Neutral Citation Number: [2015] EWHC 72 (Pat)

Case No: HC-2014-001795

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

Rolls Building
Fetter Lane, London, EC4A 1NL

Date: 21 January 2015

Before :

THE HON MR JUSTICE ARNOLD

- -

Between :

WARNER-LAMBERT COMPANY, LLC	**Claimant**
- and -	
(1) ACTAVIS GROUP PTC EHF	**Defendants**
(2) ACTAVIS UK LIMITED	
(3) CADUCEUS PHARMA LIMITED	
(4) HIGHLAND HEALTH BOARD	**Proposed Defendant**

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Justin Turner QC, **Daniel Beard QC**, **Miles Copeland** and **Tim Austen** (instructed by **Allen & Overy LLP**) for the **Claimant**
Adrian Speck QC, **Paul Harris QC** and **Ronit Kreisberger** (instructed by **Powell Gilbert LLP**) for the **First to Third Defendants**
Douglas Campbell (instructed by **RPC**) for the **Proposed Fourth Defendant**
Richard Davis (instructed by the **Treasury Solicitor**) for the **Department of Health**

Hearing dates: 13-15 January 2015
Further written submissions 16, 19, 20 January 2015

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Approved Judgment

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

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THE HON MR JUSTICE ARNOLD

MR JUSTICE ARNOLD :

Contents

Introduction

1. This case arises out of a collision between the policy of incentivising important medical research by granting second medical use patents on the one hand and other policies and practices which form part of the United Kingdom's healthcare systems (and in particular the English and Welsh systems) on the other hand.

2. The essence of the problem is fairly simply stated, although the details are more complicated. The patentee markets a prescription-only drug for three different indications under a single registered trade mark. Patent protection for the drug itself has now expired, but the patentee still has a second medical use patent for one of the three indications. A supplier of generic pharmaceuticals wishes to enter the market for the drug for the two non-patented indications, as it is lawfully entitled to do. To that end, the generic supplier obtains a marketing authorisation for a generic version of the drug limited to those two indications (a so-called "skinny label"), and it only identifies those indications in its summary of product characteristics ("SmPC") and patient information leaflet ("PIL").

3. The main immediate causes for the problem that arises are two-fold. First, not only are about 83% of prescriptions written generically, but also about 95% of

prescriptions do not state the indication for which the drug has been prescribed. As a result, the pharmacist who dispenses the prescription will generally not know the indication the drug has been prescribed for. Secondly, because the generic version of the drug will be cheaper than the patentee's product, pharmacists will have a strong commercial incentive to dispense the generic version of the drug against all generic scripts. Thus it is foreseeable that pharmacists will dispense the generic version of the drug for patients who have in fact been prescribed the drug for treating the patented indication, unless positive steps are taken to prevent this.

4. As a result, I have to resolve two main questions. The first question is whether, in such circumstances, the generic supplier will infringe the second medical use patent unless the supplier takes positive steps to prevent its generic version of the drug being dispensed for patients who have been prescribed the drug for the patented indication. The answer to this question depends on the correct interpretation of the claims of the second medical use patent, which are in the so-called "Swiss" form. If it is seriously arguable that the generic supplier will infringe, the second question concerns the steps, if any, which the generic supplier should be obliged to take pending the trial of that issue. This question is complicated by the involvement of third parties who are not under either party's control: not just prescribing doctors and pharmacists, but also healthcare organisations such as Clinical Commissioning Groups ("CCGs") (in England) and Health Boards (in Wales), regulators such as the Medicines and Healthcare Products Regulatory Agency ("MHRA") and the National Institute for Heath and Care Excellence ("NICE"), NHS England and NHS Wales, and the Department of Health itself. It is further complicated by the fact that the patentee has itself taken, and is continuing to take, steps to prevent the generic version being dispensed for patients who have been prescribed the drug for the patented indication. It is still further complicated by the behaviour of patients, many of whom do not take their own prescriptions to the pharmacy, some of whom may not remember what they have been prescribed the drug for and a few of whom may mislead their doctors for ulterior reasons.

5. The Claimant ("Warner-Lambert") is the patentee. Warner-Lambert is part of the Pfizer group, which also includes Pfizer Ltd ("Pfizer"), which holds the relevant marketing authorisation. There is no need to distinguish between the First to Third Defendants (collectively "Actavis"), who are the generic supplier. The drug is pregabalin, which is marketed by Warner-Lambert under the trade mark Lyrica for epilepsy, generalised anxiety disorder ("GAD") and neuropathic pain. Patent protection for pregabalin itself expired on 17 May 2013. Remarkably, Warner-Lambert obtained a supplementary protection certificate which extended protection for pregabalin to 17 May 2018, but allowed it to lapse for non-payment of fees, as was first noted on the Register of Patents on 14 October 2013. Warner-Lambert's data exclusivity expired in July 2014. The second medical use patent is European Patent (UK) No. 0 934 061 ("the Patent"), which has claims in Swiss form directed to pregabalin for treating pain, and in particular neuropathic pain. Actavis have applied for, and are on the verge of obtaining, a marketing authorisation for generic pregabalin limited to epilepsy and GAD. Once Actavis have obtained their marketing authorisation, they will launch their product under the trade mark Lecaent. A number of other generic suppliers have shown signs of interest in pregabalin, and one (Consilient) has already obtained a marketing authorisation.

6. Warner-Lambert alleges that Actavis will infringe the Patent. Actavis and another generic supplier (Mylan) have brought proceedings to revoke the Patent, and if successful they intend to obtain marketing authorisations and to sell pregabalin for all three indications; but that is not relevant for present purposes. I have directed that Warner-Lambert's infringement claim against Actavis be tried at the same time as the revocation claims, that is to say, in a five day window starting on 29 June 2015. Pending trial, Warner-Lambert has applied for an interim injunction requiring Actavis to take a number of steps to prevent Lecaent from being dispensed for treating pain. Actavis contend that Warner-Lambert's infringement claim has no real prospect of success, and in the alternative that the balance of the risk of injustice favours refusal of the relief sought. Actavis also argue that the relief sought is contrary to competition law.

7. The Proposed Fourth Defendant ("NHS Highland") is the Health Board for the Scottish Highlands. Warner-Lambert alleges that NHS Highland has infringed, or threatened to infringe, or procured infringement by others of, the Patent by publishing an article in its publication *The Pink One* dated October-November 2014 which is said to encourage doctors to prescribe and pharmacists to dispense generic pregabalin for all indications regardless of the patent position. Warner-Lambert has applied to join NHS Highland to this claim and to obtain interim relief against it. NHS Highland disputes that this Court has jurisdiction over the claim made against it. I have given directions for the hearing of these issues at the end of this month if that proves necessary given that Warner-Lambert and NHS Highland have been negotiating a settlement and agreement appears close.

8. On 10 December 2014 Warner-Lambert's solicitors, acting in accordance with the guidance given by Jacob LJ in *SmithKline Beecham plc v Apotex Europe Ltd* [2005] EWCA Civ 658, [2007] FSR 6 at [77], notified the Department of Health of Warner-Lambert's application, and served copies of Warner-Lambert's (and subsequently Actavis') evidence. The Department initially declined the opportunity to be represented before me, although it did provide helpful comments on behalf of itself and the MHRA through the medium of two letters from the Treasury Solicitor to Warner-Lambert's solicitors. After I had repeatedly made it clear through the parties that I would be assisted by its appearance, however, the Department relented and, on the afternoon of the third day of the hearing, instructed counsel to appear. I am grateful to the Department for its assistance, and in particular to counsel who appeared at very short notice. The value of the exercise is illustrated by the fact that, contrary to what had been indicated in an email sent by the Treasury Solicitor on the first day of the hearing, counsel informed me that he was instructed to request that, if relief was granted, Warner-Lambert's cross-undertaking in damages should extend to the Department and the NHS. Warner-Lambert agreed to this.

Second medical use patents with claims in Swiss form

9. It has increasingly been recognised over the past 30 years or so that it is important to find new uses for existing medicines. Existing medicines have the advantage that they are known compounds which have been shown to have acceptable safety profiles, and therefore need much less testing from that perspective. Experience shows that a compound which has therapeutic benefit in one application not infrequently turns out to have therapeutic benefit in another application (sometimes more than one other application) which may be quite different to the first application. Thus there is

significant potential and value in finding such second (and third, etc.) medical uses. Discovering such second medical uses requires difficult and expensive research, however. How is such research to be funded? The answer which has been provided by the European patent system is to grant patents for second (and subsequent) medical uses of known compounds. The monopoly thus conferred on the inventor who finds the second medical use provides the return on the investment required to fund the research.

10. There are two significant obstacles to the grant of patents for second medical uses under the European patent system: first, the compounds themselves are not new, which is a fundamental requirement for patentability of a product; and secondly, methods of treatment of the human (or animal) body by therapy are not patentable, in order to protect doctors from claims for patent infringement. The European patent system has attempted to overcome these obstacles in two ways.

