Warner-Lambert and Dr Reddy’s.

#### *Second medical use patents with claims in Swiss form*

4. It has increasingly been recognised over the past 30 years or so that it is important to find new uses for existing medicines. Existing medicines have the advantage that they are known compounds which have been shown to have acceptable safety profiles, and therefore need much less testing from that perspective. Experience shows that a compound which has therapeutic benefit in one application not infrequently turns out to have therapeutic benefit in another application (sometimes more than one other application) which may be quite different to the first application. Thus there is significant potential for, and value in, finding such second (and third, etc.) medical uses. Discovering such second medical uses requires difficult and expensive research, however. How is such research to be funded? The answer which has been provided by the European patent system is to grant patents for second (and subsequent) medical uses of known compounds. The monopoly thus conferred on the inventor who finds the second medical use provides the return on the investment required to fund the research.

5. There are two significant obstacles to the grant of patents for second medical uses under the European patent system: first, the compounds themselves are not new, which is a fundamental requirement for patentability of a product; and secondly, methods of treatment of the human (or animal) body by therapy are not patentable, in order to protect doctors from claims for patent infringement. The European patent system has attempted to overcome these obstacles in two ways.
6. The first way was through a piece of judicial law-making which fudged some of the difficult issues. This involved the use of claims in Swiss form i.e. “use of substance X for the preparation of a medicament (or pharmaceutical composition) for treating indication Y” (a purpose-limited process claim): see G 05/83 *Eisai/Second medical indication* [1985] OJ EPO 64.
7. The second way was through legislation, namely Article 54(5) of the European Patent Convention 2000, which enables the grant of claims in the form “product X for treating indication Y” (a purpose-limited product claim). These have now superseded claims in Swiss form. This is a more satisfactory solution to the problems, although difficulties remain.

#### *The Patent*

8. The Patent was a second medical use patent with claims in Swiss form. The claims were directed to the use of pregabalin for treating pain. The claimed priority date was 24 July 1996. The application was filed on 16 July 1997. The Patent was granted on 28 May 2003. The claims of the Patent were centrally limited on 21 January 2015. The Patent expired on 16 July 2017. The proprietor of the Patent was Warner-Lambert.
9. Claims 1, 2 and 3 of the Patent (as centrally limited on 21 January 2015) were as follows:
  - “1. Use of [pregabalin] or a pharmaceutically acceptable salt thereof for the preparation of a pharmaceutical composition for treating pain.
  2. Use according to Claim 1 wherein the pain is inflammatory pain.
  3. Use according to Claim 1 wherein the pain is neuropathic pain.”
10. Claims 4-14 were limited to various specific types of pain. Claims 5 (“post-operative pain”), 7 (“burn pain”), 8 (“gout pain”) and 9 (“osteoarthritic pain”) covered specific types of inflammatory pain. Claims 10 (“trigeminal neuralgia”), 11 (“acute herpetic and postherpetic pain”) and 12 (“causalgia pain”) covered specific types of neuropathic pain, and in particular specific types of peripheral neuropathic pain.

#### *The statutory framework*

11. Section 60 of the Patents Act 1977 provides, so far as relevant:

**“Meaning of infringement.**

(1) Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say—

...

(b) where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent;

(c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

(2) Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom.

...

(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if—

...

(c) it consists 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;

...”

12. Between 1 January 2005 and 1 October 2017 section 70 of the 1977 Act provided, so far as relevant:

**“Remedy for groundless threats of infringement proceedings.**

- (1) Where a person (whether or not the proprietor of, or entitled to any right in, a patent) by circulars, advertisements or otherwise threatens another person with proceedings for any infringement of a patent, a person aggrieved by the threats (whether or not he is the person to whom the threats are made) may, subject to subsection (4) below, bring proceedings in the court against the person making the threats, claiming any relief mentioned in subsection (3) below.
- (2) In any such proceedings the claimant or pursuer shall, subject to subsection (2A) below, be entitled to the relief claimed if he proves that the threats were so made and satisfies the court that he is a person aggrieved by them.
- (2A) If the defendant or defender proves that the acts in respect of which proceedings were threatened constitute or, if done, would constitute an infringement of a patent—
  - (a) the claimant or pursuer shall be entitled to the relief claimed only if he shows that the patent alleged to be infringed is invalid in a relevant respect;
  - (b) even if the claimant or pursuer does show that the patent is invalid in a relevant respect, he shall not be entitled to the relief claimed if the defendant or defender 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.
- (3) The said relief is—
  - (a) a declaration or declarator to the effect that the threats are unjustifiable;
  - (b) an injunction or interdict against the continuance of the threats; and
  - (c) damages in respect of any loss which the claimant or pursuer has sustained by the threats.

...”

### *Prescribing practices*

13. It is standard practice for a prescribing doctor to identify the drug prescribed by reference to its international non-proprietary name, that is to say, its generic name (such as “pregabalin”). Generic prescribing is encouraged at all levels of the healthcare system. This is for both clinical and financial reasons. The clinical reasons are that prescribing generically helps remind clinicians of the therapeutic action of the drug, enables greater certainty amongst healthcare professionals when treating a patient (e.g. when the patient moves between care providers) and promotes dispensing flexibility (and hence speed).

14. In the case of pregabalin, one estimate is that over 99% of prescriptions in England in January 2015 were written generically.
15. It is rare for prescriptions to identify the condition for which the drug has been prescribed. Although hard data is difficult to come by, it appears that no more than 5% of GPs routinely state the indication on their prescriptions. One reason for this is patient confidentiality.
16. In general, prescribing doctors will be unaware of what stocks or sources of supply the dispensing pharmacy will have available to it for fulfilling the prescription. In particular, if the prescribing doctor writes a prescription generically, and generic versions of the drug are available, the doctor will not know whether the branded product will be dispensed or a generic version, and if the latter, which one.

*“Off-label” prescribing*

17. Pharmaceuticals must receive a marketing authorisation (or licence) from a competent regulatory authority before they can be marketed. The competent authority will require evidence that the substance in question is both efficacious and safe. Marketing authorisations are granted for one or more specific indications. Generally speaking, a prescribing doctor is entitled to rely upon the fact that a drug has a marketing authorisation for a particular indication when prescribing that drug for that indication. In addition, however, prescribing doctors can, in the exercise of their own clinical judgment, prescribe an authorised drug for an unauthorised indication. Because it has been authorised, it should be generally safe (although care will need to be taken in relation to known side effects). Even if it has not been authorised for the indication in question, the prescribing doctor may have a reason for believing that the drug will be effective in treating that indication. This is commonly referred to as “off-label” prescribing.

*Dispensing practices*

18. Where the prescription is written generically, the pharmacist is free to dispense a branded drug or a generic one. Where the prescription specifies a particular brand (such as Lyrica), however, the pharmacist must dispense that brand in order to avoid (a) breaching regulation 214 of the Human Medicines Regulations 2012 (SI 2012 No. 1916) and (b) committing trade mark infringement and/or passing off.
19. In 2015 pharmacists usually did not know the indication for which a drug had been prescribed, because this was not stated on the prescription. Unless the pharmacist happened to have ascertained and recorded this information in the past, the only ways in which the pharmacist could find this out were (i) by asking the patient and (ii) by asking the prescriber.
20. So far as asking the patient is concerned, community pharmacists are required to ensure appropriate levels of privacy for conversations with patients. In principle, therefore, a pharmacist can ask a patient what indication they have been prescribed pregabalin for. There are two problems with this approach, however. The first is that the patient may not be present when the prescription is filed. The second is that, even if the patient is present, the patient may not be able accurately to answer the question.

21. So far as the first point is concerned, at a hearing in January 2015, Actavis adduced evidence from a pharmacist who had examined the pharmacy's prescription records for December 2014. During that month they received 55 prescriptions for Lyrica. Of those, only 17 were filed by the patient in person, while the remaining 38 were filed either by patients' representatives or were sent to the pharmacy as a part of its delivery service. This suggests that, in a very substantial proportion of cases, a pharmacist who received a prescription for pregabalin could not ask the patient what indication the drug has been prescribed for.
22. As for the second point, about 80% of patients with neuropathic pain are over 35, and over 27% are over 65. In the case of those over 65, they will often be receiving multiple medications for a variety of conditions. Furthermore, in many cases the conditions will be long-term ones, and so the original prescription may have been written some time ago. It may therefore be questioned to what extent such patients will be able accurately to answer a question as to the indication for which they have been prescribed pregabalin.
23. It follows that in many cases the only way, and in others the only reliable way, for the pharmacist to ascertain this information would be to contact the prescriber. It will be appreciated, however, that it might not be at all easy for the pharmacist to get through to the doctor on the telephone (or by email or other means) while the person who has brought the prescription is waiting. Even where this was possible, it was hardly a good use of busy doctors' time.

*Pfizer's marketing of pregabalin*

24. During the relevant period Pfizer marketed pregabalin for the treatment of neuropathic pain, epilepsy and generalised anxiety disorder ("GAD") under licence from Warner-Lambert under the trade mark Lyrica. The marketing authorisation was held by Pfizer. Pfizer's data exclusivity in respect of the data used to obtain the marketing authorisation expired on 8 July 2014, thus opening the market for pregabalin up for generic competition at least with respect to the treatment of epilepsy and GAD. But the market for pregabalin for the treatment of pain was protected by the Patent.

*The Mylan and Actavis proceedings down to 21 October 2015*

25. Mylan and Actavis launched separate claims challenging the validity of the Patent on 24 June 2014 and 12 September 2014 respectively. Actavis applied for a "full label" marketing authorisation for pregabalin (i.e. one covering all indications for which Lyrica had been authorised) on 9 July 2014, but subsequently they decided to launch initially under a so-called "skinny label" marketing authorisation (i.e. one which excluded the indications covered by the Patent and only covered epilepsy and GAD). They notified Warner-Lambert of this intention on 30 September 2014.
26. From late September 2014 onwards Pfizer took extensive steps to try to ensure that generic pregabalin was neither prescribed nor dispensed for the treatment of pain. Leaving aside the litigation described below, these steps included communications with a large number of stakeholders, including: (i) the Department of Health and NHS England; (ii) the National Pharmaceutical Supply Group and the Pharmaceutical Market Support Group; (iii) the Welsh Government, the Northern Ireland Executive



and the Scottish Government; (iv) the Pharmaceutical Services Negotiating Committee (“the PSNC”); (v) the National Institute for Health and Care Excellence; (vi) the Royal Pharmaceutical Society, (vii) Pfizer’s pharmacy customers; (viii) the British Pain Society and the Royal College of General Practitioners; (ix) Pharmacy Voice; (x) software providers; (xi) the Medicines and Healthcare Products Regulatory Agency; (xii) Community Pharmacy Wales and Community Pharmacy Scotland; (xiii) superintendent pharmacists; (xiv) the British National Formulary; (xv) all Clinical Commissioning Groups (“CCGs”) in England, all Health Boards in Scotland, all Health Boards in Wales and the Northern Ireland Health and Social Care Board; (xvi) the Pharmaceutical Advisors Group; (xvii) the National Pharmacy Association; (xviii) the Royal College of Physicians; (xix) the General Medical Council and the General Pharmaceutical Council; and (xx) the British Medical Association.

