Neutral Citation Number: [2015] EWCA Civ 556

Case No: A3 2015 0221
A3 2015 0669

IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT
The Hon Mr Justice Arnold
[2015] EWHC 72 (Pat)
[2015] EWHC 223 (Pat),

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 28/05/2015

Before :

LADY JUSTICE ARDEN DBE
LORD JUSTICE RYDER
and
LORD JUSTICE FLOYD

- -

Between :

WARNER-LAMBERT COMPANY, LLC	**Appellant**
- and -	
(1) ACTAVIS GROUP PTC EHF **(2) ACTAVIS UK LIMITED** **(3) CADUCEUS PHARMA LIMITED**	**Respondents**
- and -	
THE SECRETARY OF STATE FOR HEALTH	**Proposed Intervener**

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- -

Justin Turner QC and **Tim Austen** (instructed by **Allen & Overy LLP**) for the **Appellant**
Adrian Speck QC (instructed by **Powell Gilbert LLP**) for the **Respondents**
Richard Davis (instructed by the **Government Legal Department**) for the **Secretary of State for Health**

Hearing dates: 28, 29 April 2015

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Approved Judgment

Lord Justice Floyd:

1. This appeal raises an issue of construction of a patent claim in "Swiss" form, that is to say a claim for the use of a compound in the production of a medicine for use in a particular therapeutic indication. In particular, the appeal is concerned with what is meant by the requirement in such claims that the medicament be "for" a therapeutic indication. The issue is an important one, as it concerns the scope of protection to be afforded to what is recognised to be an important class of inventions in the pharmaceutical field, namely those which are concerned with the discovery of new uses for known medicines.

2. The appeal is from two judgments of Arnold J in the Patents Court. The first ([2015] EWHC 72 (Pat)) is dated 21 January 2015, and I shall refer to it as "the first judgment". The second judgment under appeal ([2015] EWHC 249 (Pat)) is dated 6 February 2015. For reasons which I will explain, I will call this "the third judgment". By the first judgment Arnold J dismissed an application by the claimant and appellant, Warner-Lambert Company LLC ("Warner-Lambert"), for mandatory interim injunctive relief against the defendants (together "Actavis") based on its European Patent (UK) No 0 934 061 ("the patent"). The judge did so on the twin grounds that Warner-Lambert had shown no serious question to be tried on direct or indirect infringement of the patent, and that the interim relief sought was not justified on the balance of justice. I initially refused permission to appeal from the first judgment on the ground that, whilst there was clearly room for argument as to the construction of the claim and the test for infringement in such cases, there was no realistic prospect of this court interfering with the judge's evaluation of the balance of justice. As Warner-Lambert needed to succeed on both issues, an appeal would have had no real prospect of overturning the judge's refusal of interim relief. I was subsequently persuaded at an oral hearing that the judge might have relied, in evaluating the balance of justice, on matters for which there was no evidence, and I accordingly granted permission in relation to both issues.

3. Subsequent to the first judgment, Actavis applied to strike out the infringement claims, no doubt encouraged by the judge's finding that Warner-Lambert had not established a serious issue to be tried. By the time of the hearing of that application on 3 February 2015 Warner-Lambert had applied to amend its particulars of infringement. In a reserved judgment ([2015] EWHC 223 (Pat)) delivered in the morning of 6 February 2015 "the second judgment") the judge explained that he considered that Warner-Lambert had still failed to plead a case of direct infringement, but nevertheless allowed that case to proceed to trial in view of the fact that an appellate court might in due course take a different view in an area of the law which was still developing, and that it was sensible in such circumstances to decide the facts first. There is no appeal from the second judgment. Warner-Lambert does not agree with the judge's reasoning in the second judgment, but given that the matter will now proceed to trial there is no order (as opposed to finding) against which it could appeal. In the third judgment, delivered later on the same day, the judge decided to strike out the claim of *indirect* infringement, and thus refused to allow it to proceed to trial. We have before us an application for permission to appeal the judge's decision on indirect infringement in the third judgment, with the appeal to follow if permission is granted. We heard full argument on indirect infringement. I would grant permission to appeal.

4. The current position is therefore that, subject to this appeal, the action is proceeding to a trial, on direct infringement only, on a date which has now been fixed for the end of June this year, notwithstanding the findings by Arnold J that the claim of direct infringement as before him at the time of the first judgment did not raise a serious issue to be tried and that the amended claim as before him at the time of his second judgment still had no real prospect of success.

5. Before us the case for Warner-Lambert was argued by Mr Justin Turner QC with Mr Tim Austen, and that for Actavis by Mr Adrian Speck QC.

The factual background

6. The patent claims the use of the drug pregabalin for the preparation of a pharmaceutical composition for treating pain (claim 1) or for treating neuropathic pain (claim 3). The remaining details of the patent do not matter for the purposes of the appeal. Patent protection for the drug molecule itself expired in 2013. I will refer to treatment for pain as "the patented indication", without predetermining any question about the scope of the claim.

7. Warner-Lambert, the patentee, is an indirect subsidiary of Pfizer Inc and part of a group of companies which includes Pfizer Ltd ("Pfizer").

8. Pregabalin is marketed by Warner-Lambert under the trade mark Lyrica with the benefit of marketing authorisations (held by Pfizer) not only for neuropathic pain but also for generalised anxiety disorder ("GAD") and epilepsy. I will refer to these two latter indications as "the non-patented indications", because no patent protection applies to the use of pregabalin in the manufacture of a medicine to treat these conditions. Lyrica had global sales in 2013 of US$ 4.6 billion. UK sales in the same year were about US$ 310 million. It is therefore an enormously successful pharmaceutical. Data made available by IMS Health showed that in the first nine months of 2014 54% of sales were for treating pain, 12% for psychiatric conditions (of which 18% was GAD), 2% for epilepsy and 32% for unspecified other diseases. Warner-Lambert says that the figure for pain is substantially higher, as some of the 32% categorised as "other diseases" is in fact for pain. Whether or not that is so is immaterial for present purposes. The market for the non-patented indications is, on any view, a real and substantial one, even if smaller than the market for the patented one.

9. Actavis' product is marketed under the trade mark Lecaent. Actavis have now obtained a marketing authorisation for Lecaent on the basis that Lecaent and Lyrica are bio-equivalent. So there can be no doubt that Lecaent is in fact suitable for treating neuropathic pain. However, the summary of product characteristics ("SmPC") and patient information leaflet ("PIL") for Lecaent only identify the medicine as suitable for epilepsy and GAD, i.e. the non-patented indications. It is important to understand that neither the SmPC nor the PIL contains any warning or injunction against using the medicine for other indications or indeed for the patented indication. The same is true of the packaging of the product. A marketing authorisation which is restricted in this way is described in the industry as a "skinny label" to reflect the narrowness of the indications compared with another authorisation with a wider range of indications. Another expression which is used is that the patented indication has been "carved out".

10. Actavis' product is made in Bulgaria by its Bulgarian group company and imported into this country for distribution here by the second and third defendants.

11. When a doctor prescribes a drug for a patient, he or she may do so by brand name or by reference only to its international non-proprietary name or "INN". Prescribing by INN is referred to as prescribing "generically", because it does not identify any particular manufacturer's product, only the drug itself. Prescribers are strongly encouraged to prescribe generically by means of guidance from NHS England and others and financial pressure from Clinical Commissioning Groups and Health Boards. Prescription software also hard- wires generic prescribing into doctors' practices, by forcing doctors to go through a decision tree which results in the prescription of the most economical drug which will be therapeutically effective.

12. Where a drug is prescribed by brand in the UK the pharmacist is obliged to dispense the branded product. Conversely where the INN is used, i.e. the drug is prescribed generically, the pharmacist is free to dispense either the branded drug or the generic one. There is a considerable incentive for the pharmacist to dispense the generic drug: the pharmacist will still be reimbursed (at least in the current circumstances relating to pregabalin) at the price for NHS reimbursement of the branded drug under the Drug Tariff. On the assumption that the generic drug is cheaper, the pharmacist will make more profit if he dispenses it.

13. Prescriptions do not normally specify the condition for which the drug is being prescribed. Accordingly, when the prescription is presented to the pharmacist the pharmacist does not know, without enquiry, what condition the patient is suffering from. Thus even if a pharmacist knows of the existence of Warner-Lambert's patent rights, and consequently that pregabalin must not be dispensed for pain, there is no indication on the prescription itself which will tell him whether the particular patient in question is suffering from pain, in which case he can dispense only Lyrica, or from one of the non-patented indications or for some "off-label" condition, in which case he would be free to dispense either branded or generic product. Enquiries of the patient may not always be practicable for reasons of confidentiality, or because the person collecting the medicine is not the patient, or because the patient may not know, or be mistaken. The pharmacist could, in theory, contact the doctor to discover what the prescription was for; but the doctor may or may not be available, and the consequent delay would be inconvenient.

14. Finally, the fact that Lecaent's SmPC and PIL contain no indication for pain is not, on its own, a hindrance to the pharmacist dispensing it for pain even if the pharmacist knows that the patient has been prescribed pregabalin for pain. The pharmacist knows that the generic product is identical, because it is bio-equivalent, to the branded product for all purposes. Although the pharmacist may not know what indication an individual prescription is for, he will know, if he thinks about it, that at least some of the prescriptions which are filled with the generic product will be in substitution for a Lyrica prescription for pain.

15. The judge found that in these circumstances it was foreseeable that a generic version of Lyrica with a skinny label will be dispensed for patients who have in fact been prescribed the drug for pain.

16. Warner-Lambert contends that, against this background, Actavis were, at the date of the issue of the claim form, threatening to infringe the patent by marketing Lecaent. Actavis and another generic manufacturer, Mylan, have applied to revoke the patent and that claim and the present infringement claim are both listed to be tried at the end of June 2015.

