Michaelmas Term
[2018] UKSC 56
On appeal from: [2016] EWCA Civ 1006

JUDGMENT

Warner-Lambert Company LLC (Appellant) *v* Generics (UK) Ltd t/a Mylan and another (Respondents)
Warner-Lambert Company LLC (Respondent) *v* Generics (UK) Ltd t/a Mylan and another (Appellants)
Warner-Lambert Company LLC (Respondent) *v* Generics (UK) Ltd t/a Mylan and another (Appellants)

before

Lord Mance
Lord Sumption
Lord Reed
Lord Hodge
Lord Briggs

JUDGMENT GIVEN ON

14 November 2018

Heard on 12, 13, 14 and 15 February 2018

Appellant	*1st Respondent (Generics (UK) Ltd t/a Mylan)*	*2nd Respondent (Actavis Group PTC EHF)*
Lord Pannick QC Thomas Mitcheson QC Miles Copeland Tim Austen (Instructed by Allen & Overy)	Adrian Speck QC Pushpinder Saini QC Kathryn Pickard (Instructed by Taylor Wessing LLP)	Adrian Speck QC Pushpinder Saini QC Kathryn Pickard (Instructed by Powell Gilbert LLP)

Interveners

(1) SS Health	Michael Silverleaf QC Nicholas Saunders	
(2) EFPIA	Christopher Stothers Laura Whiting Paul Abbott	Written submissions only
(3) ABPI	Christopher Stothers Laura Whiting Paul Abbott	Written submissions only
(4) CIPA	In-house	Written submissions only
(5) BIA	In-house	Written submissions only
(6) Medicines for Europe	Catherine Drew, (Pinsent Mason LLP)	Written submissions only
(7) British Generic Manufacturers Association	Christopher Sharp, (Pinsent Mason LLP)	Written submissions only
(8) PSNC	In-house	Written submissions only
(9) National Pharmacy Association	(Charles Russell Speechlys LLP)	Written submissions only
(10) Mr Fionan McCaul	In person	Written submissions only

LORD SUMPTION: (with whom Lord Reed agrees)

Second medical use patents

1. These proceedings raise, for the first time in the courts of the United Kingdom, the question how the concepts of sufficiency and infringement are to be applied to a patent relating to a specified medical use of a known pharmaceutical compound. An important objective of modern pharmaceutical research is the discovery of new medical uses for known molecules. This commonly involves expensive research programmes, which will not be rewarded and will therefore not happen unless patent protection is available. Patent protection for second use medical patents is, however, difficult to accommodate within the traditional scheme of patent law. Traditionally, there were two legal obstacles. First, both the product and the process by which it was prepared were known from the original patent and therefore failed the test of novelty. Secondly, its use for a new therapeutic purpose was not itself patentable because article 52(4) of the European Patent Convention (the "EPC") and section 4(2) of the UK Patents Act 1977 prevented the grant of patents for a method of treatment of the human or animal body.

2. As is now well known, in 1984 the Swiss Federal Intellectual Property Office issued a statement of practice that it would be prepared to grant patents for second use medical patents in the following form: "the use of compound X in the manufacture of a medicament for the treatment of indication Y": [1984] OJ EPO 581. Hence the expression "Swiss-form patents" for patents granted in this form. The Enlarged Board of Appeal of the European Patent Office adopted this approach shortly afterwards in *EISAI/Second Medical Indication* G 05/83 [1979-85] EPOR B241. It ruled, at para 23, that it was

> "legitimate in principle to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case in which the process of manufacture as such does not differ from known processes using the same active ingredient."

Swiss-form patents were not product patents, but purpose-limited process patents. They surmounted both obstacles because the invention is identified as neither a product nor a method of treatment but a manufacturing process for a novel purpose.