27. For present purposes, it is sufficient to refer to two of these communications. First, on 13 November 2014 Richard Cullen of Pfizer’s Legal Department sent an email to the PSNC in which he said:

“First of all let me say that making allegations of infringement against pharmacists (who are in most cases also our customers) is not something that Pfizer would engage in lightly. I also take your point that, as a general matter, patentees have not tended to assert patent infringement against pharmacists for dispensing generic product, although it certainly has happened on occasion.

...

The key issue is whether there is any relevant patent in place — if there is, then subject to the fairly narrow exception in section 60(5)(c) of the Patents Act 1977, it is indeed possible for retail pharmacists to be liable for infringement. The facts we are dealing with here are different from the usual generic launch scenario, but the bottom line is that Pfizer has in place a patent that it believes is valid and which it believes could be infringed.

...

... there are various ways in which a retail pharmacist could be said to be liable for infringement, for example if they started taking more than their non-pain demand for pregabalin supplies from generic companies with the inevitable result that neuropathic pain prescriptions were not being filled with Lyrica.

In direct response to your query we do believe that retail pharmacists would be infringing if they receive prescriptions for ‘pregabalin’ and dispense the generic, knowing it to be for treating neuropathic pain. ...”

28. Secondly, on 10 December 2014 Paula Tully, Head of the Pfizer Group’s Global Established Pharma business in the UK, sent a circular letter to the superintendent

pharmacists (who are responsible for the supervision of any other pharmacists their employer may employ) of at least 62 pharmacy chains in which she said:

“Whilst Pfizer’s pain patent remains in effect, we expect that generic manufacturers will generally only seek authorisation of their pregabalin products for use in epilepsy and generalised anxiety disorder, i.e. the two indications for which Pfizer has no patent protection. It is likely that the generic companies will initiate discussions with you about their products and we therefore think it is important for you to understand that we believe the supply of generic pregabalin for use in the treatment of pain, whilst the pain patent remains in force in the UK, would be infringing Pfizer’s patent protection and would constitute an unlawful act.”

29. On 8 December 2014 Warner-Lambert commenced *quia timet* proceedings against Actavis for infringement of claims 1 and 3 of the Patent in respect of Actavis’ skinny label pregabalin product. Warner-Lambert’s claim for infringement was made pursuant to section 60(1)(c), alternatively 60(2), of the 1977 Act. Actavis subsequently counterclaimed in respect of allegedly groundless threats made by Pfizer during the course of its communications with stakeholders referred to above. On 16 February 2015 Actavis received a skinny label marketing authorisation, and on 17 February 2015 Actavis launched their skinny label pregabalin product under the trade mark Lecaent.
30. In those proceedings I dismissed an application by Warner-Lambert for an interim injunction against Actavis for the reasons given in my judgment dated 21 January 2015 [2015] EWHC 72 (Pat) (“*Warner-Lambert I*”). Subsequently I dismissed an application by Actavis to strike out, alternatively for summary judgment dismissing, Warner-Lambert’s claim for infringement under section 60(1)(c) for the reasons given in my first judgment dated 6 February 2015 [2015] EWHC 223 (Pat) (“*Warner-Lambert IP*”), but acceded to Actavis’ application to strike out the claim for infringement under section 60(2) for the reasons given in my second judgment dated 6 February 2015 [2015] EWHC 249 (Pat) (“*Warner-Lambert IIP*”).
31. On 26 February 2015 I made an order (“the NHS Order”), largely by consent, requiring the Third Inquiry Claimant (“NHS England”) to issue guidance (“the NHS Guidance”) to CCGs in England and to the NHS Business Services Authority (“the BSA”) for transmission to NHS pharmacy contractors for the reasons given in my judgment dated 2 March 2015 [2015] EWHC 485 (Pat), [2015] RPC 24 (“*Warner-Lambert IV*”).
32. The NHS Order included a cross-undertaking in damages by Warner-Lambert in the following terms (so far as relevant):

“If the Court later finds that this Order has caused loss to ... the Dr Reddy’s group of companies, and decides that the ... Dr Reddy’s group of companies should be compensated for that loss, [Warner-Lambert] will comply with any Order the Court may make.”

33. The NHS Guidance was in the following terms:
- “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, 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®.”
34. The NHS Guidance was issued by NHS England (under the title *Important Information in Relation to Prescribing and Dispensing Pregabalin*) on 27 February 2015. CCGs were required to distribute it to GPs by 6 March 2015 and the BSA to distribute it to pharmacists by the same date. Equivalent guidance was issued in Wales on 6 March 2015 and in Northern Ireland by 16 March 2015. No equivalent guidance was issued in Scotland at that stage, but a form of guidance was subsequently issued in Scotland on 31 March 2016. The NHS Guidance was withdrawn on 17 July 2017.
35. It can be seen that there was a mismatch between the wording of paragraphs 1 and 2 of the NHS Guidance on the one hand and paragraphs 3 and 4 on the other hand. Paragraphs 1 and 2 referred to prescribing pregabalin for neuropathic pain, whereas paragraphs 3 and 4 referred to prescribing and dispensing pregabalin for pain. This was because pregabalin was only authorised for neuropathic pain (leaving aside epilepsy and GAD), but it was prescribed off-label by doctors for other types of pain, and in particular inflammatory pain, which were covered by the Patent.
36. On 28 May 2015 the Court of Appeal dismissed an appeal by Warner-Lambert against *Warner-Lambert I* and allowed an appeal by Warner-Lambert against *Warner-Lambert III* [2015] EWCA Civ 556, [2015] RPC 25 (“*Warner-Lambert CA I*”).
37. On 10 September 2015 I handed down judgment following the trial of Mylan and Actavis’ claims for revocation of the Patent, of Warner-Lambert’s claim against

Actavis for infringement of claims 1 and 3 of the Patent and of Actavis' claim against Pfizer for groundless threats [2015] EWHC 2548 (Pat), [2016] RPC 3 (*Warner-Lambert V*). In that judgment I held that:

- i) none of the claims of the Patent was obvious over any of the prior art relied upon by Mylan and Actavis;
- ii) claims 1, 3, 4, 6, 13 and 14 of the Patent were invalid on the ground of insufficiency;
- iii) even if claims 1 and 3 were valid, Actavis had not infringed those claims pursuant to section 60(1)(c) or section 60(2); and
- iv) Pfizer was liable for making groundless threats of patent infringement proceedings in the course of some of its communications with the stakeholders described above, including the email to the PSNC dated 13 November 2014 and the circular letter to superintendent pharmacists dated 10 December 2014, since those communications were threats, Actavis were aggrieved by the threats and the threats were unjustified.

38. So far as the issue of insufficiency was concerned, I concluded that claim 3 was invalid, because although the specification made it plausible that pregabalin would be effective to treat peripheral neuropathic pain, it did not make it plausible that pregabalin would be effective to treat central neuropathic pain. I held that claim 1 was invalid both for this reason and because it was not plausible that pregabalin was effective to treat all types of pain. I held that claims 10, 11 and 12 were valid because these were specific types of peripheral neuropathic pain.

39. As for infringement, I held that there was no infringement under section 60(1)(c) because infringement of a Swiss form claim required a subjective intention on the part of the manufacturer that the product be used for the treatment of the claimed indication and Actavis had had no such intention. I held that there was no infringement under section 60(2) because the claims were claims to a process of manufacture, but there was no act of manufacture (or preparation, to use the word in the claims) by any party downstream from Actavis, and in particular there was no act of manufacture by pharmacists.

40. On 16 October 2015 I gave both Mylan and Actavis on the one hand and Warner-Lambert on the other hand permission to appeal against my decisions with respect to insufficiency and I gave Warner-Lambert permission to appeal against my decision with respect to infringement under section 60(1)(c) because I was satisfied that those appeals had a real prospect of success. (The Court of Appeal subsequently gave Warner-Lambert permission to appeal on section 60(2).)

#### *Warner-Lambert's application against Sandoz*

41. The state of affairs described above was the state of affairs which prevailed when, on 21 October 2015, I heard the application by Warner-Lambert for an interim injunction against Sandoz. The background to that application is set out in full in my judgment dated 4 November 2015 [2015] EWHC 3153 (Pat) (*Sandoz P*). Summarising briefly, on 9 July 2014 Sandoz filed applications for marketing authorisation for both full

label and skinny label generic pregabalin products. Sandoz became aware of the Mylan and Actavis challenges to the validity of the Patent and decided not to bring any revocation claim of their own. On 19 June 2015 Sandoz received marketing authorisations for their full label and skinny label pregabalin products. On 26 June 2015 Sandoz launched their skinny label pregabalin product. On 2 October 2015 Sandoz notified Pfizer that Sandoz had started to supply their full label product.

42. This led to an application by Warner-Lambert for an interim injunction to restrain dealings by Sandoz in the Sandoz full label product. That application subsequently came on for a full hearing on 21 October 2015. For the reasons given in *Sandoz I*, I granted an interim injunction against Sandoz by an order dated 17 November 2015 (“the Sandoz Order”). The Sandoz Order contained a cross-undertaking in damages by Warner-Lambert in favour of various parties, but not including Dr Reddy’s or NHS Scotland. Subsequently, however, Mann J made an order by consent on 17 March 2016 extending the benefit of Warner-Lambert’s cross-undertaking to NHS Scotland with effect from 9 February 2016. For convenience I will refer to the Sandoz Order as if it had included this extended cross-undertaking at the outset.

*Developments in the Mylan/Actavis and Sandoz proceedings between 17 November 2015 and 13 December 2016*

43. On 17 December 2015 Warner-Lambert and Sandoz agreed a consent order providing for all further proceedings in Warner-Lambert’s claim against Sandoz to be stayed until the final determination of all appeals from *Warner-Lambert V* (subject to the parties having permission to lift the stay and restore the proceedings on notice after the judgment of the Court of Appeal).
44. On 13 October 2016 the Court of Appeal handed down its judgment on Warner-Lambert’s appeal against *Warner-Lambert V* [2016] EWCA Civ 1006, [2017] RPC 1 (“*Warner-Lambert CA I*”). The Court of Appeal dismissed both sides’ appeals on the issue of insufficiency. It followed that Warner-Lambert’s claim against Actavis for infringement of claims 1 and 3 failed. The Court of Appeal also considered, obiter, the infringement issues, as to which it took a different approach to that which I had taken.
45. The upshot of *Warner-Lambert CA II* was that the status of the Patent remained as it was after *Warner-Lambert V*. In summary, claims 1, 3, 4, 6, 13 and 14 had been held to be invalid, but claims 2, 5, 7, 8, 9, 10, 11 and 12 had been held to be valid.
46. The Court of Appeal refused to grant Warner-Lambert permission to appeal to the Supreme Court, but stayed the declarations of invalidity of claims 1, 3, 4, 6, 13 and 14 pending an application by Warner-Lambert to the Supreme Court. On 10 November 2016 Warner-Lambert filed an application to the Supreme Court for permission to appeal against the Court of Appeal’s conclusions with respect to the validity of claims 1, 3, 4, 6, 13 and 14. Mylan and Actavis filed statements of objection resisting the grant of permission to appeal, but contending in the alternative that, if Warner-Lambert were granted permission to appeal on the validity of claims 1, 3, 4, 6, 13 and 14, then Mylan and Actavis should be granted permission to cross-appeal on the validity of claims 10, 11 and 12. As at 13 December 2016, the Supreme Court’s decision on Warner-Lambert’s application for permission to appeal was not expected before mid-January 2017 at the earliest.