11. The first way was through a piece of judicial lawmaking which fudged some of the difficult issues. This involved the use of claims in Swiss form i.e. "use of substance X for the preparation of a medicament (or pharmaceutical composition) for treating indication Y" (a purpose-limited process claim): see G 05/83 *Eisai/Second medical indication* [1985] OJ EPO 64. The history of, and rationale for, granting patents with claims in this form was explained in detail by Jacob LJ giving the judgment of the Court of Appeal in *Actavis UK Ltd v Merck & Co Inc* [2008] EWCA Civ 444, [2009] 1 WLR 1186 at [7]-[49] and by Kitchin J (as he then was) in *Ranbaxy (UK) Ltd v AstraZeneca AB* [2011] EWHC 1831 (Pat), [2011] FSR 45 at [42]-[56].

12. The second way was through legislation, namely Article 54(5) of the European Patent Convention 2000, which enables the grant of claims in the form "product X for treating indication Y" (a purpose-limited product claim). These have now superseded claims in Swiss form, although patents with claims in Swiss form will continue to subsist for some time to come. This is a more satisfactory solution to the problems, although difficulties remain.

13. It is important to note that this case is exclusively concerned with claims in Swiss form. As the Technical Board of the Appeal of the European Patent Office explained in Case T 1780/12 *University of Texas Board of Regents/Cancer treatment* [2014] EPOR 28 at [19]-[24], claims in EPC 2000 form have a different scope of protection to claims in Swiss form. It should not be assumed that anything I say in this judgment about Swiss form claims necessarily applies to EPC 2000 claims.

The Patent

14. It is not necessary for present purposes to outline the Patent in any detail. The application was filed on 16 July 1997 with a claimed priority date of 24 July 1996. The Patent was granted on 28 May 2003 and will expire on 16 July 2017. The specification describes and demonstrates the analgesic effects of pregabalin, which had originally been developed as an anticonvulsant and as a treatment of certain anxiety disorders.

15. An application was made on behalf of Warner-Lambert to the EPO on 23 September 2014 to limit the claims centrally. Claims 1 and 3 in their proposed amended form are claims to:

> "1. Use of [pregabalin] or a pharmaceutically acceptable salt thereof for the preparation of a pharmaceutical composition for treating pain.
>
> 3. Use according to Claim 1 wherein the pain is neuropathic pain."

16. On 21 November 2014 the EPO notified Warner-Lambert that its central limitation request was allowable. Accordingly, this action is brought on the basis of these amended claims.

The abridged procedure for marketing authorisations and skinny labels

17. Article 10 of European Parliament and Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use lays downs an abridged procedure for the authorisation of generic versions of drugs on the basis of bioequivalence with the originators' products. Article 11 of the Directive provides that, for authorisations under Article 10, those parts of the SmPC of the reference product referring to indications or dosage forms which are still covered by patents need not be included. This enables the generic suppliers to carve out indications which are protected by second medical use patents from their SmPCs, and hence their marketing authorisations and PILs. Article 3 of European Parliament and Council Regulation 726/2004/EC of 21 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency contains a similar provision.

18. Where a generic product such as Lecaent has been authorised on the basis that it is bioequivalent to a product such as Lyrica, the fact that the SmPC for the former omits an indication included in the SmPC for the latter does not prevent doctors from prescribing or pharmacists from dispensing the former for that indication. Furthermore, both doctors and pharmacists will know that the product is the same despite the difference in the indications. In the present case, there is not even a difference in the dosage regime for the different indications, as in some other cases.

The market for pregabalin

19. Pregabalin is an important pharmaceutical product both therapeutically and commercially. Lyrica had global sales in 2013 of about $4.6 billion, more than any other Pfizer product. Sales of Lyrica in the UK alone were about $310 million in 2013. Sales have rapidly increased in recent years: according to NHS England, there was a 53% increase in pregabalin prescribing in England between 2011 and 2013.

20. The best evidence presently available as to the distribution of indications for which pregabalin is prescribed in the UK comes from IMS Health. The IMS data is based upon returns from about 500 GPs which record the indications for which they prescribe drugs using an international code. This data suggests that sales of Lyrica in the UK in January to September 2014 broke down as follows: 54% for treating pain (of which 44% was for neuropathic pain), 12% for psychiatric conditions (of which 18% was for GAD), 2% for epilepsy and 32% for unspecified other diseases. This would suggest quite a high level of off-label prescribing (i.e. doctors exercising their

clinical judgment to write prescriptions for indications for which pregabalin has not been authorised, as doctors are entitled to do).

21. A factor which may have a bearing on this, but which was not mentioned by either party in their evidence and which I only discovered from reading a national newspaper on the third day of the hearing, is that there is a high incidence of misuse of pregabalin. Pfizer has been aware of this issue for some time. In July 2014, following extensive discussions with the European Medicines Agency, Pfizer updated the EU product labelling for Lyrica to add the following warning:

> "Misuse, abuse potential or dependence
>
> Cases of misuse, abuse and dependence have been reported. Caution should be exercised in patients with a history of substance abuse and the patient should be monitored for symptoms of pregabalin misuse, abuse or dependence (development of tolerance, dose escalation, drug-seeking behaviour have been reported)."

22. In December 2014 Public Health England and NHS England jointly issued guidance entitled "Advice for prescribers on the risk of the misuse of pregabalin and gabapentin". This guidance draws doctors' attention to the problem of misuse of these drugs and contains advice as to how to deal with it. The guidance notes that pregabalin appears to be more sought after for misuse than gabapentin, that there is a growing illegal market, that the drugs are also being bought from online pharmacies and that prescribing per capita in secure settings is double that in the community. One of the actions advised is that, if a decision is made to prescribe these drugs for unlicensed indications, "the rationale should be discussed with the patient, appropriate consent acquired and all discussions clearly documented".

23. The DrugScope Street Drug Trends Survey 2014 published on 15 January 2015 reported as follows:

> "**Pregabalin and gabapentin misuse widespread among drug users and prisoners**
>
> Most of the 17 areas covered by the survey highlighted the significant increase in misuse of two prescription drugs, pregabalin and gabapentin, chiefly among Britain's opiate-using and prison populations. These anticonvulsant medications are increasingly prescribed to treat epilepsy, neuropathic pain and anxiety.
>
> People who misuse the drugs do so because of the feelings of euphoria they can create; they are commonly used alongside - and as enhancers to - other drugs, such as alcohol, opiates such as heroin or methadone, and diazepam. Pregabalin and gabapentin are easily available on the illicit market in 25mg to 800mg capsules, changing hands for between 50p and £2.

> Drug workers reported users displaying extreme intoxication and uninhibited, risky behaviours while on the drugs. Mixing these medications with other central nervous system depressants such as opiates and alcohol significantly increases the risk of overdose. Deaths involving pregabalin and gabapentin are on the rise and the Office for National Statistics told DrugScope that pregabalin and gabapentin were mentioned on 41 death certificates in 2013 (pregabalin on 33 and gabapentin on 9)."

24. It is obvious that one way in which pregabalin may be obtained for misuse is by a patient misleading a prescriber. Since the hearing, however, Warner-Lambert has filed evidence suggesting that this is unlikely to be a significant problem, although it does not rule out this possibility altogether (for example, where a patient conceals remission of symptoms in order to continue receiving pregabalin). This evidence also suggests that much less pregabalin is prescribed off-label than the IMS data would appear to indicate.

Treatment of neuropathic pain

25. Neuropathic pain is caused by damage to either the primary afferent sensory neurons (resulting in peripheral neuropathic pain) or certain areas of the central nervous system (resulting in central neuropathic pain). Neuropathic pain is distinct from inflammatory pain. The medications used to treat inflammatory pain are generally ineffective at treating neuropathic pain and vice versa.

26. The current NICE guidelines recommend amitriptyline, duloxetine, gabapentin and pregabalin as first-line treatments for neuropathic pain. If one of these is ineffective, another may be tried. Most NHS hospitals have a specific neuropathic pain treatment algorithm based on that proposed in a paper by Finnerup *et al*, however This involves initial treatment with amitriptyline, at a current daily dosage cost of about 11 pence. If that is ineffective, gabapentin is prescribed, at a current daily dosage cost of about 41 pence. If that is ineffective, pregabalin is prescribed, at a current daily dosage cost of about £2.30. Similar prescribing guidelines are available for GPs.

27. The therapeutic profile of pregabalin is very different to those of amitriptyline and duloxetine. Although pregabalin and gabapentin have similar profiles, a significant number of patients with neuropathic pain who respond positively to treatment with pregabalin either do not respond as well to gabapentin or only respond at doses which cause unacceptable side effects. For some patients, therefore, pregabalin is the best treatment option despite its expense.

Prescriptions

28. As noted above, the great majority of prescriptions identify the drug prescribed by reference to its international non-proprietary name ("INN"), that is to say, its generic name. Where this is the case, the pharmacist is in principle free to dispense a branded drug or a generic one. Where the prescription specifies a particular brand (such as Lyrica), the pharmacist must dispense that brand. Prescribers are encouraged to prescribe generically by a number of mechanisms, including professional guidance, guidance from NHS England, pressure from CCGs and Health Boards and

prescription software. There are certain limited circumstances in which it is recognised that doctors may properly prescribe by reference to a brand name, however. One example is the Selected List Scheme, which covers drugs which have been prescribed for a particular purpose to a particular class of patients.