17. Since the judge gave his first judgment two other generic pregabalin products have reached the market, one marketed by Dr Reddy's and another by Consilient. Consilient has put in place a scheme ("the Rewisca scheme") under which its generic product "Rewisca" is encouraged to be prescribed by that brand for the non-patented indications only. When a prescription of this kind arrives at the pharmacy, the pharmacy must then send a copy of the prescription to the wholesaler, and the wholesaler responds by sending Rewisca to the pharmacy. Rewisca will thus not be stocked on pharmacy shelves. Subject to final checking, Warner-Lambert do not assert that Consilient would infringe if it uses the Rewisca scheme. Actavis contend that such a scheme is unrealistic, and that Consilient are unlikely to make significant sales under it.

Events prior to the hearing before Arnold J

18. The chronology of events leading to the hearing before Arnold J on 13-15 January 2015 on the application for an interim injunction was set out by him at paragraphs [39] to [50] of his judgment. In summary it was as follows.

19. On 12 September 2014 Actavis commenced its revocation proceedings against the patent.

20. On 23 September 2014 Warner-Lambert's solicitors first asked Actavis' solicitors about Actavis' intentions with regard to obtaining a marketing authorisation for, and launching, a pregabalin product. On 25 September 2014 Actavis' solicitors replied that Actavis had filed an application for a marketing authorisation, but gave no further details. On 29 September 2014 Warner-Lambert's solicitors asked for a copy of Actavis' marketing authorisation application and for answers to the questions they had previously asked about Actavis' proposed launch date and expected date of grant of a marketing authorisation.

21. On 30 September 2014 Actavis' solicitors disclosed that the application for a marketing authorisation had been filed on 9 July 2014, and said that the application was being expedited and that it could be granted as early as November 2014. They also stated:

> "Actavis is therefore preparing to launch a pregabalin product in the UK with a summary of product characteristics ('SmPC') limited to the treatment of epilepsy and general anxiety disorders (a so-called 'skinny label') in December 2014 or January 2015."

22. On 1 October 2014 Warner-Lambert's solicitors asked Actavis' solicitors to explain what measures Actavis had put in place to ensure that the generic product is not used for the treatment of pain, and for the finalised launch date to be provided as soon as it was decided upon.

23. On 3 October 2014 Actavis' solicitors provided a copy of the Actavis' product PIL, noting that it did not include any indication for the treatment of neuropathic pain. The letter also explained that on launch Actavis intended to notify superintendent pharmacists specifically that its product is not indicated for the treatment of neuropathic pain. They went on to indicate that Actavis considered that this would not infringe the Patent, but recognised that Warner-Lambert might disagree.

24. On 10 October, 4 November, 19 November and 24 November 2014 Warner-Lambert's solicitors requested copies of Actavis' marketing authorisation application, SmPC and proposed notice to superintendent pharmacists.

25. In the letter dated 24 November 2014 Warner-Lambert's solicitors also stated:

> "We are of the opinion that, if your client intends to launch a generic product, it is required to take appropriate steps to ensure that it is not dispensed for the treatment of pain, including by ensuring that all pharmacists are aware that its generic product is not authorised for and should not be dispensed for the treatment of pain. As a starting point, this would seem to require an appropriate notice being placed on the outside of the packet of your client's product to ensure that this matter is brought to the attention of the pharmacist handling the product."

26. On 25 November 2014 Actavis' solicitors sent Warner-Lambert's solicitors copies of Actavis' proposed SmPC and notice to superintendent pharmacists. On 26 November 2014 Warner-Lambert's solicitors informed Actavis' solicitors that Warner-Lambert did not consider the proposed notice to be sufficient.

27. On 2 December 2014 Actavis' solicitors replied to Warner-Lambert's solicitors' letters dated 24 and 26 November 2014, stating:

> "Further, the late raising by your client of the packaging point appears to us and our client to be a tactical attempt to delay the imminent launch by our client of the pregabalin product targeted to the non-patent market. Our client is already packaging its product and the additional notice is in any event unnecessary, inappropriate, and, in our client's experience, unprecedented."

28. In a letter dated 5 December 2014 which was not received by Actavis' solicitors until 8 December 2014, Warner-Lambert's solicitors reiterated the request that the packaging of Actavis' product include a statement that the product should not be dispensed for pain. They also requested that Actavis make this an express condition of supply to any pharmacy and that Actavis inform "the prescribing authorities at the Department of Health" that their product should not be prescribed for the treatment of pain. This was the first time that Warner-Lambert had made these requests.

29. On 8 December 2014 Warner-Lambert launched the present application for interim relief.

30. On 15 December 2014 the chair of the Pharmaceutical Advisors Group emailed all Clinical Commissioning Groups in England expressing his view that prescriptions for neuropathic pain should be written by brand. On 22 December the National Institute for Health and Care Excellence ("NICE") confirmed that it had taken steps to amend its clinical guidance on pregabalin.

31. Following the hearing before Arnold J I should record the following events, set out in a chronology prepared for us by Mr Turner during the hearing.

32. Thus on 22 January 2015 the National Pharmacy Association issued guidance to superintendent pharmacists concerning the dispensing of pregabalin, saying that pharmacists should make enquiries of patients and contact the prescriber if necessary. On 2 February the Pharmaceutical Services Negotiating Committee issued guidance saying that if the medicine is being provided for the patented indication the pharmacy should dispense Lyrica and might wish to contact the prescriber.

33. On 10 February 2015 NHS England said that it would not issue guidance "at least on a timescale that is likely to be material to the litigation under way".

34. Also in February Dr Reddy launched its pregabalin product Alzain.

35. Lecaent was launched on 17 February, following the grant of its marketing authorisation the previous day.

36. On 19 February Community Pharmacy Scotland issued guidance on the dispensing of pregabalin stating that if the product is being provided for the patented indication the pharmacist should dispense Lyrica.

37. On 27 February, following Arnold J's order, NHS England issued guidance concerning the prescribing of pregabalin for pain.

38. On 9 March 2015 Consilient launched its generic product (Rewisca).

The relief sought

39. Not surprisingly, given that Warner-Lambert cannot object to supplies of Lecaent going to patients who need it for non-pain indications, the interim injunction which Warner-Lambert sought was not in the conventional form. It consisted in part of requirements for Actavis to enter into contractual arrangements with pharmacies and intermediaries and in part of notification requirements. The judge set it out in the final form which was before him:

> "1. The Defendants: (a) shall make it a condition of any oral or written agreement entered into with a pharmacy for the supply of Lecaent that the pharmacy shall use reasonable endeavours not to supply or dispense Lecaent to patients who have been prescribed pregabalin for the treatment of pain, by making reasonable enquiries of a person presenting a prescription for 'pregabalin' as to whether the prescription is for pain and/or making reasonable checks of pharmacy records for the same; and (b) shall make it a condition of any oral or written agreement entered into with an intermediary (such as a

distributor) for the supply of Lecaent that, in any onward supply of Lecaent by the intermediary, such intermediary must in turn make it a condition of any onward supply agreement for the supply of Lecaent that the receiving pharmacy shall use reasonable endeavours as specified in (a) above.

2. Insofar as the Defendants are to supply Lecaent to intermediaries (such as a distributor) they inform the Claimant's solicitors of the name of that intermediary prior to supply.

3. No later than the date of first supply of Lecaent to a pharmacy in the United Kingdom, the Defendants shall write a letter, in the form attached, to the superintendent pharmacist responsible for the pharmacy to which Lecaent is to be supplied.

4. Prior to launch of Lecaent in the United Kingdom the First, Second and Third Defendants and each of them shall ensure that each pack of Lecaent supplied to a pharmacist is accompanied by removable notification that is easily legible stating:

> 'This product is not authorised for the treatment of pain and must not be dispensed for such purposes.'

5. The Defendants shall notify in writing forthwith, and in any event before the date of first supply of Lecaent to a pharmacy in the United Kingdom, the NICE Medicines and Prescribing Centre of the Department of Health informing it that Lecaent should not be prescribed or dispensed for the treatment of pain.

6. No later than the date of first supply of Lecaent to a pharmacy in the United Kingdom, the Defendants shall write a letter, in the form attached, to all Clinical Commissioning Groups in the UK."

40. No issues arise before us on the provisions of paragraphs 3, 5 and 6 above. The remaining relief (that in paragraphs 1, 2 and 4 has now been modified to some extent as shown below:

1. The Defendants: (a) shall make it a condition of any oral or written agreement entered into with a pharmacy for the supply of Lecaent that the pharmacy shall use reasonable endeavours *as appear to be reasonable to the pharmacy in the circumstances* not to supply or dispense Lecaent to patients who have been prescribed pregabalin for the treatment of pain, ~~by making reasonable enquiries of a person presenting a prescription for 'pregabalin' as to whether the prescription is for pain and/or making reasonable checks of pharmacy records for the same~~; and (b) shall make it a condition of any oral or written agreement entered into with an intermediary (such as a

distributor) for the supply of Lecaent that, in any onward supply of Lecaent by the intermediary, such intermediary must in turn make it a condition of any onward supply agreement for the supply of Lecaent that the receiving pharmacy shall use reasonable endeavours as specified in (a) above.

2. Insofar as the Defendants are to supply Lecaent to intermediaries (such as a distributor) they inform the Claimant's solicitors of the name of that intermediary prior to supply.

4. ~~Prior to launch of Lecaent in the United Kingdom t~~ The ~~First, Second and Third~~ Defendants and each of them shall, from the date of this order, ensure that ~~each pack of~~ any Lecaent supplied to ~~a~~ pharmacists in the United Kingdom shall be in bulk packaging wherein each consignment of [*insert number*] bears a notice on its bulk packaging ~~is accompanied by removable notification~~ that is easily legible stating:

'This product ~~is not authorised for the treatment of pain and must~~ should not be dispensed for ~~such purposes~~ pain.'

41. The modified relief sought by paragraph 1 is to some extent a recognition of the fact that the contractual restrictions which Warner-Lambert wish Actavis to impose might deter some pharmacists from stocking Lecaent for the lawful purpose of dispensing it other than for pain. The modifications to paragraph 4 reflect the fact that there may be regulatory and other concerns about placing such a notice on the pack itself, particularly when it may come to the attention of a patient, and where it might be open to misinterpretation.