*Sandoz's application against Warner-Lambert*

47. On 18 November 2016 Sandoz launched an application to vary the Sandoz Order so as to enable Sandoz to market their full label product on the ground that there had been a material change of circumstances. This application was heard on 13 December 2016. On 21 December 2016 I dismissed the application for the reasons given in my judgment of the same date [2016] EWHC 3317 (Pat) (“*Sandoz II*”).
48. When explaining the genesis of the application, I recorded that it was Warner-Lambert’s evidence on the application that over 13.8% of prescriptions for pregabalin were written for indications covered by claims 2, 5, 7, 8 and 9 (“the Inflammatory Pain Claims”).
49. Sandoz relied upon two factors as, separately or cumulatively, amounting to a material change of circumstances: first, the judgment of the Court of Appeal in *Warner-Lambert CA II*; and secondly, the stance adopted by Warner-Lambert since then, as manifested in letters from Warner-Lambert’s solicitors to Sandoz’s solicitors dated 26 October 2016 and to NHS England’s solicitors dated 17 November 2016.
50. So far as *Warner-Lambert CA II* was concerned, it was common ground that that amounted to a change in circumstances, but I held that this was not a material change of circumstances.
51. I then turned to consider Warner-Lambert’s stance as set out in the letters dated 26 October and 17 November 2016. In short, Warner-Lambert had stated that it would not prevent generic companies from marketing pregabalin for indications which were only protected by claims held invalid by the Court of Appeal (although it reserved its right to claim financial remedies if successful in the Supreme Court). What this meant was that Warner-Lambert would not rely upon claim 3 in so far as it extended beyond claims 10, 11 and 12 to prevent generic companies marketing pregabalin i.e. Warner-Lambert would not seek an injunction on that basis. In particular, Warner-Lambert would not seek an injunction to prevent generic companies marketing pregabalin under intermediate labels which extended to central neuropathic pain. Warner-Lambert did not dispute that this was another change in circumstances, but again disputed that it was a material one.
52. I held that this change in circumstances was material for the reasons I gave in *Sandoz II* at [66]:

“... Whereas Warner-Lambert’s position at the time of the 17 November Order was that it relied upon claim 3 to prevent generic access to the pregabalin market prior to expiry of the Patent, it no longer does so. This matters when it comes to the assessment of the balance of the risk of injustice, because claim 3 confers a broader monopoly on Warner-Lambert than claims 10, 11 and 12, particularly if claim 3 covers both peripheral and central neuropathic pain as is Warner-Lambert’s primary contention. In particular, as noted in the preceding paragraph, it enables Sandoz to advance its argument on proportionality. That argument was not open to Sandoz in the same way at the hearing on 21 October 2015 because at that stage Warner-

Lambert was still relying upon claim 3. While it is true that I held in *Sandoz I* that Warner-Lambert had an arguable case of infringement of claims 10, 11 and 12 even if claim 3 was invalid, I went on to assess the balance of the risk of injustice on the basis that Warner-Lambert had a real prospect of success on claim 3 and I did not carry out a separate assessment on the assumption that Warner-Lambert only had a real prospect of success on claims 10, 11 and 12.”

53. I therefore proceeded to reconsider the balance of the risk of injustice depending on whether the interim injunction was continued unmodified or varied. I started by considering Warner-Lambert’s pleaded case on infringement in a passage which it is necessary to set out in full for reasons that will appear:

“77. In its current Amended Particulars of Infringement Warner-Lambert alleges infringement by Sandoz of claims 1, 3, 11 and 12 of the Patent, but not claim 10. (This is a point which appears to have been overlooked at the hearing on 21 October 2015.) On 7 December 2016, however, Warner-Lambert served draft Re-Amended Particulars of Infringement on Sandoz which add an allegation of infringement of claim 10. Counsel for Sandoz did not have instructions formally to consent to that amendment, but he accepted that the Court should proceed on the assumption that that amendment would be made. ...

78. Warner-Lambert’s draft Re-Amended Particulars of Infringement also introduce allegations of claims 2 and 8. Counsel for Sandoz indicated that Warner-Lambert’s application to introduce those allegations would be resisted. Given that, and given that there was no application by Warner-Lambert for permission to make those amendments before the Court, those allegations cannot be relied upon by Warner-Lambert for the purposes of resisting Sandoz’s application. I would add that, as I indicated to counsel for Warner-Lambert during the course of argument, my provisional view is that the allegations require further particularisation anyway.

79. What was not drawn to my attention during the course of the hearing, but I have subsequently noticed, is that Warner-Lambert’s existing Amended Particulars of Infringement allege infringement of claims 5, 7 and 9. It follows that, in principle, Warner-Lambert would be entitled to rely upon those allegations for the purposes of resisting Sandoz’s application. Counsel for Warner-Lambert did not rely upon those allegations as part of his argument, however. This is consistent with the stance adopted by Warner-Lambert at the hearing on 21 October 2015, when it did not rely upon those allegations for the purposes of its interim injunction application. I would add that my provisional view is that those allegations also require further particularisation.

80. This does not mean that claims 2, 5, 7, 8 and 9 are irrelevant for the purposes of the present application. On the contrary, those claims have been found to be valid and there is no extant challenge to that finding. It follows that, in principle, Warner-Lambert is entitled to the benefit of the monopoly conferred by those claims even if it is not in a position to allege infringement of those claims (as distinct from claims 10, 11 and 12).”
54. I went on to hold that damages would not be an adequate remedy for Warner-Lambert if the injunction were varied now so as to permit Sandoz to sell their full label product, but Warner-Lambert was successful at trial. In this context I discussed evidence which appeared to show that in England, despite the NHS Guidance, the level of prescribing of pregabalin by reference to the Lyrica brand name had peaked at just over 30% in about September 2015 and had subsequently declined slightly.
55. I also considered the impact of Warner-Lambert’s concession that it no longer relied upon claim 3 in so far as it extended beyond claims 10, 11 and 12 for the purposes of injunctive relief. I held that this made no difference for the reasons I gave at [102]:
- “... Even though the conditions covered by claims 10, 11 and 12 represent a small percentage of the pregabalin market, if the marketing of the Sandoz Full Label Product infringes those claims, Warner-Lambert is *prima facie* entitled to an injunction to prevent such marketing prior to expiry. If Sandoz were permitted to market the Sandoz Full Label Product now, it is clear that they would be quickly followed by other generic companies. Some might be able to launch very quickly after Sandoz, while others might have to wait 30-60 days. Within a couple of months, however, there would be a free-for-all in the full label market. The consequence would be further pressure on the market price of pregabalin. This would require Pfizer to spend even more money on Brand Equalisation deals if it was to try to maintain the ex-factory price of Lyrica. In practice, Pfizer might well have to cease supporting the ex-factory price in that way. Moreover, although expiry of the Patent is now less than seven months away, re-categorisation of pregabalin for the purposes of the Drug Tariff during that period remains a possibility. Pfizer would not be able put the price up again if Warner-Lambert is successful, not least because the Patent would have expired. The loss which Warner-Lambert would suffer as a result would be very difficult to quantify. The difficulty of the quantification exercise would be exacerbated by the substantial level of off-label prescribing of pregabalin for conditions covered by claims 2, 5, 7, 8 and 9, particularly given the likely uncertainty as to the extent to which that demand is met by full label as opposed to skinny label pregabalin. Moreover, it would be far from easy to quantify Warner-Lambert’s loss even in that part of the pregabalin market which is protected solely by claims 10, 11 and 12.”



56. Having considered the likely harm to Sandoz if the variation were refused, I concluded that, subject to the question of proportionality, granting the relief sought by Sandoz would create a greater risk of irremediable harm than refusing it.

57. Finally, I addressed the question of proportionality as follows:

“108. ... counsel for Sandoz placed proportionality at the forefront of his argument. In short, he submitted that an injunction to prevent Sandoz from marketing the Sandoz Full Label Product would be disproportionate when (i) the effect of the NHS Guidance was that about 30% of prescriptions in England were written by reference to the brand name Lyrica and thus could not have any generic product dispensed against them and (ii) in practice Pfizer retained about 50% of the pregabalin market, but (iii) claims 10, 11 and 12 only covered 1.13% of the market. ...

109. ... I do not consider that proportionality is a trump card for Sandoz on the present application for the following reasons. First, the figure of 1.13% ignores the rather larger part of the market (over 13.8% on Warner-Lambert's evidence) which is covered by claims 2, 5, 7, 8 and 9. As I have said, in principle, Warner-Lambert is entitled to the benefit of a monopoly of the latter part of the market even if it is not in a position to allege infringement of those claims (as distinct from claims 10, 11 and 12). It is immaterial for this purpose that Pfizer only reaches that part of the market through off-label prescribing because pregabalin is not authorised for the conditions covered by those claims.

110. Secondly, even if one disregards the part of the market covered by claims 2, 5, 7, 8 and 9, and leaving aside for the moment the effect of the NHS Guidance, the main cause of the problem which faces Sandoz is the preference which certain pharmacy chains have to stock full label product. Even though the conditions covered by claims 10, 11 and 12 represent a small percentage of the total market, Warner-Lambert is *prima facie* entitled, assuming that its claim for infringement of those claims succeeds, to use that monopoly to protect the full label market for pregabalin (as distinct from the skinny label and intermediate label markets). I do not consider it disproportionate to grant an injunction to enforce that entitlement on an interim basis. In this regard, it should not be forgotten that Sandoz have the benefit of Warner-Lambert's cross-undertakings not only with respect to the injunction, but also, to the extent that it contributes to the damage Sandoz suffer by ensuring that too large a percentage of prescriptions is written for Lyrica, the NHS Guidance. When it comes to the stage of considering whether to grant a final injunction, the position may be different ...; but that is a matter for another day.”