29. As noted above, it is very rare for prescriptions to identify the condition for which the drug has been prescribed. It seems clear from the evidence before me that there is considerable resistance to changing this. One reason for this is patient confidentiality.

Prescription software

30. Almost all prescribers use prescription software to create prescriptions. The market leader is EMIS, which supplies 53% of GP practices in the UK. The other major suppliers are Vision and SystmOne. The current EMIS software encourages the doctor to prescribe pregabalin generically, although it permits Lyrica to be prescribed. It is likely that other systems work in a similar way. In addition, there is a specific program called ScriptSwitch used by some GPs which encourages GPs to prescribe drugs generically.

The NHS Drugs Tariff

31. The NHS Drugs Tariff sets out the main mechanism by which pharmacists are paid by the NHS for dispensing drugs against NHS prescriptions. The Tariff sets out both the remuneration pharmacists receive for their services and the reimbursement price they receive for dispensing drugs. Part VIII contains a range of commonly used drugs, of which pregabalin is one. Part VIII is divided into five categories: Category A (readily available drugs, where the reimbursement price is calculated from a weighted average of the list price for four suppliers), B (where usage has declined over time), C (price based on a particular brand or supplier), E (extemporaneously prepared) and M (the most widely available drugs, where the reimbursement price is calculated by the Department of Health). The Tariff is produced monthly by the Pharmaceutical Directorate of the NHS Business Services Authority.

32. The bulk of a community pharmacist's revenue comes from his flat professional fee for each prescription item dispensed and from medicine reimbursement prices. The reimbursement price paid under the Drugs Tariff will be higher than the price paid by the pharmacy to its supplier. This means that the costs of drugs dispensed is a major commercial driver for community pharmacists.

33. At present, pregabalin is listed in Category C. Thus pharmacists can claim reimbursement at the branded product rate, whether or not the prescription is written by reference to the brand name Lyrica. If pregabalin were to be moved to Category M or Category A, the pharmacist could only claim reimbursement for the generic value of the drug. Accordingly, the pharmacist would look to dispense the cheapest product in order to maximise the difference between the cost price of the drug and the reimbursement price.

Pharmacists and patients

34. In the future, pharmacists will have access to patients' Summary Care Records, but this is only just starting to be rolled out and at present does not include the condition

for which a drug has been prescribed. As matters stand, therefore, pharmacists do not usually know the indication for which a drug such as pregabalin has been prescribed, because this is not stated on the prescription. Unless the pharmacist himself happens to have ascertained and recorded this information in the past, the only ways in which the pharmacist can find this out are (i) by asking the patient and (ii) by asking the prescriber.

35. So far as asking the patient is concerned, community pharmacists are now required to have private consultation areas where discussions with patients can take place. In principle, therefore, a pharmacist can ask a patient what indication he or she has been prescribed pregabalin for. There are two problems with this approach, however. The first is that the patient may not be present when the prescription is filed. The second is that, even if the patient is present, the patient may not be able accurately to answer the question.

36. Surprisingly, there appears to be no national data available as to the extent to which prescriptions are collected from pharmacists by persons other than the patient. Actavis adduced evidence from a pharmacist who examined his pharmacy's prescription records for December 2014. During that month they received 55 prescriptions for Lyrica. Of those, only 17 were filed by the patient in person, while the remaining 38 were filed either by patients' representatives or were sent to the pharmacy as a part of its delivery service. This is clearly a small sample, but it is the only evidence on this point before the court. What it indicates is that, in a very substantial proportion of cases, a pharmacist who receives a prescription for pregabalin cannot ask the patient what indication the drug has been prescribed for.

37. About 80% of patients with neuropathic pain are over 35, and over 27% are over 65. In the case of those over 65, they will often be receiving multiple medications for a variety of conditions. Furthermore, in many cases the conditions will be long-term ones, and so the original prescription may have been written some time ago. It may therefore be questioned to what extent they will be able accurately to answer a question as to the indication for which they have been prescribed pregabalin. There is no evidence before the court as to the age profiles of patients with epilepsy or GAD, but at least some of these patients will be in a similar position.

38. It follows that in many cases the only way, and in others the only reliable way, for the pharmacist to ascertain this information is to contact the prescriber. It will be appreciated, however, that it may not be at all easy for the pharmacist to get through to the doctor on the telephone (or by email or other means) while the person who has brought the prescription is waiting. Once the information has been obtained, however, the pharmacists can make a record for the future.

Genesis of the proceedings

39. On 24 June 2014 Mylan commenced revocation proceedings against the Patent. On 12 September 2014 Actavis commenced revocation proceedings against the Patent in advance of a case management conference in the Mylan proceedings before Birss J on 15 September 2014. On 23 September 2014 Warner-Lambert's solicitors 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.

40. 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.
>
> Actavis also wishes to launch a pregabalin product with a full label in the UK, including for the treatment of neuropathic pain, as soon as possible, but wishes to clear the way first by seeking revocation of EP(UK) 0 934 061. Such a full label launch will therefore not take place until after the hearing [of] Actavis's revocation proceedings."

41. On 1 October 2014 Warner-Lambert's solicitors asked Actavis' solicitors to explain "what measures your client has put in place to ensure that your client's 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.

42. On 3 October 2014 Actavis' solicitors repeated that they anticipated the marketing authorisation would be granted in November 2014 and that Actavis would launch in December 2014/January 2015. They also stated:

> "Our client's product will be marketed in conjunction with the attached Product Information Leaflet, which you will note does not include indication for the treatment of neuropathic pain. On launch our client also intends 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.

43. 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.

44. 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."

This was the first time that Warner-Lambert had made this request.

45. 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.

46. 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."

47. This crossed with a letter from Warner-Lambert's solicitors of the same date stating:

> "Given your client's approach, there is an urgent need to take steps that will prevent infringement of our client's patent, whilst allowing your client to market its product in respect of its authorised indications."

48. On 3 December 2014 Actavis' solicitors replied, stating:

> "You have our client's position that in its view its planned launch of the Skinny Label Product will not infringe your client's patent. However, we remain in the dark as to your client's position on what would or would not constitute patent infringement beyond the piecemeal raising of late objections to aspects of our client's launch. Please provide us with the steps which your client considers to be sufficient to prevent infringement of your client's patent by our client's Skinny Label Product."

49. 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.

50. On 8 December 2014 Warner-Lambert launched the present application for interim relief. As a temporary measure, Actavis undertook not to launch their product without giving Warner-Lambert seven days' notice. At the hearing before me, Actavis undertook not to launch prior to judgment on the application.

Steps taken by Pfizer to date

51. Pfizer has taken a series of steps to try to ensure that generic pregabalin is neither prescribed nor dispensed for pain treatment.

52. Pfizer made contact with the Department of Health in September 2014, which led to a conference call between representatives of Pfizer and the Department on 7 October 2014. During the call, Pfizer explained its position. Pfizer followed this up with a letter to the Chief Pharmaceutical Officer of NHS England, Dr Keith Ridge, on 8 October 2014. It appears from this letter that, during the call, Dr Ridge had suggested a number of stakeholders whom Pfizer should contact and that Pfizer was in the process of doing so.

53. On 3 November 2014 there was a meeting between Pfizer and NICE to discuss the situation. Pfizer followed this up with letters dated 13 November and 11 December 2014. On 22 December 2014 NICE replied stating that it had taken steps to amend NICE Clinical Guideline 73 "Neuropathic pain – pharmaceutical management". The footnote to recommendation 1.1.8 ("offer a choice of amitriptyline, duloxetine, gabapentin or pregabalin as initial treatment for neuropathic pain (except trigeminal neuralgia"). The amendment inserted the following statement:

> "In addition, the Lyrica (Pfizer) brand of pregabalin has patent protection until July 2017 for its licensed indication of peripheral and central neuropathic pain; until such time as this patent expires generic pregabalin products will not be licensed for this indication and their condition would be off-label and may infringe patent."

Warner-Lambert complains that this guidance is insufficiently prominent and that it is unlikely to have come to the attention of prescribers anyway, but it will be appreciated that that is a matter for NICE and that Actavis can hardly be blamed for it.

54. On a date which has not been revealed, but no later than 14 November 2014, Pfizer wrote to its pharmacy customers concerning Lyrica's loss of exclusivity. This letter explained the background, stated that Actavis intended to launch generic pregabalin with an authorisation and label that only covered epilepsy and GAD and said that "we therefore think it is important for you to understand that we believe the supply of generic pregabalin for use in treatment of pain, whist the pain patent remains in force in the UK, would be infringing Pfizer's patent protection and would constitute an unlawful act". The letter also stated that Pfizer expected to be in touch with the recipients in the near future "to discuss our commercial proposals for Lyrica in relation to the epilepsy and [GAD] indications". Warner-Lambert has not identified

the recipients of this letter, but I understand that it was sent to all superintendent pharmacists. Nor has Warner-Lambert revealed what "commercial proposals" it has made to pharmacies.