NHS guidance

42. It was common ground before the judge that the best solution to the problem of how to prevent Lecaent being dispensed for pain was to try to ensure that, when doctors prescribe pregabalin for pain, they always do so only by reference to the brand name Lyrica. If this were to happen, only Lyrica could and would be dispensed for pain. The pharmacist would not need to try and find out what the prescription was for. The judge considered that, as had been submitted to him, the best way to attempt to ensure that this was achieved was by guidance given by NHS England. Counsel for the Secretary of State for Health had emphasised to the judge that NHS England was an autonomous body. The Secretary of State did not consider that a failure by NHS England to issue guidance with regard to the relevance of the patent to the prescribing of pregabalin would constitute a failure by NHS England of sufficient significance to allow him to intervene. He noted, however, that NHS England might consider it appropriate to issue such guidance. If NHS England were to do so, the Department would not consider that inappropriate.

43. In the light of that response, and the further letter from the NHS England indicating that guidance would be unlikely to be issued before trial, Warner-Lambert applied to the judge for an order that NHS England should issue such guidance. Neither Actavis, nor any of the interested parties (which included other generic manufacturers interested in pregabalin and the Department of Health) opposed the making of that

order. Having satisfied himself that he had jurisdiction to make the order, the judge duly made it on 26 February 2015 for reasons given in his judgment of 2 March 2015, ([2015] EWHC 485 (Pat), "the fourth judgment"). The NHS guidance was promptly issued after the making of the order.

The statutory provisions and the allegation of infringement

44. Section 60 of the Patents Act 1977 ("the Act") sets out the acts which amount to an infringement of a patent:

> "(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—
>
> (a)where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;
>
> (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.
>
> (3) Subsection (2) above shall not apply to the supply or offer of a staple commercial product unless the supply or the offer is made for the purpose of inducing the person supplied or, as the case may be, the person to whom the offer is made to do an act which constitutes an infringement of the patent by virtue of subsection (1) above."

45. Section 60(1) distinguishes between the two known categories of patent claims, products and processes, and defines the acts which amount to infringement for each. It is now accepted by Mr Turner on behalf of Warner- Lambert that the Swiss form claim in issue here is a process claim. He relies on section 60(1)(c). In short he says that Lecaent is the direct product of a process. The process in question is the manufacture of Lecaent for the treatment of neuropathic pain. When Actavis dispose of the product they infringe because they "dispose of ... [a] product obtained directly by means of that process".

46. Section 60(2) is concerned with indirect or contributory infringement. It is usually invoked when there is no choate claim of infringement against the defendant itself, but where it can be contended that something ("a means") which is supplied to a third party has contributed to infringement (or more accurately "putting the invention into effect") by that third party. It follows that it is inherent in this type of infringement that there is at least the potential for the invention to be put into effect. It is worth noting at this stage that the section has the potential to render infringing the sale of an article, which could have been freely dealt in before the patent was granted, provided only that the sale is carried out with the requisite knowledge about the invention.

47. Indirect infringement has been extensively considered by this court in two fairly recent cases, namely *Grimme Maschinenfabrik GmbH & Co KG v Scott* [2010] EWCA Civ 1110, [2011] FSR 7 and *KCI Licensing Inc v Smith & Nephew plc* [2010] EWCA Civ 1260, [2011] FSR 8. In *KCI* at [53] Jacob LJ summarised the law in this way, giving cross-references to his judgment in Grimme:

> "i) The required intention is to put the invention into effect. The question is what the supplier knows or ought to know about the intention of the person who is in a position to put the invention into effect – the person at the end of the supply chain, [108].
>
> ii) It is enough if the supplier knows (or it is obvious to a reasonable person in the circumstances) that some ultimate users will intend to use or adapt the 'means' so as to infringe, [107(i)] and [114].
>
> iii) There is no requirement that the intention of the individual ultimate user must be known to the defendant at the moment of the alleged infringement, [124].
>
> iv) Whilst it is the intention of the ultimate user which matters, a future intention of a future ultimate user is enough if that is what one would expect in all the circumstances, [125].
>
> v) The knowledge and intention requirements are satisfied if, at the time of supply or offer to supply, the supplier knows, or it obvious to a reasonable person in the circumstances, that ultimate users will intend to put the invention into effect. This has to be proved on the usual standard of the balance of probabilities. It is not enough merely that the means are suitable for putting the invention into effect (for that is a separate requirement), but it is likely to be the case where the

> supplier proposes or recommends or even indicates the possibility of such use in his promotional material, [131]."

48. Warner-Lambert's case of infringement under section 60(2) asserts that the supply or offer to supply of Lecaent is of a means relating to an essential element of the invention, that those means are suitable for putting the invention into effect, and that Actavis had the relevant knowledge both of suitability and of the intention of ultimate users to put the invention into effect. For this purpose Warner-Lambert asserts at paragraph 5(b) of their original particulars of infringement that:

> "the invention is either pregabalin for treating pain and/or neuropathic pain or the use of pregabalin for treating pain and or neuropathic pain."

49. Section 125(1) of the Act, however, provides:

> "For the purposes of this Act an invention for a patent ... for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the ... patent, ... as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly."

50. Quite what is meant by "unless the context otherwise requires" has never been fully explored. In *Pharmacia v Merck* [2001] EWCA Civ 1610; [2002] RPC 41 at [55], a case mentioned to us by Mr Turner in reply but not cited, Aldous LJ held that "the invention", should, when considering the provisions in the Act concerned with sufficiency of disclosure, be taken to include the technical contribution made by the patentee, even though the invention was claimed as a class of compounds without more. The statutory provisions relating to sufficiency were therefore an example of a case where "the context otherwise requires". On the other hand in *Menashe Business Mercantile v William Hill Organisation Ltd* [2002] EWCA Civ 1702; [2003] RPC 31 at [24] this court held that the invention referred to in section 60(2) is that claimed in the patent.

Swiss claims and EPO authority

51. Whilst it is widely recognised that there are valuable, sometimes life-saving, inventions which are made through the discovery of the new use of a known drug, their protection in patent law is problematic. In the first place, as the drug molecule itself is not novel, there is no question of awarding the inventor of the new use absolute protection for the substance itself. Related to that problem, it is often the case that there is no physical change to the pharmaceutical itself required to give effect to the new use as compared with the old. If there were, there would be potential to claim those physical aspects to distinguish the pharmaceutical "for" the new use from the pharmaceutical "for" the old use: for example a different sized pill, or different formulation. The second problem is that, for reasons connected with protecting medical practitioners from claims for patent infringement, a patent cannot be granted for a method of treatment of humans with a therapy using the compound in

question. It follows that retreat by amendment from a product claim to a conventional method claim is not a possible answer.

52. In an attempt to circumvent these twin problems the Enlarged Board of Appeal of the European Patent Office endorsed a practice which originated in the Swiss Patent Office of granting claims for "the use of substance X for the preparation of a medicament (or pharmaceutical composition) for treating indication Y": see *Eisai (Second medical indication)* [1985] OJ EPO 64. It was thought that in this way a claim is granted which is both novel, and which does not fall foul of the prohibition on claims to methods of treatment. The claims in the present case are examples of Swiss claims.

53. Since *Eisai* the EPC has been amended by the EPC 2000 to allow for claims in a different form, namely the use of compound X for treatment of disease Y. The EPO has ceased to grant claims in the Swiss form since that decision, but claims that had already been granted in that form continue to have effect: see G 2/08 *Abbott Respiratory*. In that case the Enlarged Board put an end to the practice of granting Swiss claims, recognising that they were, to some extent, a fudge. Thus they said at 7.1.3:

> "Moreover, Swiss-type claims could be (and have been) considered objectionable as regards the question as to whether they fulfil the patentability requirements due to the absence of any functional relationship of the features (belonging to therapy) conferring novelty and inventiveness, if any, of the claimed manufacturing process. Therefore, where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so called Swiss-type claim as instituted by [*Eisai*]".

54. There are other criticisms which could be made of Swiss form claims. If the purpose of the new form of claim was to maintain the policy of preventing doctors being sued for infringement, it is difficult to see how that is achieved. As the claim is a process claim (see below), its direct product, the medicine, is an infringement, and all those who use or dispose of the product will infringe. The EPC 2000 seems even more apt to catch anyone who uses the product. As Lord Nicholls of Birkenhead said in *Sempra Metals v IRC* [2007] UKHL 34; [2008] 1 AC 561 at [51]:

> "Legal rules which are not soundly based resemble proverbial bad pennies: they turn up again and again."

55. So it is here. As I shall have to explain, thirty years after the decision in *Eisai* courts of member states are still working out how to deal with the fall-out from that case. It would have been better if doctors had been provided with a defence, or the restriction on methods of treatment repealed altogether.

56. In Case T 1780/12 *University of Texas Board of Regents/Cancer treatment* [2014] EPOR 28 at [16]-[24], a case concerned with double patenting, the Technical Board of Appeal of the EPO explained that claims in Swiss form have a different scope from EPC 2000 claims. The former are purpose limited process claims, the latter are purpose limited product claims. EPC 2000 claims do not include, as a technical

feature, the manufacture of a medicament. Because a claim to a process using a product (a physical activity) inherently involves less protection than a claim to a product (a physical entity), the scope of purpose limited process claim was inherently less than that of a purpose limited product claim.