*The Supreme Court's decision*

58. After *Sandoz II*, the Supreme Court granted Warner-Lambert permission to appeal and granted Mylan and Actavis permission to cross-appeal. It also granted the parties permission to argue the infringement issues. On 14 November 2018 the Supreme Court handed down judgment dismissing the appeal and allowing the cross-appeal [2018] UKSC 56, [2019] Bus LR 360 (“*Warner-Lambert SC*”). In brief summary, the majority of the Supreme Court agreed with the lower courts that claims 1 and 3 (and therefore claims 4, 6, 13 and 14) were invalid due to insufficiency, but held that claims 10, 11 and 12 were also invalid on the same ground because the specification of the Patent did not make it plausible that pregabalin would be effective for the treatment of any kind of neuropathic pain. It followed that Warner-Lambert’s claim for infringement of claims 1 and 3 failed. My finding that the Inflammatory Pain Claims were valid was unaffected.
59. The Supreme Court also considered, obiter, Warner-Lambert’s claims for infringement. So far as Warner-Lambert’s case under section 60(1)(c) was concerned, Lord Sumption explained:
- “63. It is common ground that Swiss-form claims are purpose-limited process claims. Claim 3 of the patent in suit is not a product claim, because the product is not novel. It is a process claim because it protects the process of ‘preparation’ (or manufacture) of a medicament containing pregabalin. It is purpose-limited because it only protects that process so far as it is undertaken ‘for’ treating neuropathic pain. The monopoly claimed is a monopoly of preparation or manufacture of the product for the designated purpose. It is not a monopoly of the subsequent use of the product for that purpose. This is the basis on which Claim 3 is consistent with the prohibition of patents for methods of treatment or diagnosis. It follows that Warner-Lambert’s allegation of direct infringement is and must be based on section 60(1)(c).
64. Section 60(1)(c) is concerned with cases where a product is obtained directly by means of the patented process. Infringement occurs whenever a person disposes of that product, offers to dispose of it, uses or imports it, or keeps it, whether for disposal or otherwise. The infringer may be, but need not be, the same as the person who makes the product. The section also applies to anyone in the downstream generic market, including wholesalers and pharmacists. Liability is strict. Provided only that the product has been obtained directly by means of the process, it extends to subsequent dealings with all and every such product irrespective of knowledge.
- ...
67. At the hearing before us, the parties were agreed that there was a mental element in infringement under section 60(1)(c). This was not because of the terms of the section itself, which

provides for strict liability. It was said to be because a mental element was intrinsic to the claim said to have been infringed. The preparation of the compound must be 'for' the treatment of the designated condition. This cannot mean 'suitable for' that purpose, for a claim thus framed would lack novelty: the product was just as suitable for the newly discovered purpose before the priority date, even if this was not generally known. Therefore, it was said, it must mean that the manufacturer must make the product with the intention that it be used for that purpose, if the product is to fall within the confines of section 60(1)(c). The difference between the parties concerned the test of intention. Actavis's case was that the test of the manufacturer's intention was subjective. The manufacturer must make the product with intent to target the patent-protected market. Arnold J accepted that submission. Warner-Lambert's primary case was that the test of the manufacturer's intention was objective, and that a manufacturer must be taken to intend the foreseeable consequences of his actions. It was therefore enough to support a case of infringement of Claim 3 under section 60(1)(c) that it was foreseeable to the manufacturer that a more than de minimis amount of it would in due course be used for the treatment of neuropathic pain.

...

70. ... after the hearing the parties addressed [the 'only packaging will do' approach] in writing, at the invitation of the court. Actavis adopted it by way of alternative to their primary case that the test required proof of subjective targeting. ...
71. It is clearly correct that this issue depends not on the meaning of section 60(1)(c) of the Patents Act but on the construction of the relevant claims in the patent. The question is what, as a matter of construction, does it mean to claim in a patent the use of pregabalin for the preparation of a medicament 'for' treating neuropathic pain. ..."
60. Lord Sumption, with whom Lord Reed agreed, considered that the answer to this question did not depend on either the subjective intention of the alleged infringer ([74]-[78]) or upon the foreseeability of the use of the medicament ([79]-[83]). Instead, he held at [84]-[85] that "in a purpose-limited process claim, the badge of purpose is the physical characteristics of the product as it emerges from the relevant process, including its formulation and dosage, packaging and labelling and the patient information leaflet which ... will identify the conditions for whose treatment the product is intended". This test properly reflected "the critical feature of Swiss-form patents, namely that the patent is for the process of manufacture, not for the subsequent use that may be made of the product". Lord Briggs, with whom Lord Hodge agreed, held that such a claim was only infringed if the alleged infringer subjectively intended to supply the medicament for the purpose specified in the claim ([121]-[174]). Lord Mance leaned in favour of Lord Sumption's test, but left open the possibility that there could be infringement even when the product was not presented

as suitable for the claimed purpose if the circumstances made it obvious that the product was in fact destined for such use ([197]-[218]).

61. Warner-Lambert's case under section 60(2) was that, by supplying Lecaent in the United Kingdom, Actavis were knowingly "supply[ing] in the United Kingdom a person ... with ... means, relating to an essential element of the invention, for putting the invention into effect". The argument was that "the invention" was the use of pregabalin to treat neuropathic pain, and that it was "put into effect" when a pharmacist dispensed a pack of Lecaent against a prescription written by a doctor for neuropathic pain. Therefore, by supplying Lecaent (directly or indirectly) to pharmacists Actavis supplied them with the means for putting the invention into effect.
62. The Supreme Court unanimously rejected this argument for the reasons given by Lord Sumption at [88]:

"The short answer to this is that the invention protected by Claim 3 is the manufacture of pregabalin for the designated use, and not the subsequent use of the product for treating patients. This is what the Court of Appeal decided, correctly in my view, in *Menashe Business Mercantile Ltd v William Hill Organisation Ltd* [2003] 1 WLR 1462, para 24, per Aldous LJ. It was the ground on which the judge struck out the indirect infringement claim on the interlocutory application of Actavis. It was re-instated by the Court of Appeal as arguable. At trial, Arnold J held that the argument was bad. In the Court of Appeal, Floyd LJ adhered to his earlier view. He accepted that *Menashe* was authority for the proposition that the 'invention' in section 60(2) was the process identified in the relevant claim. But he considered that the 'preparation' referred to in the claims might still not be put fully into effect until the pharmacist had dispensed the medicament and affixed a sticker with the patient's name on it. He warned against the danger of translating section 60(2) into infringement limited to acts upstream of manufacture. In my view Arnold J was right about this. The whole purpose of the Swiss-form for purpose-limited medical use claims is to avoid the problem of lack of novelty associated with product claims and the statutory provision which makes a method of treatment unpatentable. It is well understood that the degree of protection available from a Swiss-form claim may be more limited than that available from standard product claims. These essential features of purpose-limited patents are fatal to any attempt to construe Claim 3 as extending to steps taken by the pharmacist."

*Warner-Lambert's claim against Dr Reddy's*

63. On 13 February 2015 Dr Reddy's launched a generic pregabalin product under a skinny label and the trade mark Alzain. On 17 February 2015 Warner-Lambert commenced a claim against Dr Reddy's for infringement of claims 1 and 3 of the Patent. (Counsel for Dr Reddy's pointed out that, as in the Actavis proceedings,

Warner-Lambert's statement of case alleged infringement of "at least claims 1 and 3". Unless amended to identify another claim, however, such a plea is only an allegation of the specified claims, which is how it was treated throughout the Actavis proceedings.) Warner-Lambert's claim against Dr Reddy's was pleaded in the same way as its claim against Actavis, that is to say, raising cases under section 60(1)(c) and section 60(2) of the 1977 Act.

64. On 27 April 2015 Dr Reddy's served a Defence and Counterclaim denying infringement and counterclaiming for revocation of all the claims of the Patent and for groundless threats. The counterclaim in respect of threats alleged that Warner-Lambert was jointly liable for threats made by Pfizer in letters sent, and other communications made, to influence the actions of prescribers and pharmacists. Specific reliance was placed upon letters sent by Pfizer to its pharmacy customers in about November and December 2014.
65. On 12 May 2015 Warner-Lambert served a Reply and Defence to Counterclaim. Warner-Lambert admitted that, among other communications, in November 2014 Pfizer had written to pharmacists stating that "we believe that the supply of generic pregabalin for use in the treatment of pain, whilst the pain patent remains in force in the UK, would be infringing Pfizer's patent protection and would constitute an unlawful act". Warner-Lambert did not admit that any threats of patent infringement had been made by those communications and denied that any threats were actionable on the ground that Dr Reddy's was not a person aggrieved by such threats. Warner-Lambert did not allege that any threats were justified because pharmacists had infringed claims of the Patent.
66. On 30 June 2015 the Dr Reddy's proceedings were stayed by consent pending the first instance judgment in the Mylan and Actavis proceedings. On 7 December 2015 a further stay of the Dr Reddy's proceedings was ordered by consent pending the final judgments on appeal in the Mylan and Actavis proceedings. Nevertheless three interim orders were made containing undertakings by Dr Reddy's in return for cross-undertakings given by Warner-Lambert in addition to the NHS Order.
67. On 24 January 2020 (some 14 months after *Warner-Lambert SC*) Dr Reddy's applied for directions. This application led to Birss J (as he then was) making an order on 16 March 2020 ("the Birss Order") which:
  - i) dismissed Warner-Lambert's claim against Dr Reddy's "on the basis that claims 1, 3, 4, 6, 10, 11, 12, 13 and 14 of [the Patent] are invalid";
  - ii) declared that Warner-Lambert "has made unjustifiable threats of proceedings for patent infringement";
  - iii) ordered an inquiry as to damages suffered by Dr Reddy's (a) pursuant to Warner-Lambert's cross-undertakings and (b) "by reason of [Warner-Lambert's] unjustifiable threats of patent infringement proceedings"; and
  - iv) ordered Warner-Lambert to pay Dr Reddy's costs "of the liability phase of the action".

68. So far as points (i), (iii) and (iv) are concerned, the Birss Order was expressly made by consent. As for point (ii), the Birss Order did not record that the declaration was made by consent, but it is clear from the transcript of the hearing that that was in fact the basis upon it was made. It is clear from the order that Warner-Lambert abandoned both its infringement claim against Dr Reddy's and its defences to Dr Reddy's counterclaim for groundless threats.
69. The Birss Order recited that Warner-Lambert had made an interim payment of £185,000 in respect of Dr Reddy's' costs "of the liability phase of the action". We were told by counsel for Dr Reddy's that the total costs incurred by Dr Reddy's during the liability phase were some £484,000.
70. The Birss Order also required Warner-Lambert to write to all beneficiaries of cross-undertakings given by Warner-Lambert in connection with the Patent enclosing a copy of the Birss Order and inviting them to attend a case management conference.

*The inquiry*

71. On 5 May 2020 Dr Reddy's served Points of Claim setting out its claims against Warner-Lambert on the inquiry ordered by Birss J. In a nutshell Dr Reddy's' case is that, but for the groundless threats of patent infringement proceedings made by Pfizer and the NHS Order, Dr Reddy's would have sold more generic pregabalin in the United Kingdom than it did, would have made more profits from those additional sales, and was thus caused loss by the threats and by the NHS Order for which it should be compensated by Warner-Lambert. Two points should be noted about the Dr Reddy's claim. The first is that it embraces sales of pregabalin which would have been prescribed and dispensed for the treatment of inflammatory pain. Secondly, the claim is formulated in a manner which does not distinguish between loss alleged to have been suffered as a result of the threats and loss alleged to have been suffered as a result of the NHS Order. Dr Reddy's contends that it is neither necessary nor possible to distinguish between these causes.
72. In paragraph 30 of its Points of Claim Dr Reddy's pleaded that Warner-Lambert had made six groundless threats of proceedings for patent infringement against doctors and pharmacists, including the email dated 13 November 2014 and the letter dated 10 December 2014.
73. Warner-Lambert served its Points of Defence on 10 June 2020. Warner-Lambert admitted paragraph 30 of the Points of Claim save that it pointed out that in fact the threats had been made by Pfizer, while accepting liability for those threats.
74. Subsequently six other groups of Inquiry Claimants advanced claims pursuant to Warner-Lambert's cross-undertakings. A number of Inquiry Claimants have since agreed settlements with Warner-Lambert, and the only remaining claims are those made by Dr Reddy's and by the Seventh to Twenty-first Inquiry Claimants (collectively "NHS Scotland"). In summary NHS Scotland's case is that, but for the Sandoz Order, there would have been increased availability of generic pregabalin in the market, and this would have caused NHS Scotland to change the reimbursement category of pregabalin and reduce the reimbursement price paid to pharmacists, which would have resulted in NHS Scotland spending less on pregabalin than they did.