55. On 12 December 2014 Pfizer wrote to all CCGs in England (and, I would assume, Health Boards in Wales) concerning Lyrica's loss of exclusivity. This letter explained the background, stated that Pfizer expected generic manufacturers to launch generic pregabalin with authorisations, SmPCs and PILs that only specified epilepsy and GAD and then said:

> "In view of the above, Pfizer requests that you issue appropriate guidance prescribing clinicians within your CCG to help ensure that our pain patent is respected and that all prescribing clinicians are aware of the pain patent situation.
>
> There are a number of ways in which this might be achieve but the simplest solution, we believe, is for clinicians to be advised to prescribe Lyrica® by brand when prescribing pregabalin to treat neuropathic pain. Pharmacists will then be able to dispense Lyrica® against such prescriptions and this will ensure that they do no infringe the pain patent."

56. I have only seen one response to this, namely a letter from West Hampshire CCG dated 13 January 2015 stating:

> ".. any requirement for prescribers to prescribe by either brand or approved name dependent on indication (when there is no clinical justification to do so) is likely to prove challenging. For this reason we would expect the Department of Health to devise a practical solution ...
>
> I understand that this issue has been raised with the Department of Health and we look forward to their guidance …"

57. At some point Pfizer contacted the Pharmaceutical Advisers Group ("PAG"), which provides advice to CCGs. As a result, on 15 December 2014 Nick Beavon, who is Chief Pharmacist of Wandsworth CCG and Chair of the PAG, sent an email circular to the PAG network and the London CCG Chief Pharmacists' network about Lyrica's loss of exclusivity in which he stated:

> "It is my view that when prescribing for neuropathic pain within licence, the only appropriate action at this point in time is to prescribe by Lyrica brand to avoid confusion and infringement of patent law."

He also attached a copy of the Pfizer letter to CCGs.

58. On 16 December 2014 representatives of Pfizer attended a meeting with representatives of the Department of Health. I have only seen Pfizer's note of this meeting, which was sent by Pfizer to the Department by letter dated 9 January 2015. Three points are of particular note. First, Pfizer records that:

> "you said that the Department of Health was not able to issue guidance under the new NHS structure. However, you believed the issuing of guidance was important for Pfizer in achieving a solution, and that the PAG/Nick Beavon's communication was clear and gave those healthcare professionals who received it what they needed to act within the law. Your view is that getting prescribers to act appropriately, since it is they who hold the discretion as to whether to prescribe by reference to INN or brand, is key."

59. Secondly, Pfizer records that the Department said that it would be unwilling to change the NHS Drug Tariff or endorsement and reimbursement procedure.

60. Thirdly, Pfizer records its own position with respect to pharmacists as follows:

> "Whilst we would rather not have to take this position, ultimately, it is only because of the way the framework is set up, regarding which we have been unable to find any alternative resolution despite our best efforts to collaborate with you and various NHS stakeholders, that Pfizer must take a position in relation to the activities of pharmacists. We agree that the best fix may be elsewhere – e.g. the prescribers can prescribe by brand - but if that doesn't happen then infringement occurs, we believe, by the pharmacists (as well as the generic companies themselves)."

61. Pfizer has continued to correspond with the Department since then.

Steps taken or proposed to be taken by Actavis

62. Actavis have also taken, or offered to take, a series of steps to try to ensure that generic pregabalin is neither prescribed nor dispensed for pain treatment.

63. First, Actavis have restricted the marketing authorisation they have sought, their SmPC and their PIL to epilepsy and GAD.

64. Secondly, Actavis have offered, once the marketing authorisation has been granted, to write a letter to CCGs in England and Heath Boards in Wales. The terms of this letter are very nearly agreed between the parties and I shall deal with this topic below.

65. Thirdly, Actavis have offered, once the marketing authorisation has been granted, to write a letter to all superintendent pharmacists. Again, the terms of this letter are very nearly agreed between the parties and I shall deal with this topic below.

66. Fourthly, Actavis have offered, once the marketing authorisation has been granted, to write a letter to NICE. I do not understand Warner-Lambert to take issue with the terms of the draft letter proposed by Actavis. Given that NICE has already changed its guidance, however, I doubt that there is any point in Actavis writing to NICE.

Other generic suppliers

67. It is an important plank of Warner-Lambert's case for interim relief that Actavis are not the only generic supplier planning to launch generic pregabalin in the near future. Warner-Lambert has been in correspondence with a number of suppliers about their intentions. Some of those suppliers have disclosed at least some information about their intentions in confidence. During the hearing arrangements were made for that information to be disclosed to Actavis' counsel and solicitors in confidence and it was disclosed to me. Given the confidentiality of some of the information, I cannot reveal the full picture in this judgment, but it is necessary for me to give an outline of the position as I understand it.

68. As noted above, Consilient has already obtained a marketing authorisation. It expects to be in a position to launch its product in the near future. It has been in discussions with Warner-Lambert over proposals which are designed to ensure that its product is only prescribed and dispensed for epilepsy and GAD. Warner-Lambert accepts that, if Consilient's current proposals are implemented, then Consilient will not infringe the Patent.

69. Dr Reddy's has disclosed some information to Warner-Lambert about its plans on a confidential basis. In the light of that information, I consider it probable that Dr Reddy's will launch a generic pregabalin product authorised only for epilepsy and GAD before the trial of this claim. It does not appear that Dr Reddy's intends to adopt the same measures as Consilient.

70. Warner-Lambert contends that it is to be inferred from correspondence it has had with Teva that Teva plans to market generic pregabalin, but Teva has declined to confirm this or to reveal its intended timing or any other details. Much the same is true of Sandoz. Accordingly, it seems to me that I have to proceed on the basis that both Teva and Sandoz may launch generic pregabalin products authorised only for epilepsy and GAD before the trial of this claim and without adopting the same measures as Consilient.

71. Mylan has stated that it does not intend to launch generic pregabalin before the fourth quarter of this year, that is to say, before the date on which a first instance judgment on this claim may be expected.

72. Two suppliers have told Warner-Lambert that they do not intend to market generic pregabalin at all.

The best solution to the problem

73. As I understand the evidence and arguments before me, it is more or less common ground between all concerned that the best solution to the problem which arises in this case is to try to ensure that prescribing doctors prescribe pregabalin for the treatment of pain by reference to the brand name Lyrica rather than by reference to the generic name pregabalin. That will ensure that pharmacists only dispense Lyrica when presented with prescriptions for pregabalin which are (at least so far as the prescriber is concerned) for pain without requiring the pharmacist to know the indication for which pregabalin has been prescribed.

74. As I hope I have made clear, it does not lie within the power of either Warner-Lambert or Actavis to ensure that this happens. It depends ultimately on the behaviour of the prescribers. The prescribers can be, and are already being, influenced in a number of ways, in particular by the NICE guidance and by communications via the CCGs (and Welsh Health Boards). Warner-Lambert is understandably concerned that this is not enough, and that what is required is for two further things to happen. Actavis agree that these steps are desirable.

75. First and most importantly, Warner-Lambert contends that prescribers should be given clear guidance that, in this situation (and other future situations like it), the proper course is to prescribe by reference to the brand name for the patented indication and by reference to the generic name for non-patented indications. Counsel for the Department of Health informed me that the Department is not a position to issue such guidance. Under the National Health Service Act 2006, the Secretary of State is under a duty to promote the autonomy of NHS England and may only intervene if NHS England is guilty of a significant failure properly to discharge its functions. The Department does 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 such a failure. The Department notes, however, that NHS England may consider it appropriate to issue such guidance. If NHS England were to do so, the Department would not consider that inappropriate. I presume that the position is much the same with regard to NHS Wales. Clearly, it is a matter for NHS England and NHS Wales to decide whether or not to issue such guidance, but for my part I would encourage them to consider doing so as a matter of urgency.

76. Secondly, Warner-Lambert contends that prescription software suppliers should alter their software to make it easier for doctors to prescribe pregabalin by brand name for treating pain. Again, I would encourage them to do so. This is less important, however, since the existing software does permit Lyrica to be prescribed.

77. Before proceeding further, it is necessary to emphasise two points. The first is that Warner-Lambert is not seeking any order against Actavis which will make either of the two things described above happen. The second is that, if those things do happen sufficiently quickly, the relief which Warner-Lambert seeks against Actavis on this application will become unnecessary. It follows that, in deciding whether to grant Warner-Lambert the relief it seeks, I need take into account the prospects of those steps being taken by those responsible. I consider that there is a reasonable prospect of NHS England and NHS Wales issuing guidance in the near future, but a lower prospect of software suppliers modifying their software quickly.

The relief sought by Warner-Lambert on this application

78. The relief sought by Warner-Lambert has changed to some extent over time. I shall concentrate on the final form of the relief sought, which is an order in the following terms:

> "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."

79. As indicated above, there is little between the parties with regard to paragraphs 3 and 6 of the draft order. So far as paragraph 3 is concerned, Warner-Lambert's proposal is for a letter in the following terms:

> "**IMPORTANT INFORMATION WHEN DISPENSING PREGABALIN**
>
> **FOR DISSEMINATION TO ALL PHARMACISTS SUPERVISED BY YOU**

Dear Pharmacist

Lecaent® (pregabalin)

Following the grant of marketing authorisation, Actavis is launching Lecaent®, a generic version of pregabalin, in the UK. The purpose of this communication is to provide you with information about a patent on the use of pregabalin for pain held by Warner-Lambert Company LLC (a member of the Pfizer group of companies).