57. The Board however noted an argument that EPC 2000 protection was intended to be equivalent to Swiss claims, on the basis of a preparatory document. At [23] the Board said:

> " 23. As regards the last argument of the examining division, namely that the EPC legislator considered the two claim formats equivalent (see section VII above), the board notes that it was the intention of the legislator to provide a claim format which afforded an equivalent protection, as far as the further medical uses are concerned, to that offered by the Swiss-type claim, see decision G 02/08 of the Enlarged Board (OJ EPO 2010, 456, point 5.10.4 of the reasons) where it refers to preparatory document MR/18/00, point 4 as indicating the intention of the legislator when introducing Article 54(5) EPC as follows: "The new Article 54(5) EPC eliminates any legal uncertainty on the patentability of further medical uses. It unambiguously permits purpose—related product protection for each further new medical use of a substance or composition already known as a medicine. This protection is equivalent, as far as the further uses are concerned, to that offered by the 'Swiss type claim'. In contrast to previous Article 54(5), now Article 54(4) EPC, providing broad (generic) protection for use in a medical method for the inventor of such use for the first time, new Article 54(5) is expressly limited to a specific use. **This limitation is intended to match as closely as possible the scope of protection to the scope provided by a 'Swiss type claim'.**" (Emphasis added).

58. The Board was not persuaded by this argument that it was wrong to ascribe a different, narrower scope to Swiss claims, at least in the context of the objection of double patenting.

59. In an analogous development, in G 02/88 *Mobil (Friction reducing additive)* [1999] EPOR 73, the Enlarged Board of Appeal applied a similar novelty principle in the non-medical field. An engine oil additive which had previously been used for preventing rust was discovered to have friction reducing properties, even though the old use of the additive for preventing rust would inherently have realised the new friction effect. Mobil claimed the use of the known compound for the new purpose. The Board recognised at [7.2.1] that a claim which has no technical feature which reflects the new use, and has wording referring to such new use "which is merely mental in nature and does not define a technical feature" is not novel. However the Board explained that the proper construction of such claims is normally that the compound, when used, in fact achieves the technical effect. On that basis the known use does not, it is argued, deprive the claimed use of novelty.

60. At paragraphs 10.1 and 10.2 the Board addressed the question of what happens to the user of the prior art additive for the old purpose (with its inherent effect) who continues after the patent is granted. Does he risk infringement by continuing? The Board, being only concerned with the novelty of the claim, considered that any question of his right to continue was a matter for national law. The Board went on to point out that the same problem would arise in connection with Swiss form claims in the medical field.

English authorities

61. In *Wyeth's and Scherings' Applications* [1985] RPC 545 (Whitford and Falconer JJ sitting *en banc*) had to confront Swiss type claims in this jurisdiction for the first time. They considered that "the better view" of the construction of the UK statute was that such claims were not novel: see page 565 lines 12-22, but that having regard to the views of the Enlarged Board in *Eisai* on the construction of the corresponding provisions of the EPC, they decided it was right to construe the English statute in conformity. At page 567 line 21 to 25 they explained that the required novelty in a Swiss claim was to be found in the novel therapeutic use.

62. In *Merrell Dow v Norton* [1996] RPC 76, the House of Lords considered some of the fall-out from *Mobil*. The House declined to reject the reasoning in *Mobil* in so far as it affected novelty on the basis of an effect inherent in a prior use. At pages 92-93 Lord Hoffmann referred to the difficulties in applying the conventional approach of English patent law to infringement of such claims, namely that liability is strict and does not depend on any mental element. Such questions were not, however, in issue on the appeal. As far as novelty was concerned Lord Hoffmann said, explaining *Mobil*, that the prior description of the additive:

> "would not enable anyone to use it for the *purpose* of reducing friction, even though this would be the inevitable consequence of doing so".

63. In *Bristol Myers Squibb v Baker Norton Pharmaceuticals* [2001] RPC 1, this court was concerned with validity of a Swiss type claim. At [40] Aldous LJ observed that a Swiss claim could not be interpreted as "a product when used because that would constitute a method of treatment which is prohibited under the EPC."

64. In *Actavis UK Ltd v Merck & Co Inc* [2008] EWCA Civ 444, [2009] 1 WLR 1186 this court was concerned with whether the reasoning in *Eisai* extended to new dosage regimes. Jacob LJ, giving the judgment of the court, explained the background to Swiss claims, in particular at [7] that "such a claim steers clear of two obstacles to patentability, namely the requirement of novelty and the ban on methods of treatment of the human body by therapy." The court also noted, at [30], that the policy reasons for allowing *Mobil* and *Eisai* claims were "closely akin".

65. There was some focus in the arguments before us, on paragraphs [9] and [10] of *Actavis v Merck*:

> "So the manufacture of an old substance for use in a new treatment was considered by the Enlarged Board to be novel. The justification for novelty was the new therapeutic use. And

> since the claim was to the manufacture of the compound, it was not a claim to a method of treatment.
>
> In *BMS* Jacob J wondered how such a claim might work so far as infringement is concerned and thought it might create difficulty. And so it might in some cases (e.g. where the product is just sold as a standard product, like aspirin tablets). But in many cases the difficulty may be more theoretical than real. This is because manufacturers, particularly for prescription medicines and probably many others, have to provide detailed instructions and information about the use(s) and dosage(s) of their products. So in practice you can tell whether someone has used X for the manufacture of a medicament for the treatment of Y. He will have to say that his product is for the treatment of Y on his product information leaflet."

66. This passage is not addressing, let alone laying down any construction of the word "for". Instead it is concerned with how evidential difficulties of discovering the purpose element of the claim might in some cases be addressed. Moreover it is not in practice the case that a manufacturer "will have to say that his product is for the treatment of Y on his product information leaflet" in order to benefit from the patentee's market for the novel use. By the means of a "skinny label" he can say nothing at all about the novel indication, and leave it to the market to ensure that it is in fact dispensed for pain. The court was not addressing the problem which confronts the court on this appeal, where the PIL is silent as to an indication for which there is a large market, in circumstances where doctors and pharmacists are encouraged and incentivised towards generic prescribing, dispensing and cross-dispensing.

67. At [75] in *Actavis v Merck* the court rejected the argument that, because the only novelty was a new dosage regime, the claim was to a method of treatment. The court said:

> "In its essence the claim here is to the use of finasteride for the preparation of a medicament of the specified dosages. It is not aimed at and it does not touch the doctor – it is directed at the manufacturer."

68. Finally in *Hospira UK Ltd v Genentech Inc* [2014] EWHC 1094 (Pat) at [58] Birss J recorded that it was common ground between the parties in that case that the word "for" in such claims meant "suitable and intended for". It was not, however, necessary for him to explore any further what the second part of that phrase meant.

Cases on "intention" in other areas

69. We were referred to two authorities in other areas of the law where there is a requirement for a mental element in a tort or other civil wrong. The first was the tort of inducing a breach of contract. In *OBG v Allan* [2007] UKHL 21, [2008] 1 AC 1 Lord Hoffmann distinguished for these purposes between "ends, means and consequences". He continued at [42] to [43]:

> "If someone knowingly causes a breach of contract, it does not normally matter that it is the means by which he intends to achieve some further end or even that he would rather have been able to achieve that end without causing a breach. Mr Gye would very likely have preferred to be able to obtain Miss Wagner's services without her having to break her contract. But that did not matter. Again, people seldom knowingly cause loss by unlawful means out of simple disinterested malice. It is usually to achieve the further end of securing an economic advantage to themselves. ...
>
> On the other hand, if the breach of contract is neither an end in itself nor a means to an end, but merely a foreseeable consequence, then in my opinion it cannot for this purpose be said to have been intended. That, I think, is what judges and writers mean when they say that the claimant must have been "targeted" or "aimed at". In my opinion the majority of the Court of Appeal was wrong to have allowed the action in *Millar v Bassey* [1994] EMLR 44 to proceed. Miss Bassey had broken her contract to perform for the recording company and it was a foreseeable consequence that the recording company would have to break its contracts with the accompanying musicians, but those breaches of contract were neither an end desired by Miss Bassey nor a means of achieving that end."

70. It is true that Lord Hoffmann distinguishes between knowledge, foresight and intention, and holds that, in the context of this tort, the conduct of the defendant must be targeted or aimed at the claimant. But it is of course only to be expected that in a tort of inducing a third party to act in a particular way that the objective of getting the third party to act in that way should be a specific objective, targeted or aimed at by the defendant. It does not follow that a similar requirement should be imported into the construction of the claim in the present case.

71. The other case to which we were referred was *Three Rivers District Council v Governor and Company of the Bank of England* [2000] UKHL 33; [2003] 2 AC 1. That case was concerned with the tort of misfeasance in public office. The policy considerations which underlie their Lordships choice of the mental element for that tort are of course quite different from those which underlie the exercise in construction on which I am engaged. Mr Turner relied on it for the apparent approval of Oliver LJ's statement in *Bourgoin SA v Ministry of Agriculture, Fisheries and Food* [1986] QB 716.

> "If an act is done deliberately and with knowledge of its consequences, I do not think that the actor can sensibly say that he did not 'intend' the consequences of that act or that the act was not aimed at the person who, it is known, will suffer them."

Decisions in other member states

72. We were also taken to a number of decisions of courts in other EPC member states as well as one Australian decision.

73. *Australia.* The Australian decision was *Warner-Lambert Company LLC v Apotex Pty Limited* [2014] FCAFC 59, a decision of their Federal Court. The claim in issue was Warner-Lambert's claim for the use of pregabalin for the treatment of pain, and therefore, although dealing with the same novel therapeutic use, differs from the Swiss claim we are concerned with here. Not only that, but the Australian Patents Act had specific provisions determining the state of knowledge - "reason to believe" - of the defendant where he supplies a product to a person who intends to use it for infringement. Finally the facts in that case were apparently such that the market for the non-patented indications was virtually non-existent. Although Mr Austen properly drew this case to our attention, he did not suggest it materially assisted Warner-Lambert's case in this jurisdiction.

74. *Germany.* In Case X ZR 236/01 *Carvedilol II* (decision of 14 March 2013) the claim was to the use of the drug carvedilol for the manufacture of a medicament for the treatment of heart conditions subject to a particular dosage regime. The Federal Court of Justice considered the relevant claim lacked inventive step, but observed at paragraph 51 that there was no objection in principle to a claim in such a form, which:

> "is meant to protect the use of a chemical substance in the therapeutic treatment of the human body that is prepared for this use, such as by a specific packaging of the tablet size, an inscription on the package, or an accompanying package insert."