75. Birss J made initial directions for the conduct of the inquiry at a case management conference on 15 July 2020 and further directions at a case management conference on 18 December 2020. On the latter occasion Birss J directed that there be three trials: first, a trial of preliminary issues to determine the appropriate counterfactual assumptions for the purposes of the inquiry (referred to as the common assumptions trial or “CAT”) on the first available date after 1 June 2021; secondly, a trial of issues common to the various inquiry claims on the first available and convenient date after 22 June 2022; and thirdly a trial of all remaining issues, and in particular quantum, (“the quantum trial”) on the first available and convenient date after 29 April 2024. The quantum trial was subsequently fixed for October 2024.
76. The CAT was heard by Zacaroli J in June 2021. On 30 July 2021 Zacaroli J handed down a judgment [2021] EWHC 2182 (Ch), [2021] Bus LR 1496 in which he held that there should be a single counterfactual across all the inquiry claims in which none of the orders or threats in question had been made.
77. Following a third case management conference before Zacaroli J on 20 October 2021, on 21 December 2021 Warner-Lambert applied for permission to amend its Points of Defence in a number of respects. This application was heard by the judge at a hearing on 11, 12 and 14 January 2022. The judge made an order for directions at the conclusion of the hearing which directed that a single trial of the remaining issues on the inquiry be listed with a time estimate of five weeks for the first available and convenient date after 1 October 2023, but reserved judgment on Warner-Lambert’s amendment applications. The judge gave judgment on these applications on 3 February 2022, and made the order under appeal on 24 March 2022. In the meantime the trial had been fixed for November 2023.

#### Warner-Lambert’s proposed amendments

78. The proposed amendments with which this appeal is concerned both take as their starting points (i) my finding in *Warner-Lambert V* that the Inflammatory Pain Claims were valid and (ii) the evidence referred to in *Sandoz II* that at least 13.8% of the pregabalin dispensed in UK in 2016 had been prescribed off-label for conditions covered by the Inflammatory Pain Claims.
79. Before turning to the amendments in issue on this appeal, it is first necessary to note that, by another amendment for which Warner-Lambert sought permission, Warner-Lambert sought to raise a defence to the Dr Reddy’s claim for groundless threats pursuant to section 70(2A) of the 1977 Act on the basis that pharmacists had infringed the Inflammatory Pain Claims. The judge refused Warner-Lambert permission to make this amendment on the ground that the Birss Order had constituted a final determination of the entitlement of Dr Reddy’s to relief for groundless threats so as to preclude Warner-Lambert from relying upon a defence under 70(2A) on the inquiry. There is no appeal by Warner-Lambert against that part of the judge’s order. Accordingly, counsel for Warner-Lambert accepted that it was not open to Warner-Lambert to contend that pharmacists had infringed the Inflammatory Pain Claims in the context of the claim by Dr Reddy’s for damages for groundless threats. As will appear, however, he submitted that the position was different with respect to the claim by Dr Reddy’s under Warner-Lambert’s cross-undertakings.

80. The first amendment in issue is the insertion of a plea into Warner-Lambert's Defence to the claims by Dr Reddy's and by NHS Scotland in the following terms (taking the version applicable to NHS Scotland's claim):

"Warner-Lambert contends that, to the extent any damage is 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 the Inflammatory Pain Claims, such damage should be excluded from the final calculation of quantum.

#### PARTICULARS

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."

81. The second amendment in issue is the insertion of a plea into Warner-Lambert's Defence to the claim by Dr Reddy's in the following terms:

"Warner-Lambert contends that, to the extent that the pregabalin products sold and supplied by Dr Reddy's would have been used for or attributable to the treatment of any condition covered by the Inflammatory Pain Claims, any profits said to have arisen from such sale and supply should be excluded from the final calculation of loss of profit.

#### PARTICULARS

The dispensing of pregabalin products supplied in the UK by Dr Reddy's for or attributable to the treatment of any condition covered by the Inflammatory Pain Claims would have infringed the Inflammatory Pain Claims. Therefore, Warner-Lambert contends that Dr Reddy's may not recover any such loss of profits founded substantially upon an unlawful and/or illegal act, being in this case the infringement of a European Patent (UK). By this, Warner-Lambert does not presently bring any claim before the Court that Dr Reddy's has infringed the Patent. Without prejudice to its ability to do so, this contention is advanced in relation to the counterfactual."

#### The judge's decision on the amendments in issue

82. The judge refused Warner-Lambert permission to make the first amendment on the ground that the plea had no real prospect of success.



83. The judge held that the second amendment raised a case with a real prospect of success but nevertheless refused Warner-Lambert permission to make the amendment for two reasons. First, he held that it was an abuse of process for Warner-Lambert to advance this case now on *Henderson v Henderson* (1843) 3 Hare 100 grounds. Secondly, he held that permission should be refused on case management grounds.

A point on terminology

84. Before turning to the appeal, it is convenient to note a point on terminology. It is common to speak of courts holding that patents, or particular claims of patents, are “valid”. Indeed, it is common for courts to make declarations to that effect. Strictly speaking, however, all that any court can ever hold, or declare, is that a patent is not invalid as alleged by the party currently attacking the validity of the patent on the grounds relied upon by that party. It may be open to that party subsequently to attack the validity of the patent on different grounds, for example a new item of prior art which could not have been discovered previously with the exercise of reasonable diligence. It will certainly be open to different parties to attack the validity of the patent whether upon the same grounds or different grounds. Thus a finding or declaration that a claim is “valid” must be understood as meaning “not invalid as alleged”.
85. The relevance of this point is that Warner-Lambert rely upon the fact that I held in the Mylan and Actavis litigation that the Inflammatory Pain Claims were valid, and that conclusion was not disturbed on appeal. That is correct, but the true meaning of that finding is as I have just explained. Thus it is not in dispute that it would be open to Dr Reddy’s and NHS Scotland, subject to any valid procedural objection, to attack the validity of those claims.

The appeal: the first amendment

86. The case which Warner-Lambert seeks to advance by the first amendment is that it would be unjust and inequitable for NHS Scotland or Dr Reddy’s to recover damages pursuant to Warner-Lambert’s cross-undertakings for losses arising from the sale and supply of pregabalin which would have been used to treat a condition covered by the Inflammatory Pain Claims regardless of whether such use would have infringed or not. Accordingly, the merits of this case can be tested by considering the position where such use would not have infringed the Inflammatory Pain Claims.
87. There is no dispute as to the basic principles applicable to a claim for compensation under a cross-undertaking given in return for an interim injunction. The starting point is the statement of Lord Diplock in *Hoffmann-La Roche & Co. AG v Secretary of State* [1975] 1 AC 295 at 361:

“The assessment is made upon the same basis as that upon which damages for breach of contract would be assessed if the undertaking had been a contract between the plaintiff and the defendant that the plaintiff would not prevent the defendant from doing that which he was restrained from doing by the terms of the injunction ...”

88. The jurisdiction to award compensation on a cross-undertaking is equitable and is not contractual, however, and it is now recognised that it requires a degree of flexibility to ensure that the inquiry claimant receives the amount, and only the amount, for which it “should be compensated”. This was explained by McCombe LJ in *Abbey Forwarding Ltd v Hone (No 3)* [2014] EWCA Civ 711, [2015] Ch 309 following a thorough examination of the authorities.
89. Having accepted counsel’s submission that the correct approach is to allow for “logical and sensible adjustments” to the normal application of the contractual rules at [45]-[46], McCombe LJ cited with approval at [47] the approach to assessment of loss under a cross-undertaking set out by Aicken J in the High Court of Australia’s judgment in *Air Express Ltd v Ansett Transport Industries (Operations) Proprietary 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 was granted, is one which will be just and equitable in the circumstances of most cases and certainly in the present case. No doubt the view ... does not constitute a rigid rule and circumstances may sometimes require a different approach. However it will in my opinion be seldom that it will be just or equitable that the unsuccessful plaintiff should bear the burden of damages which were not foreseeable from circumstances known to him at the time.”
90. McCombe LJ summarised the position at [63]:
- “... I reach the conclusion that the law as to the recoverability of loss suffered by reason of a cross-undertaking is as stated by Lord Diplock in his dictum in *Hoffmann-La Roche*, 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). 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.”
91. Warner-Lambert contends that it would not be “just and equitable” to require Warner-Lambert to compensate Dr Reddy’s for the loss of profits it would have made, or to compensate NHS Scotland for costs they would have avoided, as a result of pregabalin being prescribed and dispensed for the treatment of conditions covered by the Inflammatory Pain Claims even if no-one infringed those claims. Warner-Lambert says that a “haircut” of 13.8% (or whatever the correct percentage is found to be at

trial) should be applied to Dr Reddy's' and NHS Scotland's claims as a result. As noted above, the judge held that this contention had no real prospect of success.

92. Warner-Lambert originally appealed on two grounds. Ground 1 was that the judge was wrong to conclude that the case had no real prospect of success because he had failed correctly to apply the principles as to the assessment of compensation pursuant to a cross-undertaking which I have summarised above. Ground 2 was that the amendments raised a novel point of law in a developing field of jurisprudence which should only be decided after full argument and findings of fact at trial. When granting permission to appeal, I invited the parties to consider whether the appropriate course was for this Court to decide the issue of law. Dr Reddy's and NHS Scotland supported that course being adopted. Warner-Lambert initially opposed it, but at the hearing adopted the same position as the other parties. Although counsel for Warner-Lambert submitted that ground 2 survived this concession in so far as there were factual disputes to be resolved at trial, I disagree. Ground 2 is inconsistent with the agreement of the parties that the Court should decide the issue of law. Furthermore, there are no relevant facts in dispute.
93. In my judgment Warner-Lambert's contention is wrong in law. The purpose of cross-undertakings is to enable parties who have suffered loss as a result of orders having been made which it turns out should not have been made to obtain compensation. As Warner-Lambert accepts, it must be assumed for present purposes that factual causation will be established, that is to say, Dr Reddy's and NHS Scotland would not have suffered the losses claimed but for the orders in question. Furthermore, this is not an issue as to foreseeability, and so it must be assumed at this stage that the losses claimed were foreseeable. If the losses were foreseeably caused by the orders, then justice and equity require that Dr Reddy's and NHS Scotland be compensated by Warner-Lambert for those losses. As discussed below, it might be different if the prescribing and dispensing of pregabalin for the treatment of inflammatory pain in the counterfactual world would have infringed the Inflammatory Pain Claims. Absent infringement, however, such supplies would have been entirely lawful. Nor is it suggested that Warner-Lambert could lawfully have prevented such supplies in any way other than relying upon the Patent.
94. Warner-Lambert's principal argument in support of its appeal is that infringement is irrelevant because this is an issue as to the application of equitable principles for the determination of compensation pursuant to cross-undertakings in damages, and not an issue of substantive patent law. That is a self-contradictory argument. It amounts to saying that compensation would be unjust and inequitable because Warner-Lambert had a valid monopoly conferred by the Inflammatory Pain Claims, but this has nothing to do with substantive patent law. It is only because of substantive patent law that Warner-Lambert had a monopoly, however.
95. Warner-Lambert's secondary argument it is that it is necessary to distinguish between the monopoly conferred by a patent on the one hand and the right conferred on the patentee (and/or its exclusive licensee) to bring claims for infringement in respect of certain acts on the other hand. Warner-Lambert draws an analogy with the primary obligation to comply with a contract and the secondary obligation to pay damages for breach of contract. The distinction which Warner-Lambert draws is wrong. Prior to 1 June 1978 letters patent conferring a monopoly on the holder were granted by the Crown in the exercise of the Royal prerogative and the scope of the monopoly was

defined by the wording of the letters patent. Since the 1977 Act came into force patents (not letters patent) have been granted by what is now the United Kingdom Intellectual Property Office pursuant to the statute, and no monopoly is conferred by a patent save that which results from the terms of the statute. Thus there is no monopoly in respect of acts which do not infringe the patent. To the extent that it is possible to make an analogy with the distinction drawn in the field of contract law, the primary obligation is not to infringe the patent and the secondary obligation is to pay damages for infringement.