Background

The basic composition patent for pregabalin and the associated Supplementary Protection Certificate have now expired. However, a second patent (EP 0 934 061) protecting pregabalin's use in the treatment of pain, owned by Warner-Lambert Company LLC, is still in force.

Actavis considers that this second patent is invalid, and has commenced court proceedings seeking its revocation, which will come for trial in June 2015. Warner-Lambert considers that certain activities of Actavis infringe the patent. This will also be decided at trial in June 2015.

Lecaent® Indications – what Actavis has informed prescribers and considerations for you

Section 4.1 of the Summary of Product Characteristics explains what the product is currently indicated for. Pending clarification from the court as to the status of the second patent, Lecaent® is marketed by Actavis only for those therapeutic indications that are not protected by the second patent, namely Epilepsy and Generalised Anxiety Disorder ('GAD'). Actavis has informed prescribers that Lecaent® is currently not indicated for the treatment of Neuropathic Pain and generic pregabalin should not be prescribed for this indication while the second patent is in force *and that instead Lyrica should be prescribed for this indication while the second patent is in force*. If you choose to dispense Lecaent® for use for pain Warner-Lambert have stated that they consider your company would risk infringing the patent.

Actavis will let you know when the position changes. It is Actavis' intention to launch a generic pregabalin product indicated for the treatment of neuropathic pain in addition to epilepsy and GAD if it receives confirmation from the court that the second patent is invalid.

> If you have any questions in relation to Actavis' pregabalin product, please contact [INSERT DETAILS FOR ACTAVIS MEDICAL INFORMATION]."

80. By the end of the hearing, Actavis' only substantial objection to this draft was to the inclusion of the words I have italicised (there are also a couple of minor points on wording, but these do not affect the substance of the letter). Actavis have concerns as to the appropriateness of these words from a regulatory perspective. I do not propose to go into details. Suffice it to say that I accept that Actavis' concerns are reasonable and that I do not consider that it will significantly prejudice Warner-Lambert if these words are omitted. Actavis also contend, and I accept, that they should not be required to send the letter before receipt of their marketing authorisation.

81. Turning to paragraph 6, Warner-Lambert's proposal is for a letter in the following terms:

> "**IMPORTANT INFORMATION WHEN PRESCRIBING PREGABALIN**
>
> Dear Prescriber
>
> **Lecaent® (pregabalin)**
>
> Following the grant of marketing authorisation, Actavis is launching Lecaent®, a generic version of pregabalin, in the UK. The purpose of this communication is to provide you with information about a patent on the use of pregabalin for pain held by Warner-Lambert Company LLC (a member of the Pfizer group of companies).
>
> **Background**
>
> The basic composition patent for pregabalin and the associated Supplementary Protection Certificate have now expired. However, a second patent (EP 0 934 061) protecting pregabalin's use in the treatment of pain, owned by Warner-Lambert Company LLC, is still in force.
>
> Actavis considers that this second patent is invalid, and has commenced court proceedings seeking its revocation, which will come for trial in June 2015. Warner-Lambert considers that certain activities of Actavis infringe the patent. This will be decided at trial in June 2015.
>
> **Lecaent® indications – impact on prescribing practice**
>
> Section 4.1 of the Summary of Product Characteristics explains what the product is currently indicated for. Pending clarification from the court as to the status of the second patent, Lecaent® is marketed by Actavis only for those therapeutic indications that are not protected by the second patent, namely

> Epilepsy and Generalised Anxiety Disorder ('GAD'). Lecaent® is currently not indicated for the treatment of Neuropathic Pain and generic pregabalin should not be prescribed for this indication while the second patent is in force. *Instead, you should prescribe Lyrica (by brand) when the medicine is to be used for pain.* If pharmacists dispensing your prescriptions were to choose to dispense Lecaent® for use for pain Warner-Lambert have stated that they consider pharmacists would risk infringing the patent.
>
> Actavis will let you know when the position changes. It is Actavis' intention to launch a generic pregabalin product indicated for the treatment of neuropathic pain in addition to epilepsy and GAD if it receives confirmation from the court that the second patent is invalid.
>
> If you have any questions in relation to Actavis' pregabalin product, please contact [INSERT DETAILS FOR ACTAVIS MEDICAL INFORMATION]."

82. Again, Actavis contend, and I accept, that the italicised words should be omitted and that the letter should be sent to CCGs (and Health Boards) once the marketing authorisation has been received. Actavis also object to the inclusion of the following sentence, but I see no objection to prescribers being informed of Warner-Lambert's position.

83. As for paragraph 5 of Warner-Lambert's draft order, as I have said, I see no point in Actavis being required to send it to NICE. The same goes for the Department of Health. Both NICE and the Department are well aware of the position.

84. Thus the major points of dispute concern paragraphs 1 (contractual terms) and 4 (notice on the packaging). I shall approach these heads of relief on the basis that Actavis will send the letters to the pharmacists and to CCGs and Health Boards as discussed above. Both forms of relief are directed at pharmacists. In both cases, the objective is to try to ensure that pharmacists do not dispense Lecaent for the treatment of pain. As I have said, if Warner-Lambert is successful in ensuring that prescribers prescribe Lyrica (as opposed to generic pregabalin) for pain, these heads of relief will not be necessary.

85. So far as the notice on the packaging required by paragraph 4 is concerned, Warner-Lambert's demand has changed over time. To begin with, it was for a permanent sticker bearing the wording set out above. Then, it was for a removable sticker bearing that wording. The MHRA stated that it considered that neither of these would comply with Directive 2001/83/EC and the Human Medicines Regulations 2012. Accordingly, Warner-Lambert's current demand is for a removable cellophane wrapper bearing the notice specified. Counsel for the Department of Health informed me that the MHRA did not wish to express a view as to whether this would comply with the Directive or not, and that it was aware that views within the EU are divided on this question. Accordingly, the first difficulty with this head of relief is that it may put Actavis in breach of the Directive. (I should make it clear that counsel for Warner-Lambert disputed that there would be any contravention of the Directive, but I do not

feel able to determine this question, since I have not had full argument on it.) Furthermore, even if Actavis will not be in breach of the Directive, they may fall foul of the Association of the British Pharmaceutical Industry's Code of Practice (a matter I heard even less argument about).

86. The second difficulty is efficacy. All that such a notice would achieve would be to bring it to the pharmacist's attention (if the pharmacist did not already know) that Lecaent should not be dispensed for pain. But this would not help the pharmacist to know whether the prescription had been written for treating pain.

87. As for the contractual terms required by paragraph 1, again the question of efficacy arises. This has two aspects. The first concerns enforcement. Even if Actavis comply with the order, it does not necessarily follow that the contractual terms would be imposed all the way down the contractual chain of supply to the dispensing pharmacist. Furthermore, counsel for Warner-Lambert made it clear that Warner-Lambert would not attempt to enforce this requirement directly against any of the other parties in the chain. The second aspect concerns the difficulty for the dispensing pharmacist of ascertaining from the person presenting the prescription what condition pregabalin has been prescribed for. I have considered this above.

88. In addition to the question of efficacy, the Department of Health has expressed the concern that the imposition of such terms may compromise the professional autonomy of the dispensing pharmacist.

89. A final point to note at this stage is that counsel for Warner-Lambert did not concede that Actavis would not infringe the Patent if it took all the steps required by Warner-Lambert's proposed order despite being invited to do so by counsel for Actavis. It is inherent in Warner-Lambert's case that, to the extent that those steps were ineffective, Activis would still infringe the Patent and would still have to pay damages or account for profits in respect of their infringing sales.

Principles to be applied

90. Counsel for Actavis pointed out that the relief sought by Warner-Lambert on this application was mandatory in character, but he rightly did not suggest that this meant that Warner-Lambert had to overcome any special hurdle. As Lord Hoffman explained when giving the advice of the Privy Council in *National Commercial Bank Jamaica Ltd v Olint Corp Ltd* [2009] UKPC 16. [2009] Bus LR 1110:

> "16. …. It is often said that the purpose of an interlocutory injunction is to preserve the status quo, but it is of course impossible to stop the world pending trial. The court may order a defendant to do something or not to do something else, but such restrictions on the defendant's freedom of action will have consequences, for him and for others, which a court has to take into account. The purpose of such an injunction is to improve the chances of the court being able to do justice after a determination of the merits at the trial. At the interlocutory stage, the court must therefore assess whether granting or withholding an injunction is more likely to produce a just result. As the House of Lords pointed out in *American*

Cyanamid Co v Ethicon Ltd [1975] AC 396 that means that if damages will be an adequate remedy for the plaintiff, there are no grounds for interference with the defendant's freedom of action by the grant of an injunction. Likewise, if there is a serious issue to be tried and the plaintiff could be prejudiced by the acts or omissions of the defendant pending trial and the cross-undertaking in damages would provide the defendant with an adequate remedy if it turns out that his freedom of action should not have been restrained, then an injunction should ordinarily be granted.