75. *Carvedilol* is the first indication in the cases cited to us of an approach which suggests that, for there to be infringement of the Swiss form claim, there must be some physical manifestation of the new use in the medicine itself or its immediate surroundings. In case 4A O 145/12 *Chronic Hepatitis C Treatment* (decision of 19 December 2006) the Landgericht Dusseldorf dealt with a Swiss claim for the use of a compound for treating hepatitis C in a particular patient group defined by a number of parameters. The court first cited an earlier decision of the Federal Court of Justice, at [52] to [53]:

> "Inherent in the "purpose-limited product protection" is a final element, namely a particular purpose actualisation. This forms a key constituent of the protected invention, which is only realised through the actualisation of the inherent purpose. If this purpose is neither aimed for nor attained in a purposive way, but instead a purpose other than that identified in the patent claim is actualised, then there is no utilisation of the patent (...)
>
> ... For answering the question whether the purpose pursued is that identified in the patent or a different purpose, a practically reasonable yardstick must be applied that leaves no room for sophistry. The fact that a product is suitable - inter alia - for the

> purpose stated in the patent in suit does not mean that it also actualises that purpose. Instead, for utilisation of the teaching protected in the "purpose-limited claim", it is also necessary that the purpose inherent in the patent in suit is achieved (actualised) to a practically considerable extent in the sense of the specific objective of the patented teaching."

76. Thus, as the court said at [54], there was only a possibility of utilisation if the specific end use of the invention specified in the patent claim is "aimed for or attained in a purposive way".

77. At [56], however, the court introduces the concept of "manifest making-up" (German - "*sinfällige Herrichtung*"). A manifest making-up may lie in the particular configuration of the substance or article, or in the addition of a package leaflet. The addition of a package leaflet may be treated as a notional part of "manufacture". The article has to be "set up as such for the patented use":

> "This means that there must be a direct and purposive connection between the measure of manifest making up on the one hand and the production and sale of the product on the other hand, this connection holding the user unambiguously to the patent-protected use."

78. At [68] and [69] the court appears to reject a submission that the acts of third parties in substituting the defendant's drug for the claimant's for the patented indication were to be attributed to the defendant.

79. Next we were referred to the decision of the Oberlandesgericht Dusseldorf in Case I-2 U 54/11 dated 31 January 2013 ("*Cistus*"). The claim was for the use of a natural compound (cistus) for making a composition with anti-viral activity. The patentee relied on direct infringement only. At [123] to [125] the court refers to "the obvious arrangement" which is again a translation of "*sinfällige Herrichtung*". This might lie in the formulation and packaging of the medication "aimed at the special usage purpose".

80. The patentee in that case relied on general advertising statements put out in support of the product by those who made it. As these did not form part of the "*sinfällige Herrichtung*", they were disregarded. The court did not accordingly have to decide whether they were to be attributed to the patentee.

81. It would therefore appear from these cases that what the German courts look for in these circumstances is some outward manifestation in the manufacture itself (which may include the packaging, but not advertising) which can be specifically attributed to the new use. But it may be that the desire to avoid "sophistry" and an investigation into the facts involving the drawing of inferences as to what the manufacturer's knowledge or intention may have been, has resulted in the introduction of a rule which may be narrower than is legally necessary. If a manufacturer is actively inducing, for example by advertising, the use of his product for the patented indication, it is difficult to see, on any basis, why the manufacture is not "for" the patented indication. To be fair to Mr Speck, he did not invite us to go as far down this road as the German courts had done. He nevertheless adopts the notion expressed in

the *Chronic Hepatitis* case that the end use of the invention must be aimed for or attained in a purposive way.

82. Whilst the hearing of this appeal was in progress we were informed by Mr Turner that the Landgericht Hamburg had recently announced its decision to grant preliminary injunctions against five generic manufacturers under the German designation of the patent in suit. We were subsequently provided with translations of these judgments. It is sufficient to consider only Case 327 O 140/15 *Warner-Lambert Company LLC v Aliud Pharma GmbH.*

83. Aliud had been granted a marketing authorisation for pregabalin for the non-patented indications: i.e. a skinny label along the same lines as Actavis' in the case before us. Aliud entered into a discount agreement to supply pregabalin with a health insurance provider which was not expressly limited to the non-patented indications. Aliud made no attempt to point out that its offer did not extend to the treatment of neuropathic pain. Guidance issued to doctors by the local insurers' and physician's association encouraged prescribing of the generic product for all indications including pain.

84. Warner-Lambert claimed indirect infringement of the patent. The court described the claim in the following way:

> "With its accession to the above mentioned discount agreement, the Respondent indirectly infringes (contributory infringement) claims 1 and 3 of the patent at issue (§ 10 of the German Patent Law), since the discount agreement was aimed at the prescription and supply of Pregabalin-type drugs for the treatment of neuropathic pain and, therefore, must be understood to include the pain indications that are covered by the patent at issue."

85. Aliud argued that the acts of the doctors and pharmacists in prescribing and dispensing generic pregabalin for pain should not be ascribed to Aliud, and also that there was no "manifest preparation", which I suspect is yet another translation of "*sinfällige Herrichtung*".

86. The court upheld Warner-Lambert's indirect infringement argument, at least for the purposes of granting a preliminary injunction. In explaining the corresponding provision of the German patent law the court said at page 16 of the translation, citing the *Air Heater* decision referred to in *Grimme* at [122] and [130], that it allowed enforcement of the patent:

> "in advance of an imminent direct patent infringement. According to the case law of the Bundesgerichthof the elements of strict liability can arise even when no direct patent infringement follows."

87. I do not read this passage as suggesting that the possibility of patent infringement, or at least of putting the invention into effect, is not a necessary ingredient. The court elsewhere appears to recognise the need to establish a downstream infringement or the intention to commit one, but appears to assume that the pharmacist commits one (see

e.g. paragraph bridging pages 25-6). Also on page 16 the court recognised that the means must be such that:

> "..the indirect use of the invention – with all its inherent characteristics – is possible by the buyer".

88. The court considered that pregabalin was a means relating to an essential element of the invention (page 18 of the translation) and that the only additional thing required for a direct infringement was "the use for the indication of pain". The court noted that there was no mention in the user information of the pain indication, but considered that by Aliud's unconditional participation in the unlimited tenders for the discount contract the effect was the same. German prescribing practice required the pharmacist to dispense the generic medicine where the doctor has prescribed generically or where the doctor has not expressly ruled out the replacement of the drug with one with the same active ingredient. The pharmacist could do so where the generic drug shared *one* identical area of application and which possesses the same or an interchangeable dosage form. The pharmacist does not receive any information about the indication for which a drug is prescribed.

89. At pages 21 onwards the court considered the suggestion that there was "manifest preparation", in connection with the allegation of indirect infringement in this case. The court, at paragraph 3(cc)(1) of the judgment, asserts that the use of an ingredient for the production of a substance already equates to the use of the substance for this purpose. This is to treat Swiss claims and EPC 2000 claims as equivalent. The court then says:

> "At present the medicinal product is in any case to be regarded as manifestly prepared for use within the meaning of the production use patent in this case because it can be used as it stands for the treatment of neuropathic pain. No further physical steps or addition of physical means are needed, all that is needed is a definition of its purpose. This definition of purpose or use is currently made by the substituting pharmacist ... It is within the nature of contributory patent infringement that acts done in the sphere of the buyer are attributed to the offering party, even if it has no control over such acts, because that is precisely what strict liability under § 10(1) Patent Act means. Legally, the Respondent must therefore for this reason accept that the actions of the pharmacist may be attributed to it precisely because the pharmacist's act of substitution, as already explained, can reliably be foreseen, and is legally provided for."

90. The court referred to and distinguished *Cistus*, both because indirect infringement was expressly disclaimed in *Cistus* and because there was a distinction between the "steering effect" of promotional statements as compared to legal standards binding on pharmacists. *Carvedilol II* was also held not to assist the Respondents. The court also expressed disagreement with some aspects of the decision of the Landgericht Düsseldorf in *Chronic Hepatitis*.

91. The court recognised that only a limited injunction was justified, given that the means in question were capable of legitimate use. It was for judicial assessment what precautionary measures the provider of a means which can be used both off-patent and in infringement of a patent must take to exclude unauthorised uses of the patent.

92. Both parties made written submissions following the hearing about the Landgericht Hamburg's case. Warner-Lambert submitted, not surprisingly, that it suggested that their case of indirect infringement was at least arguable. Actavis submitted that it was another case, like the Dutch case of *Sun v Novartis* discussed below, where the circumstances might justify a finding of subjective intent.

93. *The Netherlands.* In *Schering v Teva* Case HA ZA 10-437, a decision of the District Court of the Hague dated 10 November 2010, the claim was for the use of ribavirin in the manufacture of a pharmaceutical composition for treating hepatitis C in which the composition was in combination with another substance for administration to a particular patient group. The patent appears to be related to the one the subject of the German *Chronic Hepatitis C* decision discussed above. Teva had obtained marketing authorisations covering generic ribavirin. Teva took steps to vary the marketing authorisation so as to avoid any suggestion that the product was indicated for the relevant class of patients, and to ensure that the indications were aimed at the excluded classes. Teva did not apparently market any product under the marketing authorisations. The court concluded that there was no infringement or threat of infringement ([4.2]). The court concluded that the relevant (patented) group of patients was "*specifically excluded*" by the marketing authorisations and that this was sufficient to fall outside the protection conferred by the patent. The court rejected an argument that there was some positive suggestion in the SmPC to use the generic ribavarin in combination with interferon. The court then added:

> "This might be different in the hypothetical case - which does *not* occur in the case at hand – that *proof* would be furnished of the fact that due to the examination described in [the particular passage of the SmPC said to encourage the specified use] and the conclusion drawn from this Teva's generic ribavarin – whether or not prompted to do so – is most certainly also prescribed for [the relevant patient group]."