3. This development responded to a real problem, namely the difficulty of obtaining patent protection for second uses that may have been truly inventive and involved costly research. But it has given rise to formidable analytical problems as a result of the need to apply to Swiss-form patents a statutory scheme which was not designed to accommodate them. For this reason they were regarded with suspicion as intellectually impure by patent lawyers in the United Kingdom. In *John Wyeth and Brother Ltd's Application* [1985] RPC 545, they were adopted with express misgivings by the Patents Court in the interests of uniformity among states party to the EPC. But in spite of the misgivings, they have achieved a secure place in United Kingdom patent law, and neither party to this appeal challenges them in principle. Some of the difficulties associated with them were resolved when the EPC was revised in November 2000 to provide for (among other things) the grant of purpose-limited product patents: see article 54(5) of the revised Convention. Corresponding changes were made to the Patents Act 1977 by the Patents Act 2004. Once these changes came into effect, in 2011, Swiss-form patents ceased to be issued by the European Patent Office. EPC 2000 patents give rise to difficulties of their own, some of which are very similar. But this appeal is not concerned with them.

The patent in suit

4. Warner-Lambert is a company in the Pfizer Group. It is the proprietor of European Patent No 0641330 for Isobutylgaba for the treatment of seizure disorders, notably epilepsy. Pregabalin is a derivative of Isobutylgaba, which is also referred to by its chemical name (S)-3-(aminomethyl)-5-methylhexanoic acid. It is marketed by Warner-Lambert under the brand name "Lyrica". Patent No 0641330 expired in the United Kingdom on 17 May 2013.

5. The present appeal concerns a second European Patent, EP(UK) No 0934061, entitled "Isobutylgaba and its derivatives for the treatment of pain", with a priority date of 24 July 1996 ("the Patent"). The claims of the Patent are all purpose-limited. Those which are principally relevant are Claims 1, 2 and 3, which are in the following terms:

> "1. Use of (S)-3-(aminomethyl)-5-methylhexanoic acid or a pharmaceutically acceptable salt thereof for the preparation of a pharmaceutical composition for treating pain.
>
> 2. Use according to Claim 1 wherein the pain is inflammatory pain.

> 3. Use according to Claim 1 wherein the pain is neuropathic pain."

It is common ground that the skilled person to whom the Patent is deemed to be addressed is a team consisting of a neuroscientist and a clinician specialising in the treatment of pain. To explain what the skilled team would understand by the terms used in the claims, it is necessary to say something about what was known at the priority date about the physiology of pain.

6. The second edition of *Classification of Chronic Pain Syndromes and Definitions of Pain Terms*, published in 1994 by the International Association for the Study of Pain, defined "pain" very broadly. It is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage." At the priority date, pain was classified into a number of different types. The distinctions between them were neither absolute nor consistently understood. But it was generally recognised that pain fell into two broad categories: nociceptive and neuropathic pain.

> *Nociceptive pain* is produced by noxious external stimuli such as heat, extreme cold, intense mechanical pressure or chemicals. These stimuli stimulate fibres known as nociceptors, which transmit impulses via the spinal cord to the brain, where they are perceived as pain. Nociceptive pain has a bio-protective function. It alerts the brain to the presence of noxious stimuli so that appropriate avoidance measures can be taken. This type of pain resolves with treatment of the underlying cause.

> *Inflammatory pain* is a type of nociceptive pain. The body's response to an injury involves the release of chemical mediators which increase the sensitivity of nociceptors causing pain both at the site of the injury or in the surrounding area. Like other nociceptive pain, inflammatory pain resolves with the treatment of the underlying cause. In 1996, well known and efficacious treatments were available for treating inflammatory pain. They included analgesics (eg paracetamol), non-steroidal anti-inflammatory drugs (eg aspirin, ibuprofen) and opioids of various strengths.