17. In practice, however, it is often hard to tell whether either damages or the cross-undertaking will be an adequate remedy and the court has to engage in trying to predict whether granting or withholding an injunction is more or less likely to cause irremediable prejudice (and to what extent) if it turns out that the injunction should not have been granted or withheld, as the case may be. The basic principle is that the court should take whichever course seems likely to cause the least irremediable prejudice to one party or the other. This is an assessment in which, as Lord Diplock said in the *American Cyanamid* case [1975] AC 396, 408:

> ‘It would be unwise to attempt even to list all the various matters which may need to be taken into consideration in deciding where the balance lies, let alone to suggest the relative weight to be attached to them.’

18. Among the matters which the court may take into account are the prejudice which the plaintiff may suffer if no injunction is granted or the defendant may suffer if it is; the likelihood of such prejudice actually occurring; the extent to which it may be compensated by an award of damages or enforcement of the cross-undertaking; the likelihood of either party being able to satisfy such an award; and the likelihood that the injunction will turn out to have been wrongly granted or withheld, that is to say, the court's opinion of the relative strength of the parties' cases.

19. There is however no reason to suppose that, in stating these principles, Lord Diplock was intending to confine them to injunctions which could be described as prohibitory rather than mandatory. In both cases, the underlying principle is the same, namely, that the court should take whichever course seems likely to cause the least irremediable prejudice to one party or the other: see Lord Jauncey in *R v Secretary of State for Transport, Ex p Factortame Ltd (No 2)* [1991] 1 AC 603 , 682–683. What is true is that the features which ordinarily justify describing an injunction as mandatory are often more likely to cause irremediable prejudice than in cases in which a defendant

> is merely prevented from taking or continuing with some course of action: see *Films Rover International Ltd v Cannon Film Sales Ltd* [1987] 1 WLR 670, 680. But this is no more than a generalisation. What is required in each case is to examine what on the particular facts of the case the consequences of granting or withholding of the injunction is likely to be. If it appears that the injunction is likely to cause irremediable prejudice to the defendant, a court may be reluctant to grant it unless satisfied that the chances that it will turn out to have been wrongly granted are low; that is to say, that the court will feel, as Megarry J said in *Shepherd Homes Ltd v Sandham* [1971] Ch 340, 351, 'a high degree of assurance that at the trial it will appear that the injunction was rightly granted'.
>
> 20. For these reasons, arguments over whether the injunction should be classified as prohibitive or mandatory are barren: see *Films Rover* [1987] 1 WLR 670, 680. What matters is what the practical consequences of the actual injunction are likely to be. …"

91. As is common ground, there is no precedent for the relief sought by Warner-Lambert. That itself is not a bar to the relief being granted. In applying the well established principles to the unusual situation before the court, however, it is important to appreciate that the relief which Warner-Lambert seeks against Actavis is intended not to affect Actavis' own conduct so much as the conduct of third parties. Moreover, those third parties are not before the court. It follows, in my judgment, that the principles must be applied with particular care.

Serious issue to be tried?

92. The first question I have to decide is whether Warner-Lambert's claim for infringement of the Patent raises a serious issue to be tried.

Claim under section 60(1)(c)

93. As is common ground, Swiss form claims are process claims: see *Wyeth's and Scherings' Applications* [1985] RPC 545 at 563 (Whitford and Falconer JJ sitting *en banc*) and *University of Texas* at [16].

94. Accordingly, Warner-Lambert's primary claim for infringement of the Patent is under section 60(1)(c) of the Patents Act 1977, which makes it an infringement to keep, dispose of or offer to dispose of "any product obtained directly by means of [the claimed] process". Warner-Lambert contends that Lecaent is a product obtained directly by means of the process of claims 1 and 3 of the Patent.

95. There is no dispute that, if Actavis (or their manufacturer) carry out the process of claims 1 and 3, then Lecaent will be a product obtained directly by means of that process. The dispute is as to whether the manufacture of pregabalin by Actavis (or their manufacturer) would fall within the claims upon their proper interpretation. The issue concerns the interpretation of the words "for treating (neuropathic) pain".

96. As counsel for Actavis submitted, however, before turning to that issue, it is first necessary to put it in its proper context by considering the meaning and effect of the remainder of the claim, namely "use of [pregabalin] … for the preparation of a pharmaceutical composition". As Jacob LJ explained in *Actavis v Merck* at [75], such a claim "is not aimed at and does not touch the doctor - it is directed at the manufacturer." Nor does such a claim touch the pharmacist (except in the case of extemporaneous preparation by the pharmacist). Thus the process will be carried out by Actavis (or their manufacturer), not by the prescriber or the pharmacist.

97. 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". This was also common ground at the hearing before me, although counsel for Warner-Lambert reserved the right to contend otherwise at trial.

98. It is common ground that Lecaent is a product obtained by the use of pregabalin for the preparation of a pharmaceutical composition which is *suitable* for treating (neuropathic) pain. This follows from the Patent and from Pfizer's marketing authorisation. The issue which divides the parties is whether Lecaent is a product obtained by use of pregabalin for the preparation of a pharmaceutical composition which is *intended* for treating (neuropathic) pain. This depends on two questions: first, whose intention is relevant, and secondly, what is meant by "intended"?

99. So far as the first question is concerned, counsel for Warner-Lambert submitted that the relevant intention was not that of the manufacturer, but that of the person who disposes, or offers to dispose, of pregabalin. I do not accept this submission. As I have explained, the claim is to a process of manufacture and it is directed at the manufacturer. It is not a claim to the resulting pharmaceutical composition, nor is it directed at a person who disposes of the pharmaceutical composition. It follows that the relevant intention is that of the person who carries out the process, here Actavis (or their manufacturer).

100. Turning to the second question, counsel for Warner-Lambert submitted that it was sufficient for this purpose that 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. So far as the factual position is concerned, there is, of course, no dispute that Actavis intend to sell pregabalin, as they are lawfully entitled to do. Nor did counsel for Actavis dispute that it was at least seriously arguable that it was foreseeable that, unless steps were taken to prevent it (such as prescribing pregabalin for (neuropathic) pain by reference to the Lyrica brand name), pharmacists would be likely to dispense pregabalin for treating (neuropathic) pain, and that Actavis knew that that was the case. But is such knowledge sufficient? Actavis contend that it is not, and that what is required is a subjective intention on their part that the pharmaceutical composition should be used for treating (neuropathic) pain.

101. Counsel for Warner-Lambert advanced four arguments in support of the contention that such knowledge was sufficient. First, he submitted that, as a matter of policy, it ought to be, because second medical use patents would be difficult to enforce if subjective intention on the part of the manufacturer was required. I will return to the policy argument below, but at this stage I would observe that a requirement of subjective intention would not mean that second medical use patents could never be

enforced. If, for example, a manufacturer puts the patented indication on the SmPC or PIL, that will be strong evidence of a subjective intent to carry out the process for that purpose. Likewise if the manufacturer promotes prescribing or dispensing of the product for the patented purpose in another way. Without prejudging Warner-Lambert's claim against NHS Highland, the patentee may also have a remedy if someone else promotes prescribing or dispensing of the product for the patented indication.

102. Secondly, counsel for Warner-Lambert drew an analogy with the interpretation of section 60(2) of the 1977 Act adopted by the Court of Appeal in *Grimme Maschinenfabrik GmbH & Co KG v Scott* [2010] EWCA Civ 1110, [2011] FSR 7 as summarised by Jacob LJ in in *KCI Licensing Inc v Smith & Nephew plc* [2010] EWCA Civ 1260, [2011] FSR 8 at [53]:

> "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]."

103. As counsel for Actavis submitted, however, there are two problems with this analogy. First, section 60(2) is a specific statutory provision which makes particular conduct an infringement. If Warner-Lambert has a claim under section 60(2), it does not need a claim under section 60(1)(c). I shall consider that question separately below. Secondly, section 60(2) expressly distinguishes between the knowledge of the supplier of the essential means and the intention of the user. That does not assist Warner-Lambert to establish that knowledge on the part of the supplier equates to intention.

104. Thirdly, counsel for Warner-Lambert drew an analogy with the tort of procuring breach of contract. He submitted that this tort was established if (i) the defendant knew of the existence of the contract, (ii) the defendant intended to interfere with its performance or was reckless as to whether that would happen and (iii) breach of contract resulted from the defendant's conduct. So far as recklessness being sufficient was concerned, he relied in particular on the judgment of Diplock LJ in *Emerald Construction Co Ltd v Lowthian* [1966] 1 WLR 691 at 703.