94. It is perhaps significant that the court considered that prescribing for a non-approved indication would be a breach of the Medicines Act. Accordingly one reading of the above passage is that, if doctors were in fact lawfully prescribing for the patented indication on the strength of the statements in the SmPC, then it could properly be said that the generic medicine was for the patented indication.

95. *Novartis v Sun* is a decision of the Court of Appeal of the Hague dated 27 January 2015 which considered only indirect infringement of a Swiss form claim. The claim in that case was for the use of zoledronic acid for the preparation of a medicament for the treatment of osteoporosis in a particular dosage form and for a particular dosage regimen. An alternative use for zoledronic acid which was not patented was Paget's disease, but the market for Paget's disease was less than 3%, the remaining 97% of the patentee's sales being for osteoporosis. Sun originally applied for a marketing authorisation for both indications, but subsequently carved out the osteoporosis indication when Novartis objected. The carve out was not indicted on the published

version of the SmPC on the official website however. With the benefit of its marketing authorisation for Paget's disease alone, Sun won a tender for the supply of zoledronic acid to a medical insurer. This meant that Sun's zoledronic acid would be the only form of the drug dispensed to a patient insured with that insurer except in the case of medical necessity. Pharmacists were thus obliged to dispense Sun's product even in a case where the doctor prescribed the patentee's brand. After Sun had won the tender it sent the insurer an email indicating as "a formality" that zoledronic acid was only licensed for Paget's disease and that osteoporosis was covered by Novartis' patent.

96. In the Dutch form of provisional or streamlined proceedings known as "*kort geding*", the appeal court held that Sun's activities amounted to contributory infringement. There was no allegation of direct infringement. It was common ground that zoledronic acid was a means relating to an essential element of the invention. Sun had the requisite knowledge of the infringing use of its product for the purposes of indirect infringement. As the Court put it:

> "Sun therefore had to know that its product would be supplied for the patented indication at the end of the vertical trading chain. The sale of 142 units of the Generic Product over the months January and February 2014 alone entails that Sun must realise that its product will also be supplied and used for the patented application with [*sic*] a certainty bordering on probability. ...
>
> Sun has argued that it cannot be reproached for these matters, as these are the consequences of the preference policy applied by [the insurer] and of the tender issued by [the insurer] which did not permit conditional subscription (only for use with the indication of Paget's disease). The court of appeal is *a priori* of the opinion that this does not exonerate Sun. Under the given circumstances, in which it was clear to Sun in advance that [the insurer's] procedures would unavoidably lead to the Generic Product also being used for osteoporosis and thus for the indication protected under the patent, it was up to Sun to do everything possible to prevent the Generic Product from being supplied for the treatment of osteoporosis, which could infringe the Novartis patent. Sun failed in this respect."

97. The Hague Court of Appeal does not appear to have been asked to consider whether, in the context of indirect infringement of a Swiss claim, it is necessary for there to be a person downstream of the supplier who uses the drug in the manufacture of a medicament.

98. The above survey of these cases from other EPC member states demonstrates to my satisfaction that the law relating to both direct and indirect infringement of Swiss claims is far from settled. A universal formulation of a principle which can be applied to determine whether a medicament is for a therapeutic purpose has not yet emerged. Furthermore there has been no analysis of precisely how indirect infringement occurs when there is no downstream act of manufacture.

The judgments of Arnold J

99. In a commendably succinct judgment on what is a very difficult question Arnold J started by recording that it was common ground that the word "for" in claims such as those in the patent were to be understood as "suitable *and intended* for". It was further common ground that pregabalin was suitable for treating neuropathic pain. The questions were twofold: whose intention was relevant, and what was comprised in the requirement of intention. Warner-Lambert said it was sufficient if Actavis intended to sell pregabalin and knew that pharmacists were likely to dispense it for treating neuropathic pain if positive steps were not taken to prevent this. Actavis contended that such knowledge was not sufficient and that what was required was a subjective intention on their part that Lecaent should be used for treating pain. The judge accepted Actavis' argument that subjective intention on the part of the manufacturer was required. As Warner-Lambert did not allege subjective intention on the part of the manufacturer, there was no serious question of direct infringement to be tried under section 60(1)(c).

100. So far as indirect infringement was concerned, the judge dismissed this allegation on the basis that there could only be infringement on this basis if there could be a person further down the supply chain who could do an infringing act. Pharmacists do not use Lecaent to manufacture a pharmaceutical composition: it has already been manufactured before they receive it.

101. The judge then turned to the balance of justice, following the well known approach explained by Lord Diplock in *American Cyanamid v Ethicon* [1975] AC 396, in case he was wrong about whether there was a serious question to be tried. Having considered the various factors urged upon him, he considered that "wrongly" granting the additional relief was more likely to cause Actavis substantial unquantifiable harm than wrongly refusing it would cause Warner- Lambert. In the case of the requirement for Actavis to put a notice on its packaging, the balance was "firmly tipped against" making such an order, whilst in the case of the contractual terms the balance was more even, but still came down in favour of refusing the relief.

102. Although the judge's second judgment is not in issue on this appeal, it is worth noting that at paragraph [2] he recorded that Actavis accepted that it was both necessary and sufficient to show "subjective intention" that the manufacturer's acts are *aimed or targeted* at the consequence that the pharmaceutical composition will be used for treating the specified condition.

103. In his third judgment the judge explained why the section 60(2) indirect infringement case should be struck out and not proceed to trial. He gave three main reasons for doing so:

    i) The indirect infringement case was premised on interpreting a Swiss claim in the same way as an EPC 2000 claim. That was contrary to settled jurisprudence and hopeless.

    ii) Section 60(2), unlike section 60(1)(c) was not a developing area of law: the law was well settled. There was therefore no compelling reason for a trial.

iii) Warner-Lambert would have abandoned their section 60(2) case had it not been for the decision of the Dutch court in *Novartis v Sun*, but that case provided Warner-Lambert with no assistance. Moreover the section 60(2) case had not been pressed, other than as an appendage to the 60(1)(c) argument, in either of the two hearings to date.

The submissions on this appeal

104. Mr Turner submitted that the judge had wrongly construed the claim of the patent. He submitted, as he had before the judge, that the requirement that there be use of pregabalin in the manufacture of a medicine for treating pain was satisfied if it was foreseeable by Actavis or by a reasonable person in the shoes of Actavis that users would intend to use pregabalin for pain. The judge had been wrong to accept Actavis' submission that subjective intention, or "aiming" or "targeting" was required.

105. Mr Turner submitted that the judge failed to accord a purposive construction to the claim. Relying on Lord Hoffman's speech in *Kirin Amgen v Hoechst Marion Roussel* [2004] UKHL 46, he submitted that the skilled addressee of the patent would understand that the patentee was using the language of the claim to protect the invention of the new therapeutic use of pregabalin. He would therefore not be inclined to adopt meticulous verbal analysis of the words used, particularly when he knows that the patentee is obliged to claim in this manner to protect inventions of this type. The addressee would know that the inventive contribution lies in the new use, not in any step in the manufacture. He or she would not expect to be able to make use of that contribution in circumstances where it is known or reasonably foreseeable that pregabalin will be used for pain.

106. Mr Turner also points out that both the Dutch (*Novartis v Sun)* and now the German (*Warner-Lambert v Aliud*) courts have been able to find indirect infringement of Swiss claims, despite the fact that there is no downstream manufacture of a pharmaceutical composition. He submits therefore that the section 60(2) case should be allowed to proceed to trial here as well.

107. Mr Speck's principal argument was that the skilled person would realise that the purpose of Swiss form claims was to steer a course between the twin perils of lack of novelty (by covering known activities) and lack of patentability (by monopolising methods of treatment). The skilled addressee would appreciate this and would understand that the claim had to be construed in a way which required the defendant to conduct himself differently from someone practising the prior art. A requirement of "aiming" or "targeting" would achieve this objective, because a person using pregabalin for the known indications could not and would not aim or target the new use. This argument had been correctly accepted by the judge.

108. Moreover, the skilled person would recognise that a Swiss claim, being a process claim, was necessarily of smaller scope than a product claim such as an EPC 2000 claim. It would be wrong to construe such claims as if they were product claims and to give the patentee equivalent protection. Although the skilled person would appreciate that the Swiss claim did not give full protection to the patentee's contribution to the art, he or she would appreciate that the protection had been crafted in that restricted way in order to give the patentee some protection, when the alternative was no protection at all.

109. Mr Speck also maintains his argument that there cannot be indirect infringement unless there is at least the possibility of some act of infringement downstream. He supports the judge's conclusion that no such downstream infringement can arise on the Swiss claim in the present case, where no act of manufacture is carried out by the pharmacist.

Discussion and assessment on arguable case

110. Both parties are agreed that the issues of law which arise on both types of infringement are ones which are capable of being decided on the materials before us. The Secretary of State for Health ("the Secretary of State"), who was represented before us by Mr Richard Davis of counsel, indicated to us at the end of the hearing, and somewhat to everyone's surprise, that he would prefer us not to decide those issues, but to leave them over to trial where the Secretary of State intended to make a formal application to intervene.

111. I do not consider that the course advocated by the Secretary of State for Health is a sensible one for us to follow for a number of reasons. Given the parties' agreement that the issue is capable of resolution now, it is plainly desirable that we should decide it so the parties know where they stand. Secondly, with great respect to the Secretary of State, I am not persuaded that the court needs his assistance on what is essentially an issue of substantive patent law. Whilst it is true to say that Arnold J allowed the Secretary of State to appear at the hearing before him, that was because issues arose as to the guidance which might be given by NHS England to prescribing doctors. No such requirement for assistance from the Secretary of State has arisen on this appeal.

112. Following the hearing the Secretary of State did make some submissions on the substantive patent law issue before us. I will deal with the point he raises, nevertheless, later in this judgment.