96. Warner-Lambert contends that this argument is supported by what I said in *Sandoz II* at [80]: “Warner-Lambert is entitled to the benefit of the monopoly conferred by those claims even if it is not in a position to allege infringement of those claims”. This statement must be seen in context, however. Read in context, it does not support Warner-Lambert’s case.
97. The context was that the court was faced with an issue as to whether to continue an interim injunction in the light of a material change in circumstances. The question was what course would have the lowest risk of causing irremediable harm. As discussed at [78]-[79] Warner-Lambert had got itself into a difficulty: although it had pleaded infringement of claims 5, 7 and 9, the allegations required particularisation and in any event had not been relied upon when the injunction was obtained; while Warner-Lambert had failed to apply to amend to add allegations of infringement of claims 2 and 8 and also needed to particularise those. But that difficulty did not mean that it was inconceivable that Warner-Lambert would be able to get itself into a position to be able to allege infringement of the Inflammatory Pain Claims at trial; on the contrary it was conceivable that it would be able to do so. Importantly, there was no finding that such allegations would have no real prospect of success.
98. Furthermore, as discussed extensively in *Warner-Lambert I-II* and *V* and *Warner-Lambert CA I and II*, one of the consequences of Warner-Lambert’s case on infringement under section 60(1)(c) was that it exposed pharmacists to strict liability if it was foreseeable to the manufacturer of a skinny label pregabalin product (let alone a full label pregabalin product) that the product would be prescribed, even off-label, by doctors for one of the claimed indications. That case had been accepted by the Court of Appeal in *Warner-Lambert CA II*, subject to the qualification that liability would not attach where the manufacturer took all reasonable steps to prevent pregabalin being prescribed or dispensed for the claimed indications. Moreover, it remained possible that Warner-Lambert would be able to persuade the Supreme Court to accept its case without even that qualification. Thus, as matters then stood, there was a real prospect that it would be held that pharmacists would infringe the Inflammatory Pain Claims by dealing in the Sandoz full label product.
99. Finally, the same points would apply to full label products launched by other generic suppliers: those suppliers might infringe the Inflammatory Pain Claims and so might pharmacists dispensing their products.
100. The possibility that the Inflammatory Pain Claims would be infringed by Sandoz, other generic suppliers and pharmacists was relevant to the assessment both of whether Warner-Lambert would suffer irremediable harm and of proportionality for the reasons explained at [102] and at [109] respectively. Neither passage suggests that

the Inflammatory Pain Claims would have been relevant if there was no question of them being infringed by anyone, however.

101. Warner-Lambert also argue that there is a difference between infringement proceedings and a claim under a cross-undertaking in damages in that the former is prospective and the latter is retrospective. Again, this is wrong. Most patent infringement claims contain both a retrospective element and a prospective element: has the defendant infringed a valid claim by its past acts and does it threaten to commit such acts in future? If the defendant has infringed in the past that will found a claim for financial relief. If the defendant threatens to commit infringing acts in the future that will found a claim for an injunction. In some cases there may be no threat to infringe in future, and the issue is purely as to financial relief for past acts. In other cases there have been no infringing acts to date, and the issue is purely as to whether the defendant should be restrained from infringing in future. Warner-Lambert's claim against Actavis began as a claim for an injunction in respect of future acts, but by the time it came to trial Actavis had been committing the allegedly infringing acts for some time. Thus the fact that a claim under a cross-undertaking in damages concerns the past does not materially differentiate it from a claim for infringement.
102. Finally, I should mention that Warner-Lambert criticised a passage in the judge's judgment at [39]-[42] in which he compared the inequity relied upon by Warner-Lambert with that occasioned to the Inquiry Claimants by their inability to claim compensation due to the fact that claims 1 and 3 of the Patent were found to be invalid. It is unnecessary to consider whether Warner-Lambert's criticism is well-founded because it would not assist Warner-Lambert even it was, but for the avoidance of doubt I should not be taken as endorsing the judge's reasoning in that passage.

#### The appeal: the second amendment

103. The case that Warner-Lambert advances by the second amendment is that (i) the dispensing of Dr Reddy's' pregabalin product by pharmacists would have infringed the Inflammatory Pain Claims, and therefore (ii) recovery by Dr Reddy's of losses claimed in respect of such dispensing is barred by the doctrine of illegality.

#### *Real prospect of success?*

104. The judge held that this case had a real prospect of success. Dr Reddy's contends that limb (i) has no real prospect of success. There was some debate during the course of argument about limb (ii), and in particular whether the decision of the Supreme Court in *Les Laboratoires Servier v Apotex Inc* [2014] UKSC 55, [2015] AC 430 that patent infringement was not a relevant form of illegality because it was neither criminal nor quasi-criminal had survived the subsequent decision of the Supreme Court in *Patel v Mirza* [2016] UKSC 42, [2017] AC 467; but Dr Reddy's does not contend that Warner-Lambert has no real prospect of success on this part of its case.
105. Dr Reddy's argues that the allegation that pharmacists would have infringed the Inflammatory Pain Claims has no real prospect of success for two reasons. The first is that the allegation is wholly unparticularised: the plea is pure assertion with no supporting facts whatever. This point was not taken before the judge. Counsel for Dr Reddy's explained that Dr Reddy's wished to defeat the amendment application once

and for all, rather than face the issue being deferred until the amendment was properly particularised. In my view the amendment is not allowable as it stands, but I will assume that this defect would be rectified if Warner-Lambert had a viable case.

106. The second reason given by Dr Reddy's is that Warner-Lambert has no tenable case that pharmacists would have infringed the Inflammatory Pain Claims in any event. The first point to note in this regard is that the judge understood Warner-Lambert to be advancing its case under section 60(1)(c) alternatively section 60(1)(b). Counsel for Warner-Lambert explained to this Court, however, that Warner-Lambert was not relying upon section 60(1)(c), but upon section 60(1)(b) alternatively section 60(2). Warner-Lambert contends that (i) a pharmacist who dispensed the Dr Reddy's product would have committed an act of "preparation of a pharmaceutical composition" by affixing a patient label to the product and (ii) the pharmacist would have known, or it would have been obvious to a reasonable person in the circumstances, that some of the product was to be used for the treatment of inflammatory pain.
107. Although, for reasons that will appear, it is not necessary to rest my decision upon the point, in my view neither way of putting the claim has a real prospect of success. So far as the claim under section 60(2) is concerned, the Supreme Court in *Warner-Lambert SC* was unanimous in holding that the preparation of the pharmaceutical composition was undertaken by the manufacturer and not by a pharmacist who merely applied a patient label. Although that holding was obiter, it was based on *Menashe Business Mercantile Ltd v William Hill Organisation Ltd* [2003] 1 WLR 1462, which is binding Court of Appeal authority. In my opinion there is no realistic prospect of the Supreme Court reaching the opposite conclusion in future. The fact that the present claim is concerned with dispensing pregabalin for off-label use makes no difference to this.
108. Turning to the claim under section 60(1)(b), this suffers from the same flaw as the claim under section 60(2). In order to infringe under section 60(1)(b) a pharmacist would have had to "use[] the process", but pharmacists did not use the claimed process for the reasons given by the Supreme Court.
109. A further difficulty with both claims is that, as explained above, in most instances pharmacists would not have known what condition the medication had been prescribed for. Counsel for Warner-Lambert submitted that this did not matter, because it was sufficient that the prescriber knew. That cannot be right. A claim under section 60(1)(b) requires the person using the process to have the relevant state of mind, while a claim under section 60(2) requires the supplier of the means to have the relevant state of mind. Both claims are directed at the pharmacist, and thus it is the pharmacist who must have the relevant state of mind. Counsel for Warner-Lambert also submitted that it was sufficient that it would have been foreseeable that some of the pregabalin had been prescribed off-label for a claimed condition, but this submission faces two difficulties. The first is that the Supreme Court unanimously rejected foreseeability as the test of what was required by the word "for" in the claims. Secondly, even if foreseeability is sufficient to satisfy the claims, section 60(1)(b) and section 60(2) – unlike section 60(1)(c) – both require the presence of a specific mental element for each act of alleged infringement.

110. The judge expressed the view that, if the affixing of a label to a packet of pregabalin did constitute preparation of a pharmaceutical composition, then there was a strong case for saying that it also constituted the “extemporaneous preparation ... of a medicine” within section 60(5)(c) of the 1977 Act, and thus was exempted from infringement. He concluded, however, that this was a novel point of law which ought not to be decided on an amendment application, but rather should be determined after full argument at trial in the light of the facts. Given my conclusions above and below, it suffices to say that I find it very hard to see how affixing a label could be “preparation of a pharmaceutical composition” but not “extemporaneous preparation ... of a medicine”.

*Abuse of process?*

111. There is little dispute as to the principles governing abuse of process on *Henderson v Henderson* grounds. It is sufficient for present purposes to cite two passages from the authorities which are relied upon by Warner-Lambert. The first is from the speech of Lord Bingham in *Johnson v Gore Wood & Co* [2002] 2 AC 1 at 30-31:

“... *Henderson v Henderson* abuse of process, as now understood, although separate and distinct from cause of action estoppel and issue estoppel, has much in common with them. The underlying public interest is the same: that there should be finality in litigation and that a party should not be twice vexed in the same matter. This public interest is reinforced by the current emphasis on efficiency and economy in the conduct of litigation, in the interests of the parties and the public as a whole. The bringing of a claim or the raising of a defence in later proceedings may, without more, amount to abuse if the court is satisfied (the onus being on the party alleging abuse) that the claim or defence should have been raised in the earlier proceedings if it was to be raised at all. I would not accept that it is necessary, before abuse may be found, to identify any additional element such as a collateral attack on a previous decision or some dishonesty, but where those elements are present the later proceedings will be much more obviously abusive, and there will rarely be a finding of abuse unless the later proceeding involves what the court regards as unjust harassment of a party. It is, however, wrong to hold that because a matter could have been raised in earlier proceedings it should have been, so as to render the raising of it in later proceedings necessarily abusive. That is to adopt too dogmatic an approach to what should in my opinion be a broad, merits-based judgment which takes account of the public and private interests involved and also takes account of all the facts of the case, focusing attention on the crucial question whether, in all the circumstances, a party is misusing or abusing the process of the court by seeking to raise before it the issue which could have been raised before. As one cannot comprehensively list all possible forms of abuse, so one cannot formulate any hard and fast rule to determine whether, on given facts, abuse is to be

found or not. Thus while I would accept that lack of funds would not ordinarily excuse a failure to raise in earlier proceedings an issue which could and should have been raised then, I would not regard it as necessarily irrelevant, particularly if it appears that the lack of funds has been caused by the party against whom it is sought to claim. While the result may often be the same, it is in my view preferable to ask whether in all the circumstances a party's conduct is an abuse than to ask whether the conduct is an abuse and then, if it is, to ask whether the abuse is excused or justified by special circumstances. Properly applied, and whatever the legitimacy of its descent, the rule has in my view a valuable part to play in protecting the interests of justice."