> *Neuropathic pain*, unlike nociceptive/inflammatory pain, is pathological. It has no bio-protective function. It is caused by damage to the nervous system itself. Neuropathic pain was defined in the second edition of the IASP's *Classification of Chronic Pain* as "pain initiated or caused by a primary lesion or dysfunction of the nervous system." The nervous system comprises the central nervous system, ie the brain and spinal cord, and the peripheral nervous system, ie the nerves outside those structures. Critical to the issues

in these proceedings is the distinction between *peripheral neuropathic pain*, which arises from damage or dysfunction of the peripheral nervous system; and *central neuropathic pain*, which is rarer and arises from damage or dysfunction of the central nervous system, for example as a result of a stroke, multiple sclerosis or spinal cord injury. The symptoms of neuropathic pain (of either kind) are more severe than those of nociceptive/inflammatory pain. They include perceptions of burning, shooting pain and electric shock pain. Moreover, unlike nociceptive/inflammatory pain, neuropathic pain is persistent, sometimes for years or for life. It was in 1996, and still is, notoriously difficult to treat neuropathic pain. In particular, treatments which were efficacious against nociceptive/inflammatory pain, such as non-steroidal anti-inflammatory drugs, were not regarded as effective for the treatment of neuropathic pain.

Finally, it is necessary to mention *allodynia* and *hyperalgesia*, two terms which feature prominently in the evidence. Both are symptoms of pain. Allodynia is pain experienced in response to a stimulus that would not normally be expected to cause pain. Hyperalgesia is an increased response to a thermal or mechanical stimulus that one would normally expect to be painful, but less so. It may be primary hyperalgesia (occurring at the site of an injury) or secondary hyperalgesia (occurring in the area surrounding the site of the injury).

7. Lyrica received a marketing authorisation in the European Union for the treatment of peripheral neuropathic pain and epilepsy in July 2004 and for the treatment of central neuropathic pain in September 2006. It is also authorised for the treatment of generalised anxiety disorder (or GAD). Lyrica is one of four first-line treatments recommended by NICE for neuropathic pain. It is one of the Pfizer Group's most successful drugs in the United Kingdom.

The present proceedings

8. Generics (UK) Ltd (trading as Mylan) and Actavis Group PTC EHF are pharmaceutical companies that are mainly engaged in marketing generic pharmaceutical products. Actavis markets a generic pregabalin product under the brand name "Lecaent", which was launched in February 2015. Caduceus Pharma Ltd hold the marketing authorisation for Lecaent in the European Union. For convenience I will refer to Actavis and Caduceus together as "Actavis". Lecaent is marketed under a "skinny label", ie for the treatment of some indications only. The Summary of Product Characteristics prepared for the purpose of obtaining marketing authorisation and the Patient Information Leaflet included in the packet state that the conditions for which Lecaent is indicated are epilepsy and GAD, for which patent protection has expired.

9. In these proceedings, Mylan and Actavis claimed the revocation of the Patent on the ground of lack of inventive step and insufficiency, and Warner-Lambert claimed against Actavis for infringement of Claims 1 and 3.

10. The judge, Arnold J [2015] EWHC 2548 (Pat), rejected the arguments based on lack of inventive step, and these are no longer in issue. But he held that Claim 1 (pain) and Claim 3 (neuropathic pain) were invalid. In summary, this was because he found that there was sufficient disclosure in the specification to support the claim that pregabalin was efficacious in the treatment of inflammatory pain and peripheral neuropathic pain, but not central neuropathic pain. Since the judge construed Claim 1 as extending to all pain and Claim 3 as extending to all neuropathic pain, including central neuropathic pain, both claims failed for insufficiency. It followed that Claim 4 (cancer pain), Claim 6 (phantom limb pain) and Claim 14 (fibromyalgia), all of which in the judge's view either were or could involve central neuropathic pain, failed on the same ground. Claim 13 (idiopathic pain, ie pain of unknown origin) failed on a more fundamental ground: there was nothing whatever in the specification which appeared to support it. The result of the judge's decision was to remove patent protection for the manufacture of pregabalin for the treatment of neuropathic pain, save for those subsidiary claims directed solely to peripheral neuropathic pain. The judge rejected as an abuse of process an application after judgment to amend the patent by narrowing the claims in terms which would arguably have made them valid.

11. The Court of Appeal (Floyd, Kitchin and Patten LJJ) [2016] EWCA Civ 1006 upheld the judge's findings, except that they considered that fibromyalgia was not neuropathic pain but an idiopathic pain. Since they agreed that the claim relating to idiopathic pain was invalid, this made no difference to the outcome. The Court of Appeal upheld his decision on abuse of process.