Direct infringement

113. I start with the claim of direct infringement under section 60(1)(c) of the Act. The issue under this subsection is a question of construction of the claim. Like any such question, the task for the court is to determine what the skilled reader of the patent would understand the patentee to be using the language of the claim to mean. In this connection there is a certain amount of common ground in that both sides accept that the claim must involve some form of mental element. It is thus not sufficient to construe "for" in the conventional, objective sense of "suitable for". The reason is that the skilled person would understand that the claim so construed could not possibly distinguish over known uses of the known drug. Pregabalin as used for the known use would be "suitable" in this sense for the new use. To construe the claim as covering the manufacture of a drug merely because it was suitable for pain treatment would be to give it a scope which was far broader than the patentee's contribution to the art.

114. The next point to note is that both parties have retreated to a degree from the common ground before the judge that "for" means "suitable and intended for". Thus Mr Turner, in his written submissions, whilst continuing to accept that the claim requires an element of "intention-like *mens rea*", submits that it is wrong to start with the word "intention" and embark on an exercise of deciding what that means, and to go on to

hold that that form of intention must be attributed to the manufacturer. The word in the claim is "for", which denotes purpose. Mr Speck, for his part submits that it is not appropriate to fix on the word intention and then embark "on a wide ranging review of how the word 'intention' or 'intended' is used in different areas of the law" when the real issue is what the mental element in the claim is. I agree that a search for the appropriate meaning of "intention" which does not appear in the claim, is likely to throw one off the scent.

115. One important matter to have in mind is the distinction between the technical subject matter of the claim, on the one hand, and the rights which a patent gives rise to in national law to the owner of a patent based on that technical subject matter, on the other. This distinction was clearly made by the Enlarged Board in *Mobil* at paragraph 3.3:

> "As touched upon previously in paragraph 2.5 above, the protection conferred by a patent is to be determined by interpretation of the terms of the claims, and the rights of the patent proprietor flow from the protection which is conferred. There is a clear distinction between the protection which is conferred and the rights which are conferred by a European patent, however. The protection conferred by a patent is determined by the terms of the claims (Article 69(1) EPC), and in particular by the categories of such claims and their technical features. In this connection, Article 69 EPC and its Protocol are to be applied, both in proceedings before the EPO and in proceedings within Contracting States, whenever it is necessary to determine the protection which is conferred.
>
> In contrast, the rights conferred on the proprietor of a European patent (Article 64(1) EPC) are the legal rights which the law of a designated Contracting State may confer upon the proprietor, for example, as regards what acts of third parties constitute infringement of the patent, and as regards the remedies which are available in respect of any infringement."

116. In *Kirin Amgen* [2004] UKHL 46, for example at [34], Lord Hoffmann, used the expression "*the technical matter for which the patentee seeks protection in the claims*" to describe what it is that the skilled person is trying to ascertain. On the other hand, the primary rights which the patent gives in national law are those set out in section 60 of the Act.

117. The distinction in the present case between the technical subject matter for which the patentee seeks protection in the claims and the legal rights which flow from it is perhaps obscured because the word "use" appears both in the claim and in section 60(1)(c). However in the claim ("use ... in the manufacture"), the use is a step in a process, whereas in the statutory provision it is concerned with whether there is use by some person of the process as a whole.

118. Thus the first question is to determine the category of claim and its technical features: the technical subject matter of the claim. We know from the authorities cited above that the claim is a process claim. The skilled person would understand that the

technical features of the present claim extend beyond making pregabalin, yet fall short of including the step of actually using pregabalin for treating pain. Instead it includes a feature concerned with the ultimate purpose of the product manufactured, namely the intentional treatment of pain. I would describe the subject matter of the claim, therefore, as making pregabalin for patients to whom it will be intentionally administered for treating pain. Making pregabalin for patients to whom it is to be administered for the non-patented indications is not within the technical subject matter of the claim. Only the former category of manufacture makes use of the technical contribution of the patentee.

119. I think the skilled person would understand the technical subject matter of the claim in the way I have indicated because he or she would first understand that it was necessary for the claim to include a manufacturing step to ensure that the claim does not touch the doctor, and fall foul of the method of treatment exclusion. However the skilled person would understand that any manufacturing step is adequate for this purpose, as the doctor does not manufacture the medicament.

120. The skilled person would understand that the claim in question owes its novelty to the discovery of the new therapeutic use of the medicament. This emerges from a number of the cases, for example see the passages from *Eisai* quoted at [26] and [27] in *Actavis v Merck*. As Jacob LJ said at the end of [27]:

> "the novelty of the process (i.e. use of X in the manufacture of a medicament for Y" comes from the "new therapeutic use".

121. Thus the skilled person would understand that the technical subject matter of the claim was concerned with the ultimate end use of the medicament, from which it derived its novelty. The therapeutic treatment is of course new because, and only because, it is carried out with the intention of producing the new therapeutic effect. The prior use of the compound may have in fact produced the effect, for example if a patient taking it for GAD or epilepsy was at the time experiencing pain as well. This demonstrates, to my mind, that it is the intention for which the compound is administered which is at the heart of the invention.

122. Against that background the skilled person would understand the word "for" in the claim to be providing a link between the act of manufacture using pregabalin and the ultimate intentional use of the drug by the end user to treat pain. The critical issue for me to decide is what is sufficient to constitute that link. An extreme view might be that if the drug is in fact used for the patented indication then it has been made "for" that indication, whatever the manufacturer's intention might be. Mr Turner did not contend for that construction. I think he was right not to do so. It would mean that a manufacturer could not tell whether he had made use of the subject matter until after, and perhaps a long time after, he had disposed of the product. The realistic candidates are therefore (a) foreseeability that the drug will intentionally be used for the patented indication and (b) a subjective intention to that effect.

123. Mr Speck is right that the skilled person would understand the purpose of the Swiss form of claim to be that of avoiding the twin perils of lack of novelty and lack of patentable subject matter. However, as this court made clear in *Actavis v Merck*, the objection of lack of patentable subject matter is overcome by the fact that the claim is a manufacturing process claim. The skilled person would thus appreciate that there is

no reason to imply a narrow or strict mental element in order ensure that this peril is avoided.

124. If Mr Speck were correct that a subjective mental element on the part of the manufacturer were necessary in order to provide the claim with novelty, there would be powerful reasons for adopting it. However, I do not see how that can in fact be so. If a product is "for" a particular therapeutic indication if it is reasonably foreseeable that it will be used intentionally for the treatment of pain, then it will not be rendered lacking in novelty by showing that products in the prior art had been manufactured in circumstances when it was not possible to foresee such a result.

125. Mr Speck's point is a slightly different one, namely that no-one should be prevented by the grant of a patent from doing that which they did, or could have done, before. He called this the "golden thread" of English patent law. That principle is not, however, an entirely reliable one. It was relied on in *Merrell Dow (supra)* to suggest that the patent was invalid because it would have the effect of restraining the continuance of the prior use. The principle was ineffective there because the old use itself was "uninformative". At pages 86-87 Lord Hoffmann recognised that a gap had opened up under the 1977 Act between anticipation and infringement. The present case is another situation in which one cannot rely on the principle, because the subject matter of the invention is concerned with the purpose of acts which are in themselves no different from those which were done before. In any case it is not correct that the patent can prevent that which was done before. It was not possible before the patent was granted to foresee that the product would intentionally be used for treating pain.

126. The test which I have proposed has structural similarities to that under section 60(2), where the question is also what a person (in that case the seller) knows or could reasonably foresee about the end use of a product. That, of course, is not a reason for adopting it when construing the claim in this patent. It does, however, provide confirmation that the test I have proposed is a workable one. On the other hand, I can see real difficulties with the application of an "aiming or targeting" test in the present circumstances if it means more than the test I have proposed. It means in effect that the patentee must prove that it is Actavis' wish or desire that they sell some Lecaent for pain. How does the patentee go about establishing this wish or desire if it is not enough to show that it is known or foreseeable that some of their product is being intentionally used for pain? It seems to me that there is substance in Mr Turner's complaint that to adopt such a strict requirement of intention will rob Swiss claims of much of their enforceability.

127. I can therefore see no reason why the skilled person would conclude that the word "for" implied subjective intent. He would understand that the manufacturer who knows (and for this purpose constructive knowledge is enough) or could reasonably foresee that some of his drug will intentionally be used for pain is making use of the patentee's inventive contribution, in the same way as a manufacturer who actively desires that result. In my judgment, therefore, the skilled person would understand that the patentee was using the word "for" in the claim to require that the manufacturer knows (in the above sense) or can reasonably foresee the ultimate intentional use for pain, not that he have that specific intention or desire himself.

128. In reaching his conclusion that it was the manufacturer's intention that was determinative, the judge relied on what Jacob LJ said in *Actavis v Merck* at [75],

namely that claims in Swiss form were aimed at the manufacturer and did not touch the doctor. I think the judge may have read too much in to this passage. Jacob LJ was there considering whether the claim was a disguised claim to a method of treatment. The inclusion of a manufacturing step ensures that it is not. Jacob LJ was not addressing the nature of the mental element in the claim. It is, I think, important to bear in mind that there are two mental elements involved: the question is what the manufacturer knows or foresees about the intentional use of the drug by the end user which counts.

129. Turning to the second question, section 60(1)(b) makes it an infringement to use the process. Unlike "offering a process for use" and indirect infringement under section 60(2), liability under this part of section 60(1)(b) has no mental requirement: liability is strict. How does one tell whether a manufacturer is using the manufacturing process of the claim, and therefore rendering himself liable for patent infringement? The answer must be when he manufactures pregabalin when he knows or foresees that users will intentionally administer it for pain.

130. A number of hard cases were canvassed in argument. Firstly, suppose a manufacturer has been selling the medicine in question from before the priority date. Is it fair that he be made an infringer when his sales increase because of the uptake of the old product for the new use, and when he has done nothing to solicit this new business? I think the answer to any potential unfairness in such a case may lie in the relief to be granted. A general injunction prohibiting sale of the product itself is plainly not justifiable, and it may be unjust and inconvenient (to invert the words in section 37 of the Senior Courts Act) to grant an injunction at all. The same may follow even where the manufacturer was not a prior user, such as in this case, where to grant an unqualified injunction would unfairly prejudice his right to sell the drug for the non-patented indication.