112. The second is the statement of Clarke LJ in *Dexter Ltd v Vlieland-Boddy* [2003] EWCA Civ 14 at [50]:

"... it is one thing to say that A should bring all his claims against B in one action, whereas it is quite another thing to say that he should bring all his claims against B and C (let alone against B, C, D, E, F and G) in one action. There may be many entirely legitimate reasons for a claimant deciding to bring an action against B first and, only later (and if necessary) against others."

113. The judge held, in summary, that Warner-Lambert could and should have advanced a claim for infringement of the Inflammatory Pain Claims as part of its case against Dr Reddy's prior to the Birss Order, and that it was an abuse of process for Warner-Lambert to do so now. All of the facts that Warner-Lambert relied upon were known to it prior to 16 March 2020, and the Birss Order was a final determination of all issues of liability.
114. Warner-Lambert contends that the judge fell into error for a number of reasons which I will consider in turn.
115. First, Warner-Lambert contends that the judge overlooked the fact that Warner-Lambert was already alleging infringement of the Inflammatory Pain Claims in its existing Points of Defence, and that that fact should have led the judge to conclude that the amendment would not be an abuse of process. It is not in dispute that Warner-Lambert briefly advanced this contention before the judge, but the judge did not address it in his reserved judgment. That suggests that he thought there was nothing in it. If infringement of the Inflammatory Pain Claims was already being alleged, Warner-Lambert would not need to amend. Moreover, Warner-Lambert did not raise this point in its original grounds of appeal or skeleton argument, but only in oral argument and then only in the context of the judge's case management reason for refusing the amendment. This led, however, to an application by Warner-Lambert to amend its grounds of appeal to advance the point in relation to both the judge's reasons.
116. In my judgment the existing Points of Defence do not allege infringement of the Inflammatory Pain Claims, and certainly do not allege that the Inflammatory Pain



Claims would have been infringed by pharmacists. The paragraphs relied upon by Warner-Lambert respond to two paragraphs in Dr Reddy's Points of Claim which allege that *Warner-Lambert SC* established that "none of the acts in relation to the ... dispensing of Alzain ... relied upon herein as giving rise to a loss to Dr Reddy's would ever have led to an infringement of the Patent by Dr Reddy's" and therefore Warner-Lambert "had no legitimate basis for any objection" to those acts. That was probably an unnecessary plea for Dr Reddy's to make, since acts are presumed to be lawful unless and until someone alleges and proves that they are unlawful, but nevertheless Dr Reddy's makes it. In response Warner-Lambert denies that there was any finding with respect to infringement of the Inflammatory Pain Claims and asserts that "the valid Inflammatory Pain Claims may have been infringed". Leaving aside the fact that it is wholly unparticularised, this is not an allegation that the Inflammatory Pain Claims would have been infringed, still less is it an allegation that the Inflammatory Pain Claims would have been infringed *by pharmacists* as opposed to *Dr Reddy's*. This is significant for the reasons explained below.

117. Secondly, Warner-Lambert points out that, although the judge correctly referred to Warner-Lambert's claim as being one of infringement of the Inflammatory Pain Claims *by pharmacists* while considering whether the claim had a real prospect of success at [48]-[52], when it came to considering whether it was an abuse of process at [56]-[69] the judge said that Warner-Lambert could and should have advanced a claim for infringement of the Inflammatory Pain Claims *by Dr Reddy's* prior to the Birss Order. This does not necessarily mean that the judge reached the wrong conclusion, however.
118. Thirdly, Warner-Lambert argues that the judge was wrong to conclude that Warner-Lambert could have advanced its present claim prior to the Birss Order. Warner-Lambert points out that the present claim is concerned with what pharmacists would have done had the orders in question not been made, i.e. in the counterfactual world, whereas its claims prior to the Birss Order were concerned with what Dr Reddy's had actually done. As counsel for Warner-Lambert put it, Warner-Lambert now seeks to rely upon infringement of the Inflammatory Pain Claims as a shield not a sword. This only became possible once Dr Reddy's brought its claim for compensation.
119. I do not accept this argument. Counsel for Warner-Lambert was unable to identify any relevant difference between the counterfactual world and the actual facts that happened prior to the Birss Order. Furthermore, he accepted that it was implicit in Warner-Lambert's case that there had been infringement of the Inflammatory Pain Claims by pharmacists in the actual world. It follows that, if Warner-Lambert is right that, assuming that pharmacists would have dispensed more of the Dr Reddy's pregabalin product had the orders not been made, the pharmacists would have infringed the Inflammatory Pain Claims, Warner-Lambert could have advanced exactly the same claim in respect of the actual dispensing of the Dr Reddy's pregabalin product prior to the Birss Order. It could have advanced the claim in two ways: first, as part of its original claim against Dr Reddy's, since it could have alleged that Dr Reddy's was jointly liable for such infringements (using the claim as a sword); and secondly, and in any event, by way of defence to Dr Reddy's claim for groundless threats (using the claim as a shield). So far as the first way of advancing the claim is concerned, it was implicit in Warner-Lambert's pleaded case against Dr Reddy's that pharmacists were infringing claims 1 and 3. Warner-Lambert could

easily have alleged infringement of the Inflammatory Pain Claims by pharmacists as well, and it could have alleged that Dr Reddy's was jointly liable for such infringements because Dr Reddy's shared a common design with the pharmacists that its pregabalin product should be dispensed against generic prescriptions. Equally, it would have been a simple matter for Warner-Lambert to plead infringement of the Inflammatory Pain Claims by pharmacists as justifying the threats it had made to pharmacists.

120. Fourthly, Warner-Lambert argues that, even if it *could* have advanced the present claim prior to the Birss Order, it does not follow that it *should* have done so. Warner-Lambert particularly relies upon two points in support of this argument. The first is that its claims against Dr Reddy's prior to the Birss Order alleged infringement by Dr Reddy's, whereas its present claim alleges infringement by pharmacists. The second point is that the present claim is advanced by way of defence to the claim by Dr Reddy's under the cross-undertakings and not by way of original claim or even by way of defence to the claim by Dr Reddy's for groundless threats.
121. In my judgment neither of these points assists Warner-Lambert. The present claim is still being advanced against Dr Reddy's (albeit by way of an affirmative defence to the claim by Dr Reddy's for compensation). Thus this is not a case about sequential claims against different parties. Furthermore, the present claim is inconsistent with Warner-Lambert's acceptance at the time of the Birss Order that it was liable for groundless threats. If the present claim were a good one, then it would have afforded Warner-Lambert a partial defence to the threats claim. Moreover, Warner-Lambert is bound by the judge's decision that it would be inconsistent with the Birss Order for it now to allege actual infringement by pharmacists of the Inflammatory Pain Claims and his reasoning holds good for infringement in the counterfactual world which is relevant to the claim under the cross-undertakings. The claim is also inconsistent with Warner-Lambert's acceptance that its claim for infringement against Dr Reddy's should be dismissed and the liability phase of the action brought to an end. The Birss Order provided that the infringement claim was dismissed "on the basis that" the other claims were invalid, thus highlighting the fact that there had been no finding that the Inflammatory Pain Claims were invalid. Accordingly, if the present claim were a good one, Warner-Lambert should have raised it then to support a claim for infringement against Dr Reddy's as a joint tortfeasor with the pharmacists. Contrary to the submission of counsel for Warner-Lambert, this would not have required Warner-Lambert to join any pharmacist as a defendant to the claim, let alone all such pharmacists.
122. Fifthly, Warner-Lambert argues that, even if it would be an abuse of process for Warner-Lambert to sue pharmacists for infringement of the Inflammatory Pain Claims in the counterfactual, Dr Reddy's is not entitled to rely upon this because Dr Reddy's has not been twice-vexed and is neither party nor privy to the abuse against the pharmacists.
123. This argument is misconceived for two reasons. First, there is no question of Warner-Lambert suing pharmacists for infringement in the counterfactual. As Warner-Lambert itself points out, the counterfactual concerns what would have happened if the orders had not been made. Dr Reddy's does not suggest that Warner-Lambert could, let alone should, sue pharmacists for acts they did not commit. Secondly, for the reasons explained above, Dr Reddy's is twice vexed. Dr Reddy's had to defend

itself against Warner-Lambert's infringement claim, and to overcome Warner-Lambert's defence to its own claim for groundless threats. The Birss Order finally established that Dr Reddy's had not infringed the Patent and that Dr Reddy's was entitled to damages for groundless threats. The claim that Warner-Lambert seeks to introduce by this amendment re-opens both those matters.

124. Lastly, Warner-Lambert relies upon a principle which is stated in *Spencer Bower: Reliance-Based Estoppel* (5th edition) at paragraph 7.1 as follows:

“If A [the estoppel raiser] establishes all the requisite elements of an estoppel, an affirmative answer may remain open to B [the party estopped] that the estoppel would deprive B of rights protected by public policy, would prevent B performing a public duty, would give to B a power which the law denies him, or would give the jurisdiction it lacks. The court will refuse an estoppel on these grounds, as they are matters of public policy even if unpleaded. This defence, that the estoppel would unacceptably subvert the public policy of a rule of law, has been called the defence of ‘illegality’, although it might more clearly be named the defence of ‘subversion’ to distinguish it from the defence of illegality to any claim based on a criminal or ‘quasi-criminal’ act ...”.

125. In my judgment this principle does not assist Warner-Lambert either. We are not concerned here with reliance-based estoppel, but with abuse of process. Abuse of process is juridically distinct even from cause of action estoppel and issue estoppel, let alone reliance-based estoppel: see *Virgin Atlantic Airways Ltd v Zodiac Seats UK Ltd* [2013] UKSC 46, [2014] AC 160 at [17]-[25] (Lord Sumption). Furthermore, Warner-Lambert is not relying upon rights protected by public policy. Warner-Lambert wishes to set up a defence to the claim by Dr Reddy's for compensation pursuant to Warner-Lambert's cross-undertakings. The right that Warner-Lambert invokes is a private right which give rises to an ordinary civil action in tort. Although the patent system exists because it is judged to be in the public interest, the right to assert infringement is conferred purely for the benefit of the proprietor (and/or exclusive licensee) of the patent, not to benefit the public, and it is a right which can be waived by the proprietor (and/or exclusive licensee). Moreover, as discussed above, the defence that Warner-Lambert seeks to advance involves a claim about what would have happened in the counterfactual world. Above all, the fact that, on Warner-Lambert's case, there would have been infringement by pharmacists, and hence arguable illegality, cannot trump Warner-Lambert's abuse of process in advancing the case now when it could and should have advanced the case prior to the Birss Order.