105. The leading authority on this branch of law is now the decision of the House of Lords in *OBG Ltd v Allan* [2007] UKHL 21, [2008] 1 AC 1, where Lord Hoffmann said:

> "40. The question of what counts as knowledge for the purposes of liability for inducing a breach of contract has also been the subject of a consistent line of decisions. In *Emerald Construction Co Ltd v Lowthian* [1966] 1 WLR 691, union officials threatened a building contractor with a strike unless he terminated a sub-contract for the supply of labour. The defendants obviously knew that there was a contract - they wanted it terminated - but the court found that they did not know its terms and, in particular, how soon it could be terminated. Lord Denning MR said (at pp; 700-701)
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> > 'Even if they did not know the actual terms of the contract, but had the means of knowledge - which they deliberately disregarded - that would be enough. Like the man who turns a blind eye. So here, if the officers deliberately sought to get this contract terminated, heedless of its terms, regardless whether it was terminated by breach or not, they would do wrong. For it is unlawful for a third person to procure a breach of contract knowingly, or recklessly, indifferent whether it is a breach or not.'
>
> 41. This statement of the law has since been followed in many cases and, so far as I am aware, has not given rise to any difficulty. It is in accordance with the general principle of law that a conscious decision not to inquire into the existence of a fact is in many cases treated as equivalent to knowledge of that fact (see *Manifest Shipping Co Ltd v Uni-Polaris Insurance Co Ltd* [2003] 1 AC 469). It is not the same as negligence or even gross negligence: in *British Industrial Plastics Ltd v Ferguson* [1940] 1 All ER 479, for example, Mr Ferguson did not deliberately abstain from inquiry into whether disclosure of the secret process would be a breach of contract. He negligently made the wrong inquiry, but that is an altogether different state of mind.
>
> 42. The next question is what counts as an intention to procure a breach of contract. It is necessary for this purpose to distinguish between ends, means and consequences. 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. As I said earlier, the Dunlop employees who took off the tyres in *GWK Ltd v Dunlop Rubber Co Ltd* (1926) 42 TLR 376 intended to advance the interests of the Dunlop company.
>
> 43. 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."

106. As counsel for Actavis submitted, it can be seen from this passage that Lord Hoffmann distinguishes between the requirements of knowledge and intention. So far as knowledge is concerned, he says that blind-eye knowledge is enough. But so far as intention is concerned, he says that it is not enough that breach of contract is a foreseeable consequence of the defendant's acts. Accordingly, this analogy does not assist Warner-Lambert either. Actavis' conduct in selling Lecaent will not be targeted or aimed at ensuring that Lecaent is dispensed for pain.

107. Fourthly, counsel for Warner-Lambert adopted my suggestion that there might be an analogy with the equitable protective duty described by Buckley LJ in *Norwich Pharmacal Co v Customs & Excise Commissioners* [1974] AC 133 at 145-146 and with the duty imposed on intermediaries by Article 8(3) of European Parliament and Council Directive 2001/29/EC of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society and Article 11 of European Parliament and Council Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights considered in *Cartier International AG v British Sky Broadcasting Ltd* [2014] EWHC 3354 (Ch).

108. I entirely accept that, as these authorities show, there are circumstances in which an intermediary who knows that goods in his possession will, if disposed of by another, infringe an intellectual property right or who knows that his services are being used by third parties to infringe an intellectual property right, can come under a duty to take positive steps to prevent or reduce such infringement. As counsel for Actavis pointed out, however, such duties arise in circumstances where the person in question knows of infringement by another. This does not assist Warner-Lambert to establish that Actavis will infringe unless it is shown that others will infringe; but that is not the case. Furthermore, Warner-Lambert does not rely upon any extra-statutory duty upon Actavis, but only upon section 60(1)(c).

109. Counsel for Actavis submitted that the word "for" in claims 1 and 3 of the Patent should be given a purposive construction, and that the only construction which gave effect to the purpose of Swiss form claims, and the policies underlying the granting of such claims, was to interpret "for" as meaning "suitable and (subjectively) intended for". Furthermore, he argued that Warner-Lambert's construction failed to achieve this. In this regard, he drew attention to the position of an inventor who patents a first medical use for a compound and markets the compound for that use. Subsequently, a second inventor patents a second medical use for the same compound and markets the compound for that use. The first inventor carries on marketing the compound for the first use. For reasons such as those discussed in this judgment, it is foreseeable that the first inventor's product will in fact be dispensed for the second use. If foreseeability is enough, the first inventor will infringe the second patent simply by carrying on doing what he was doing before the second patent was applied for. The

same is true if foreseability is not enough, but actual knowledge that the first inventor's product is being dispensed for the second use is enough. Nothing less than a requirement of subjective intention will protect the first inventor from infringement. The same applies to a third party who sells the same product for the same purpose as the first inventor.

110. Counsel for Actavis also cited decisions from a number of European jurisdictions which support the proposition that subjective intent is required, although he accepted that none of them established that this was settled law:

i) *Actavis v Merck* at [10] (Jacob LJ);

ii) *Carvedilol II* (German Federal Court, Case X ZR 236/01, 19 December 2006) at [51-1];

iii) *Chronic Hepatitis C Treatment* (Düsseldorf District Court, Case 4a O 145/12, 14 March 2013) at [51]-[56];

iv) *Schering Corp v Teva Pharma BV* (District Court of the Hague, 10 November 2010) at [4.6]; and

v) *Wyeth v Arafarma Group SA* (Madrid Court of Appeal, Case 539/07, 23 April 2008) at p. 32.

111. Counsel for Warner-Lambert had no cogent answer to this argument, and I accept it. Accordingly, I hold that the word "for" in Swiss form claims imports a requirement of subjective intention on the part of the manufacturer that the medicament or pharmaceutical composition will be used for treating the specified condition.

112. Since Warner-Lambert does not rely upon any allegation of subjective intention on the part of Actavis for the purposes of this application, I conclude that Warner-Lambert's claim under section 60(1)(c) does not raise a serious question to be tried. I should add that counsel for Warner-Lambert informed me that Warner-Lambert intended to apply for permission to amend its Particulars of Infringements to plead a case of subjective intent. I shall hear argument on that application when it is made.

113. In the alternative to its primary claim, Warner-Lambert claims for infringement through the supply of essential means under section 60(2) of the 1977 Act. Counsel for Warner-Lambert did not press this claim. He was right not to do so. There can be only be infringement under section 60(2) if there can be infringement by the person supplied or by a user further down the chain of supply (although it is not necessary for there actually to be an infringing act). This is not the case here, since no wholesaler or pharmacist will use Lecaent to prepare a pharmaceutical composition.

114. Finally, I should add that Warner-Lambert also has a pleaded case under section 60(1)(a) of the 1977 Act. Counsel for Warner-Lambert did not mention this in his submissions at all. Again, he was right not to do so. Claims 1 and 3 of the Patent are not product claims. Warner-Lambert cannot succeed under section 60(1)(a) if it fails under section 60(1)(c) and 60(2).

115. Although I have concluded that Warner-Lambert's claim does not give rise to a serious question to be tried, in case I am wrong about that, I shall go on to consider the application on the assumption that there is a serious question to be tried.

Harm to Warner-Lambert if no relief is granted

116. Warner-Lambert contends that, if no relief is granted, but it is successful at trial, it will suffer unquantifiable and irreparable harm between now and judgment. Actavis dispute this.

117. Counsel for Warner-Lambert relied on a line of cases in which it has been held that a patentee who markets a patented drug will suffer unquantifiable and irreparable harm if a generic supplier enters the market pending trial, but is then excluded from the market by a final injunction at trial, particularly where the evidence shows that other generic suppliers are likely to follow suit, as is the case here. The patentee will suffer unquantifiable harm because calculating the profits it has lost will be very difficult and irreparable harm because generic competition will lead to price depression which will be difficult to reverse.

118. In my judgment, the reasoning in those cases cannot be translated directly to this case, for a number of reasons. First, Actavis is lawfully entitled to enter the market for pregabalin for the treatment of epilepsy and GAD (and, indeed, all indications other than pain). The same is true of Actavis' competitors. To the extent that this causes Warner-Lambert loss of sales and/or leads to price depression, that is something of which Warner-Lambert cannot complain. It is only losses specifically related to the pain sector of the market that Warner-Lambert can complain about.

119. Secondly, as discussed above, the best solution to the problem is for doctors to prescribe Lyrica for pain. If the NHS issues appropriate guidance, that is likely to happen and Warner-Lambert is unlikely to suffer recoverable loss.

120. Thirdly, even if no such guidance is issued, Warner-Lambert has already taken steps, and Actavis have already agreed to take steps, to try to discourage the prescribing and/or dispensing of Lecaent for pain. Warner-Lambert will only suffer recoverable loss if and to the extent that those steps are ineffective.

121. Fourthly, even if Warner-Lambert is successful at trial, it is very unlikely to obtain relief against Actavis which makes it absolutely certain that pregabalin is not dispensed for pain in the future. Counsel for Warner-Lambert declined to commit himself as to the final relief which Warner-Lambert would seek at trial, but it is difficult to see that Warner-Lambert could do any better than to obtain a final order requiring Actavis to put a notice on its packaging and to impose contractual terms on its customers. For the reasons explained above, I am not persuaded that, even leaving aside the regulatory difficulties, requiring Actavis to put a notice on its packaging is likely to make a significant difference. As for the imposition of contractual terms, this is more likely to make a significant difference, but it is unlikely to be completely effective.

122. Fifthly, so far as the losses feared by Warner-Lambert depend upon pregabalin being moved from Category C of the NHS Drugs Tariff to Category M or Category A, this is unlikely to happen before trial. This would only happen after pregabalin had

become readily available and there had been negotiations between the Department of Health and the Pharmaceutical Services Negotiating Committee. Counsel for the Department told me that this would not happen until May 2015 at the earliest, and was unlikely to happen until some time after that. He also repeated to me an assurance which the Department had given Pfizer in correspondence that the Department would take the unusual circumstances relating to pregabalin into account in any such negotiations.