131. Mr Speck points out that, even if an injunction is not granted, the manufacturer may have to pay damages based on the patentee's profit margin, which, if on a sufficient scale, would potentially make his sales of the non-patented indication uneconomic. This is a justifiable concern, but it is not a basis for adopting the narrow claim construction for which he contends. The scope of the claim cannot realistically depend on a national rule about damages, so that it would mean something different in a territory where only royalty damages were available.

132. Another hard case is that in which a defendant has taken all the steps open to him to avoid his medicine being prescribed for the new use, yet those steps are, due to the structure of the marketplace, insufficient to stop it happening. Actavis' test would provide a defence in those circumstances, because the defendant could credibly say that he did not target those sales which he was striving manfully to prevent. The hard case arises because of the peculiarities of the UK's market place for drugs. Normally a vendor of a product can control by contract the uses to which his product is put and require any intermediary to include similar terms. I do not think we should allow the regulatory environment to dictate the scope of the claim in this way.

133. Applying the law as I believe it to be, it is plain that Warner-Lambert have an arguable case of infringement. On the assumption that infringement is shown at trial, it does not follow that unqualified relief will follow as of right. Those are issues for the trial or any enquiry which follows.

Indirect infringement

134. It will be seen that courts of two member states have, at least in provisional proceedings, granted relief to prevent what they considered to be indirect infringement of Swiss claims without any express indication of how they considered that the invention would be put into effect.

135. I agree that there are difficulties with the indirect infringement claim for the reason which the judge gave, namely the absence of a downstream event which, as a whole, can be regarded as putting the invention into effect. However, for three reasons, each of which is in my judgment sufficient, I would allow the indirect infringement case to go to trial.

136. The first reason is that which I have already given, namely that the courts of two EPC member states considering this same question have held that, at face value, indirect infringement can arise in these circumstances.

137. The second reason is that, if, as I have held, there is a case of threatened or actual infringement of the process claim under section 60(1)(b), then it follows that dealings downstream in the direct product of the process are also infringements under section 60(1)(c). Although this may not add anything to the direct infringement case, it is wrong to strike it out as a viable additional cause of action.

138. The third reason is that I consider it is arguable to say that when section 60(2) speaks of "putting the invention into effect", it may be legitimate to look not just at whether any one person is carrying out the invention in a sense which would give rise to liability of that person for an act of infringement. It may be that the invention is put into effect if pregabalin is manufactured by one person and supplied to another who intentionally uses it for the treatment of pain. In those circumstances, a person who supplies pregabalin with the requisite knowledge (i.e. that prescribed in section 60(2) itself) does provide means suitable and intended to put the invention into effect, albeit by the combination of manufacturer and user, rather than by any one person alone. It may be that this is the reasoning which underlies the decisions in the Dutch and German cases which I have referred to.

139. An analogous problem arises where one step of a two step process is carried out by A and the second step is carried out by B. Absent a claim of joint tortfeasance, could it not be said that by supplying the result of the first step to B, A is contributing to putting the invention into effect (by A and B together)?

140. It follows that I would allow the appeal against the striking out of the section 60(2) claim.

The point made by the Secretary of State

141. For completeness I should deal with the point made by the Secretary of State for Health, which is the following. The Secretary of State adopts the common ground that the prohibition on patentability of methods of treatment arose from the desire to protect the freedom of doctors to prescribe. Thus he submits that the prohibition on patentability of methods of treatment should affect "the infringement scope of the claim" so that those practising a method of treatment can in no circumstances be held

to infringe. Accordingly, so he argues, the knowledge or intent required by the claim must be confined to the manufacturing stage. To rely on intent further down the chain would inevitably lead to a finding of at least contributory infringement by those practising methods of treatment.

142. I cannot follow this argument. Firstly, it seems to me that it confuses the subject matter of the claim and the rights to which the subject matter gives rise. I have explained what I consider to be the technical subject matter of the claim above. I do not see how the technical subject matter of the claim can involve a limitation based on the identity of an alleged infringer. Secondly, even if one assumes that there is a requirement of intent "confined to the manufacturing stage", the potential for infringement by those in the chain continues to exist: there will be infringement by using the product of the process when the manufacturer has the requisite intention. It seems to me, therefore, that the construction advanced by the Secretary of State does not begin to provide a solution for the problem he perceives.

Balance of justice

143. The arguments on the issue of where the balance of justice lay followed familiar lines. Warner-Lambert contended that if there was significant dispensing of Lecaent for pain there would be price competition in the market, forcing it in due course to lower its prices, and thereby change the pricing structure in the market place pending trial. Because of well recognised difficulties, it would be impossible for Warner-Lambert to raise its prices if successful at trial. Thus the competition pending trial had the potential to cause Warner-Lambert irreparable harm.

144. Actavis contended that it had already taken significant steps to prevent Lecaent being prescribed for pain, and that the further steps were likely either to be ineffective or cause Actavis irreparable harm. Thus it was too late to incorporate stickers onto each pack of Lecaent, and the contractual restrictions on pharmacists would have a chilling effect on Actavis' sales of Lecaent for lawful, non-patented indications.

145. It is not necessary to rehearse these arguments in great depth, because Mr Turner's argument on this aspect of the case focused on one aspect of the judge's reasoning. The judge considered, as did the parties, that the best solution to the problem, at least for interim purposes, was for the NHS to give guidance. In assessing the balance of justice, therefore, he correctly thought it necessary to form an assessment of how likely it was that such guidance would be issued. The judge concluded that there was a reasonable prospect of such guidance being issued. Mr Turner submits that there was no evidence at all to support that conclusion. He further submits that the judge should have gone on and decided how likely it would be that such guidance would be followed.

146. As to the first point, it is fair to say that there was little by way of concrete material before the judge from which to make a scientific prediction as to the probabilities of the NHS issuing guidance. But the judge had made it clear that he considered that it should issue such guidance, and the Department of Health, whilst considering that it had no power to intervene in the autonomous activities of the NHS, had certainly not placed any obstacles in its way. I see no reason why the judge was not therefore entitled to form a view as to the likelihood of guidance being issued, and weigh that in the balance.

147. The point has, as it seems to me, now lost any theoretical force it might have had, since the judge has, by his fourth judgment, directed the NHS to issue guidance and such guidance has in fact been issued. With hindsight it might be said that the judge has under-estimated the likelihood of the guidance being given. I would therefore reject this first point.

148. I cannot accept the second point either, namely that the judge should have gone on to consider how effective the guidance might be. The parties appear to have approached the hearing below on the common basis that guidance would be effective. The fact that Warner-Lambert took the trouble to seek an order for such guidance is an indication that they thought it would be effective, at least to some extent. No submissions appear to have been made to the effect that the guidance would be ineffective.

149. Mr Turner made a variety of other criticisms of the judge's judgment. So for example he says that the judge should have concluded that letters to superintendent pharmacists would not reach sufficiently into the prescribing chain to have a real effect. I was not impressed with this or any of the other points, which, as it seemed to me, were simply an attempt to re-argue the case which was argued before the judge. It is not open to this court to interfere with a judge's evaluation of the factors relevant to the balance of justice unless he has taken into account matters which he should not have done, or ignored matters which he should have taken into account, or is wrong. I did not think Mr Turner's further point came close to meeting this demanding threshold.

150. Apart from these points, Mr Turner sought to persuade us to grant the modified relief that I have set out above in order to mitigate the chilling effect which the imposition of contractual terms might potentially have on Actavis' sales for non-patented indications, and to meet regulatory objections to including a warning label on the package intended to be handed to the patient. Even assuming it is proper for us to embark on this rather crude negotiation, I do not think either point helps Warner-Lambert. The modification to the contractual terms was intended to avoid any objective standard of reasonableness being applied to the pharmacist as to the nature of the enquiries he needed to carry out as to the purpose of the prescription, leaving it, in effect, to his sole discretion. I think the amendment robs the contractual term of any force. At the same time I doubt that pharmacists will be more encouraged to enter into contracts with this term than with the original one. Moreover if Actavis stress the loose nature of the contractual restriction, they lay themselves open to suggestions that they can safely be ignored.

151. As to the requirement to include a warning on the outer packaging, I also doubt whether this will have much effect. We have no evidence as to the stage at which outer packaging is removed, the persons by whom it is removed, and as to the likelihood of any such warning notice coming to the attention of the dispensing pharmacist.

152. In my judgment, the judge properly evaluated the material before him on this aspect of the case and came to a conclusion with which this court could not interfere.

The application to adduce further evidence

153. Warner-Lambert applied to adduce a further witness statement of their solicitor Ms Dagg. It was said to update us on the various matters since the date of Arnold J's judgments. We read the evidence *de bene esse* and said that we would decide on its admissibility when giving judgment. Mr Turner did not press for the admission of this evidence very strongly.

154. I would not admit the evidence. The main purpose of the evidence, as it seems to me, is to support a case that the guidance given by the NHS has not thus far been effective to prevent Lecaent being prescribed for pain.

155. Whilst this court will more readily admit further evidence on an interim application, this should not to be permitted to result in a free-for-all. The court is engaged in a review of the judge's exercise of discretion on the material before him. If further evidence goes to falsify some important assumption made by the judge, and there is some excuse for it not being deployed before him, it may well be admissible. But the further evidence in the present case satisfies neither of these criteria. Instead it seems to me to be directed to a new case, namely that the NHS guidance is not effective, contrary to the common position as it existed before the judge.

Conclusion

156. Although I have come to a different view from the judge as to whether Warner-Lambert's cases of direct and indirect infringement are arguable, I agree with the judge's assessment of the balance of justice in this particular case. I would therefore dismiss the appeal from his first judgment, grant permission for and allow the appeal from his third judgment and refuse the application to adduce fresh evidence. I would also dismiss the application by the Secretary of State to intervene.

Lord Justice Ryder

157. I agree.

Lady Justice Arden DBE

158. I also agree.