12. It followed that infringement did not arise, neither of the claims said to have been infringed being valid. The judge and the Court of Appeal differed on the test for infringement in a case where the monopoly conferred by the patent was confined to manufacture for a particular use. The judge held that if Claims 1 and 3 had been valid, they would not have been infringed. The Court of Appeal held that he had applied the wrong test, and declined to decide the point in the absence of the findings of fact which, on their preferred test, would have been required.

13. On the present appeals, Warner-Lambert contend that all the claims of the Patent were valid, although they have made no effort to justify Claim 1 (pain), Claim 13 (idiopathic pain) or Claim 14 (fibromyalgia). Their real object is to establish the validity of their claims in relation to neuropathic pain or, if they cannot achieve that, then at least those claims which relate to peripheral neuropathic pain, which is by far the commonest type. Actavis and Mylan for their part cross-appeal in support of

their case that none of the claims in relation to neuropathic pain are valid. The only claims whose validity they accept are those which are limited to inflammatory pain, for which there is currently no marketing authorisation.

14. In these circumstances, the issues in the present appeal fall under four heads:

(1) The construction of the claims, and in particular Claim 3 (neuropathic pain).

(2) The sufficiency of the disclosure in the specification.

(3) Amendment and abuse of process.

(4) The test for infringement of a patent for a manufacturing for a limited use.

For reasons which will become apparent, on the view which this court takes of the law, not all of these issues arise in the circumstances of this case. However all of them raise unresolved questions of considerable general importance, which have been fully argued not only by the parties, but by the Secretary of State and other interveners potentially affected by statements of principle in the courts below. It is therefore proposed to deal with all of them.

15. Since we are not all agreed on every point, it may assist if I summarise the conclusions of the court at the outset:

(1) The court unanimously affirms the view of both courts below that Claim 1 extends to all pain and Claim 3 to all neuropathic pain, whether peripheral or central. It unanimously affirms Arnold J's decision rejecting Warner-Lambert's application to amend the patent so as to limit the scope of these claims.

(2) The court holds by a majority (Lord Sumption, Lord Reed and Lord Briggs), that the disclosure in the specification supports the claims so far as they extend to inflammatory pain but not to any kind of neuropathic pain. It follows that Claims 1 and 3 fail for insufficiency, and that Warner-Lambert's appeal must be dismissed and Actavis's and Mylan's cross-appeal allowed.

(3) I hold, together with Lord Reed, Lord Hodge and Lord Briggs, that if Claims 1 and 3 had been valid, they would not have been infringed. We differ, however, as to the reasons. I consider, together with Lord Reed, that the intention of the alleged infringer is irrelevant and that the sole criterion of infringement is whether the product as it emerges from the manufacturing process, including any labelling or accompanying leaflet, is presented as suitable for the uses which enjoy patent protection. The judge found (paras 443-447) that Lecaent was sold with patient information leaflets to the effect that it was for the treatment of seizure disorders and GAD. Lord Mance agrees that the test depends on the objective appearance and characteristics of the product as it is prepared, presented and put on the market, but leaves open the possibility (i) that in rare cases the context may make it obvious that these are not to be taken at face value, and (ii) that there may be circumstances in which the generic manufacturer should positively exclude use for the patent-protected purpose. Lord Hodge and Lord Briggs prefer the view of Arnold J that the test is whether the alleged infringer subjectively intended to target the patent-protected market. Arnold J found (para 661) that they did not.

This paragraph has been approved by the authors of all the other judgments.