#### *Case management*

126. The judge also refused to permit the amendment on case management grounds. His reasoning, in essence, was that it would require a substantial trial on infringement and validity of the Inflammatory Pain Claims with a strong likelihood of appeals to the Court of Appeal and potentially the Supreme Court. This would be a burdensome and costly exercise, and it would risk derailing the inquiry trial fixed for November 2023. Moreover, the inquiry was concerned with damages arising out of events between late

2014 and July 2017 and had been underway since March 2020. Thus it was too late for Warner-Lambert to raise the case when it did.

127. Warner-Lambert accepts that this was a discretionary case management decision by a judge who was well placed to take it by virtue of his familiarity with the issues, but submits that he was plainly wrong to say that the amendment was raised too late given that it was first proposed in correspondence on 15 November 2021, nearly three years before the quantum trial which was then listed for October 2024. Warner-Lambert accepts that it is now no longer feasible for the infringement and validity issues to be tried in advance of the main inquiry trial which is listed for November 2023, but submits that they could be tried afterwards. Furthermore, Warner-Lambert says that this would not be unduly prejudicial to Dr Reddy's because Dr Reddy's could be awarded whatever sum is found due at the main inquiry trial subject to a retention of 13.8% (or whatever the correct percentage is found to be) to abide the outcome of the infringement and validity issues.
128. Dr Reddy's argues, among other things, that Warner-Lambert's solution to the procedural difficulty Warner-Lambert finds itself in is unworkable because it assumes that it is possible to differentiate between losses of Dr Reddy's due to the orders containing the cross-undertakings and losses due to groundless threats, since Warner-Lambert only contends that the haircut should be applied to the former and not the latter. Dr Reddy's disputes that this is possible, however. In this regard it may be noted that a number of the threats relied upon were made before the NHS Order. It may also be noted that both the threats and the NHS Guidance were aimed at influencing prescribing doctors and dispensing pharmacists.
129. Given my conclusion on abuse of process, it is not necessary to reach a conclusion on this issue and I shall abstain from expressing any view.

### Conclusion

130. For the reasons given above I conclude that the judge was correct to refuse Warner-Lambert permission to make both amendments. I would therefore dismiss the appeal.

### **Lord Justice Nugee:**

131. I agree.

### **Lord Justice Males:**

132. I agree that this appeal must be dismissed for the reasons given by Lord Justice Arnold. In view of the interesting arguments advanced, I will state my essential reasoning briefly in my own words.
133. This appeal carries a considerable amount of procedural baggage, as Lord Justice Arnold has demonstrated. Once the background is understood, however, there are as it seems to me two short points for determination.

### **The first proposed amendment – real prospect of success**

134. The first proposed amendment relates to both remaining inquiry claimants, Dr Reddy's and NHS Scotland. Warner-Lambert seeks to plead as follows (I quote from

the Defence to NHS Scotland's claim, but the Defence to the claim by Dr Reddy's is materially the same):

“Warner-Lambert contends that, to the extent any damage is said to have arisen from sale and supply of 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.

### **PARTICULARS**

It would be unjust and inequitable for [the inquiry claimant] 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.”

135. As Warner-Lambert made clear, this amendment does not depend on showing that the supply and sale of pregabalin for the treatment of inflammatory pain would infringe any of the claims of this much-litigated Patent. Rather, it depends upon the notion that the monopoly granted to a patentee is not the same thing as, and is somehow wider than, the right to bring infringement proceedings. In essence, Warner-Lambert contends that it would be unfair for the inquiry claimants' damages to include lost sales of pregabalin, even though that would not have involved any infringement of the Patent, because it was Warner-Lambert which had disclosed to the public in the first place the idea of using pregabalin to treat inflammatory pain.
136. In support of this supposedly wider monopoly Warner-Lambert seizes on what Lord Justice Arnold said at first instance in *Warner-Lambert Co LLC v Sandoz GmbH* [2016] EWHC 3317 (Pat) (*Sandoz II*):

“80. This does not mean that claims 2, 5, 7, 8 and 9 [the Inflammatory Pain Claims] are irrelevant for the purpose of the present application. On the contrary those claims have been found to be valid and there is no extant challenge to that finding. It follows that, in principle, Warner-Lambert is entitled to the benefit of the monopoly conferred by those claims even if it is not in a position to allege infringement of those claims (as distinct from claims 10, 11 and 12.”
137. The issue is whether this amendment has any real prospect of success. In my judgment it plainly does not.
138. The right granted to a patentee is statutory. The monopoly granted is defined by the claims (see section 14 of the Patents Act 1977 and, in the European context, articles 83 and 84 of the European Patent Convention). The right granted is to restrain (in accordance with ordinary equitable principles), and/or to obtain financial compensation for, infringement of the claims. Nothing more, nothing less. The

patentee takes the risk that, as a result of disclosure of his invention, competitors may find a way of using the process or making the product which does not infringe the patent. If they are able to do so, that is the result of ordinary competition, which is in the public interest. If, by obtaining an interim injunction, a patentee prevents competitors from engaging in non-infringing activity and thereby causes them loss, there is nothing unjust or inequitable in requiring the patentee to compensate them for such loss.

139. Even taking what was said in *Sandoz II* at [80] in isolation, I can see nothing to support Warner-Lambert's suggestion that the monopoly granted to a patentee is not the same thing as, and is wider than, the right to bring infringement proceedings. But when the passage is viewed in context, including that a claim for infringement of the Inflammatory Pain Claims had been pleaded but not yet particularised, and that the state of the law on infringement was uncertain while the issue was on its journey to the Supreme Court, the position is even clearer.
140. In my view this proposed amendment does not raise a novel issue of law (which in any event we have now decided). Rather, it is contrary to basic and well-established principles of patent law.

### **The second proposed amendment – abuse of process**

141. The second proposed amendment affects only Dr Reddy's. Warner-Lambert seeks to plead that:

“Warner-Lambert contends that, to the extent that the pregabalin products sold and supplied by Dr Reddy's would have been used for or attributable to the treatment of any condition covered by the Inflammatory Pain Claims, any profits said to have arisen from such sale and supply should be excluded from the final calculation of loss of profit.

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The dispensing of pregabalin products supplied in the UK by Dr Reddy's for or attributable to the treatment of any condition covered by the Inflammatory Pain Claims would have infringed the Inflammatory Pain Claims. Therefore, Warner-Lambert contends that Dr Reddy's may not recover any such loss of profits founded substantially upon an unlawful and/or illegal act, being in this case the infringement of a European Patent (UK). By this, Warner-Lambert does not presently bring any claim before the Court that Dr Reddy's has infringe the Patent. Without prejudice to its ability to do so, this contention is advanced in relation to the counterfactual.”

142. This amendment, in contrast with the previous amendment, does depend on proof that the supply and sale of pregabalin to treat inflammatory pain would infringe the Patent. The plea of infringement is wholly unparticularised, which would itself be a sufficient reason to refuse permission to amend. A major new issue, requiring in effect a separate trial in which issues of validity and infringement would be hotly contested,

ought not to be introduced at this stage of the litigation without a full understanding of what it involves. Explanation in a skeleton argument, or in the course of oral submissions, is not a satisfactory substitute for a properly particularised pleading.

143. Warner-Lambert did explain in its skeleton argument that the plea is not of infringement by Dr Reddy's, but by pharmacists dispensing pregabalin, and is not a plea that pharmacists actually infringed in the real world, but that they would have done so if they had dispensed pregabalin for the treatment of inflammatory pain in the counterfactual world (i.e. if they had not been restrained by injunction or prevented by the NHS Guidance from doing so). In response to questions from the court seeking to understand the case further, Mr Tim Austen explained that Warner-Lambert's case is not that such supply would have infringed section 60(1)(c) of the Patents Act, but that it would have infringed section 60(1)(b) and section 60(2). He submitted that a case under section 60(1)(b) had not been advanced in the action which went to the Supreme Court (*Warner-Lambert Co LLC v Generics (UK) Ltd* [2018] UKSC 56, [2019] 3 All ER 95), that in any event what was said about infringement in the Supreme Court was *obiter* even on issues on which all the judges agreed, and that a case of infringement by pharmacists would give rise to different factual issues. Mr Austen recognised some of the many difficulties of this way of putting the case, but expressed the candid hope that if the case were again to reach the Supreme Court, it would be heard by a different constitution which might be more sympathetic to Warner-Lambert's submissions.
144. In my judgment the case which Warner-Lambert seeks to advance is not open to it. It founders on the rock of the order dated 16<sup>th</sup> March 2020 made by Mr Justice Birss, which terminated the liability phase of these proceedings. That order, among other things, declared that Warner-Lambert had made unjustifiable threats of proceedings for patent infringement, and ordered that there should be an inquiry as to damages suffered by Dr Reddy's (a) pursuant to the cross undertakings and (b) by reason of Warner-Lambert's unjustifiable threats of patent infringement proceedings. Those threats were principally made against pharmacists throughout the country. It follows that Mr Justice Birss's order finally determined that the threats were unjustified. But if (as Warner-Lambert now seeks to allege) the supply of pregabalin by pharmacists for the treatment of inflammatory pain constituted an infringement of the Patent, the threats would not have been unjustified: in order to avoid infringing, pharmacists would have been required to ensure that any supply of pregabalin was not for the treatment of inflammatory pain, which in practice they would have found very difficult to do. Accordingly the amendment would subvert the order made by Mr Justice Birss, which was not appealed and in any event was effectively made by consent. It is therefore too late for Warner-Lambert to advance a case of infringement by pharmacists. If it wished to do so, it could and should (at least) have pleaded such a case as a defence to the unlawful threats claim.
145. More generally, it is clear that the order made by Mr Justice Birss was intended to bring the liability phase of the proceedings to an end, and equally clear that Warner-Lambert could have pleaded a positive case in the liability phase that the supply of pregabalin by pharmacists for the treatment of inflammatory pain infringed the Patent. In my judgment, it not only could but should have done so if it wished to advance such a case. That case would have raised precisely the same legal and factual issues as the proposed amendment.

146. It is necessary to apply a “broad, merits-based judgment which takes account of the public and private interests involved and also takes account of all the facts of the case, focusing attention on the crucial question whether, in all the circumstances, a party is misusing or abusing the process of the court by seeking to raise before it the issue which could have been raised before” (see Lord Bingham in *Johnson v Gore-Wood & Co* [2002] 2 AC 1 at 30). That is what the judge did. In my judgment he was right to conclude that the proposed amendment is an abuse of process. That is enough to dismiss the appeal so far as this amendment is concerned.
147. For these purposes I have been prepared to assume that the proposed amendment, if properly particularised, may be well-founded as a matter of law, although I have grave reservations about that, for the reasons explained by Lord Justice Arnold. However, I would not decide the appeal on that ground. Dr Reddy’s did not argue in the court below that the proposed amendment did not have a real prospect of success. Nor did it invite this court to uphold the judge’s decision on that ground in its Respondent’s Notice. Instead, on the afternoon of the second day of the hearing, Mr Brian Nicholson KC handed up a proposed amendment to Dr Reddy’s Respondent’s Notice stating that the judge “could of his own motion also have relied upon the allegation that pharmacists would – in the counterfactual – have infringed the patent, as having no realistic prospect of success”. He acknowledged that the point had to be put this way because Dr Reddy’s had not advanced any submission about this to the judge. It seems to me, however, that if the parties agree, or are prepared to proceed on the basis that, a proposed amendment has a real prospect of success on the merits, a judge is not to be criticised, and cannot be said to have been wrong, for taking that position at face value.