123. I accept that the entry of generic competition into the market for pregabalin for treating epilepsy and GAD is likely to lead to price competition in that market. It is evident from Pfizer's reference to "commercial proposals" in its letter to pharmacies (see paragraph 54 above) that Pfizer is taking steps to deal with this. As I have explained, however, Warner-Lambert cannot complain about that. What matters for present purposes is the likelihood of irreversible price depression in the market for pregabalin for treating pain. In the absence of a change in Drug Tariff Category, I consider it unlikely that the price of pregabalin for treating pain will drop significantly between now and trial. Even if it does, I consider that, in the unusual circumstances present here, it is likely that Warner-Lambert will be able raise the price back to its current level if it is successful at trial.

124. Nevertheless, I consider that it will be difficult to quantify Warner-Lambert's loss if no order is made now, but an order is made at trial. This is partly because it will be difficult to ascertain what percentage of Actavis' sales of Lecaent have been dispensed for pain, particularly having regard to the steps taken by both parties and others to ensure that it is not prescribed or dispensed for pain, and partly because it will be even more difficult to determine what difference it would have made if the order had been granted, and in particular if contractual terms had been imposed. I am not convinced, however, that the scale of the loss that Warner-Lambert will suffer in the period between now and judgment is likely to be substantial.

Harm to Actavis if relief is granted

125. Actavis contend that, if the relief sought by Warner-Lambert is granted but Warner-Lambert is unsuccessful at trial, they will suffer unquantifiable and irreparable harm. Warner-Lambert disputes this.

126. One of Actavis' complaints is that they will lose "first mover" advantage, that is to say, the advantage of being the first generic entrant into a market. I accept that this is an advantage to a generic supplier and that loss of this advantage is difficult to quantify. In the present case, however, it is by no means certain that Actavis will be first to market. Given that Consilient already has a marketing authorisation, Consilient may be first to market, although the measures it is taking may constrain its marketing somewhat. Furthermore, other suppliers may be close to launching their products.

127. Nevertheless, I consider that Actavis are likely to suffer unquantifiable loss in two ways. First, if Actavis are required to put a notice on their packaging, this will delay Actavis' entry into the market. Actavis will need to find a packaging contractor which can do this and the contractor will need to do the necessary work. This will take some time, although it is not clear how long. In addition, Actavis will need to at least notify the MHRA of this packaging under the MHRA's "show and tell" procedure, which takes effect in two weeks. But if one supposes that Actavis' entry into the market is

delayed by two weeks, it will be very difficult to quantify the loss which Actavis have sustained as a result. This will be all the more so if other players enter the market during that period.

128. Secondly, it is clear from Actavis' evidence that the requirement to put a notice on the packaging and the imposition of contractual terms are both likely to deter pharmacists from stocking Lecaent. In the case of the notice, the need to remove the cellophane wrapper would place a small extra burden on the pharmacist. More importantly, in both cases, pharmacists will be concerned that they may not be able to comply through no fault of their own if the prescription is for generic pregabalin and does not state the indication. This concern is particularly acute with the proposed contractual terms. To the extent that pharmacists are deterred, Actavis will be excluded from the non-patented market. It will be very difficult to determine what sales Actavis have lost, however, since Actavis have no track record of pregabalin sales.

129. Particularly for the second reason, I consider that Actavis are likely to suffer substantial unquantifiable loss if the order sought by Warner-Lambert is wrongly granted.

Clearing the path, status quo and delay

130. Warner-Lambert contends that Actavis have failed to "clear the path" for their generic launch and that preservation of the status quo favours the grant of relief. Actavis contend that Warner-Lambert has delayed both in preparing for generic entry into the pregabalin market and in seeking relief and that this favours refusal.

131. As noted above, patent protection for pregabalin as a product lapsed with effect from 18 May 2013. That will have been known to Warner-Lambert some time between then and 14 October 2013, and will have been known to interested competitors since 14 October 2013. Data exclusivity expired in July 2014, and both Warner-Lambert and its competitors will have known of this in advance. Accordingly, Warner-Lambert has had since some time between 18 May and 14 October 2013 to prepare for the present situation, while Actavis has had since 14 October 2013 to make its plans.

132. It is well established that, where a generic supplier intends to market a product covered by a patent which the generic supplier contends is invalid, then the proper course for the generic supplier is to commence revocation proceedings to "clear the path" for the launch of its product sufficiently far in advance of launch to enable the validity of the patent to determined prior to the launch date: see *SmithKline Beecham plc v Apotex Europe Ltd* [2003] EWCA Civ 137, [2003] FSR 31 at [38]-[40] (Aldous LJ). As counsel for Actavis accepted, this principle has also been applied in cases where the generic supplier has a non-infringement argument available to it.

133. Counsel for Warner-Lambert submitted that this principle was applicable to the present case. He adopted my suggestion that what Actavis ought to have done was to proceed as follows. First, as soon as they formed the intention to market generic pregabalin for epilepsy and GAD, Actavis should have written to Warner-Lambert asking it to acknowledge that the disposal etc by Actavis of generic pregabalin with an MA, SmPC and PIL limited to epilepsy and GAD would not infringe the Patent. Secondly, when Warner-Lambert declined to give that acknowledgement, Actavis should have launched proceedings for a declaration of non-infringement pursuant to

section 71 of the 1977 Act alternatively the Court's inherent jurisdiction. Counsel for Warner-Lambert submitted that, if Actavis had taken that course, the infringement issue could have been finally determined by now. I accept this submission, and I accept that, other things being equal, this factor would favour the grant of interim relief.

134. Apart from the factor that I have just mentioned, however, I do not accept that preservation of the status quo favours relief. This is for two reasons. First, as Warner-Lambert accepts, Actavis are lawfully entitled to launch Lecaent for epilepsy and GAD (and, indeed, for off-label prescribing for other indications except pain). Given that Lyrica is currently the only pregabalin product available, the status quo will change once Actavis (or whoever else is first to market) launches Lecaent in any event. Secondly, in so far as the status quo comprises the behaviour of others (such as NICE, the CCGs and Health Boards, prescribers and pharmacists), as described above, Warner-Lambert has itself already tried to change this, and has had some success. Furthermore, the relief sought by Warner-Lambert is essentially directed at compelling Actavis to take steps further to change such behaviour.

135. Counsel for Actavis submitted that Warner-Lambert had delayed in taking steps to prepare for generic entry into the pregabalin market. He argued that Warner-Lambert had known since some time between 18 May and 14 October 2013 that it had lost patent protection for indications other than pain and had known that it would lose data exclusivity in July 2014. It was inevitable that generic suppliers would obtain marketing authorisations and launch generic pregabalin as soon as they could after July 2014. Yet Warner-Lambert had not taken any steps to deal with this situation until September 2014, and in particular had not taken steps to ensure that pregabalin was prescribed for pain by reference to the brand name Lyrica until then. I accept this submission, and I accept that this favours refusal of relief, but in my view this is not as strong a factor as Actavis' failure to bring declaratory proceedings.

136. Counsel for Actavis also submitted that Warner-Lambert had delayed in launching its application. He pointed out that Warner-Lambert had known that Actavis were proposing to launch their pregabalin product in December 2014 or January 2015 since 30 September 2014, but had not requested a notice on the packaging until 24 November 2014, had not requested the imposition of contractual terms until 5 December 2014 and had not launched the application until 8 December 2014. He pointed out that, had Warner-Lambert moved more quickly, the application could have been determined some time in advance of Actavis' receipt of its marketing authorisation. The significance of this particularly relates to the packaging requirement, since Actavis has been deprived of time in which to take the necessary steps to comply with any order. I accept this submission.

Balance of the risk of injustice

137. In my judgment, granting the relief sought by Warner-Lambert would create a greater risk of injustice than refusing it. In my view, wrongly granting the relief is more likely to cause Actavis substantial unquantifiable harm than wrongly refusing it is likely to cause Warner-Lambert substantial unquantifiable harm. Taking into account the other factors considered above, including the likely efficacy of the measure, I consider that the balance is firmly tipped against ordering Actavis to put a notice on its packaging.

In the case of the contractual terms, I consider that the balance is more evenly weighted, but still comes down in favour of refusing relief.

Competition law

138. Having regard to the conclusions I have reached above, Actavis do not need to rely upon their competition law arguments. I shall therefore not lengthen this judgment by considering those arguments. I should make it clear, however, that, had I concluded both that there was a serious issue to be tried and that the balance of the risk of injustice otherwise favoured the grant of the relief sought by Warner-Lambert, I would not have refused such relief on competition law grounds.

Summary of conclusions

139. For the reasons given above, I conclude that:

i) there is no serious issue to be tried with regard to Warner-Lambert's claim that Actavis will infringe the Patent by marketing Lecaent; and

ii) even if there was a serious issue to be tried, the balance of the risk of injustice would favour refusal of the relief sought by Warner-Lambert.