Construction and amendment

16. Claim 3 claims "use of [pregabalin] for the preparation of a pharmaceutical composition for treating neuropathic pain". The question is whether "neuropathic pain" in its context means all neuropathic pain, including central neuropathic pain (as Actavis and Mylan contend), or only peripheral neuropathic pain (as Warner-Lambert say). I will call these the broad and narrow constructions respectively. Both the judge and the Court of Appeal decided without, it seems, much difficulty, in favour of the broad construction. I agree with them. In my opinion they were plainly right about this. Lord Briggs has dealt fully with the reasons, in terms with which I agree, and I shall not lengthen this judgment by repeating them. I also agree, for the reasons which he gives, that the judge was right to reject Warner-Lambert's attempt to amend the patent so as to confine Claim 3 to peripheral neuropathic pain. For reasons which will become apparent in the following section, the amendment would not have saved Claim 3 even if it had been allowed.

Sufficiency and plausibility

17. Elementary as it is, it is worth reminding oneself at the outset of the juridical basis on which patents are granted, sometimes called the "patent bargain". The inventor obtains a monopoly in return for disclosing the invention and dedicating it

to the public for use after the monopoly has expired. The point was succinctly made by Lord Mansfield in *Liardet v Johnson* (1778), quoted in Hulme, "On the History of Patent Law", (1902) 18 LQR 280, 285:

> "The condition of giving encouragement is this: that you must specify upon record your invention in such a way as shall teach an artist, when your term is out, to make it - and to make it as well by your directions: for then at the end of the term, the public shall have benefit of it. The inventor has the benefit during the term, and the public have the benefit after ..."

The principle remains the foundation of modern patent law, and is recognised in the case law of both the United Kingdom and the European Patent Office. In *EXXON/Fuel Oils* (T 409/91) [1994] OJ EPO 653, at paras 3.3 and 3.4, the EPO Technical Board of Appeal observed that it was

> "the general legal principle that the extent of the patent monopoly, as defined by the claims should correspond to the technical contribution to the article in order for it to be supported, or justified. … This means that the definitions in the claims should essentially correspond to the scope of the invention as disclosed in the description. … Although the requirements of articles 83 and 84 are directed to different parts of the patent application, since article 83 relates to the disclosure of the invention, whilst article 84 deals with the definition of the invention by the claims, the underlying purpose of the requirement of support by the description, insofar as its substantive aspect is concerned, and of the requirement of sufficient disclosure is the same, namely to ensure that the patent monopoly should be justified by the actual technical contribution to the art."

The principal conditions of validity, novelty, inventive step, industrial application and sufficiency are all, in one way or another, directed to satisfying the principle thus expressed.

18. Sufficiency is a condition of validity relating not to the underlying science but to its disclosure in the patent. Section 14 of the Patents Act 1977 provides:

> "(3) The specification of an application shall disclose the invention in a manner which is clear enough and complete

> enough for the invention to be performed by a person skilled in the art.
>
> …
>
> (5) The claim or claims shall -
>
> (a) define the matter for which the applicant seeks protection;
>
> (b) be clear and concise;
>
> (c) be supported by the description; and
>
> (d) relate to one invention or to a group of inventions which are so linked as to form a single inventive concept."

These provisions correspond to EPC articles 83 and 84, which read:

> "83. The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
>
> 84. The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description."

Section 72(1) of the Act, which corresponds to EPC article 138, mirrors section 14(3). It provides for the revocation of the patent, inter alia on the ground that

> "(c) the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art."

19. Lord Mance has expressed the view that sufficiency is a rule of judge-made law. It would I think be more exact to say that it is a statutory rule, which is

fundamental to the public interest that justifies the issue of the patent. The contribution of judges has been to work out principles on which it can be applied to Swiss-form patents. Section 14 of the Patents Act and the corresponding provisions of the EPC assume that an invention will be sufficiently disclosed if the specification enables it to be "performed". In the case of a patent for a new product or process, that assumption is almost always correct. The skilled person will discover that it works by replicating it in accordance with the specification. But the assumption is not correct in the case of a second use patent. The invention is not the compound or the process of its manufacture. The skilled person already knows how to make the product from the prior art disclosed in the original patent. The invention consists in the new purpose for which the product is to be manufactured. If sections 14(3) and 72(1)(c) are read literally and as an exhaustive statement of the requirement of sufficiency, all that needs to be disclosed is the new purpose, which is enough to enable it to be administered to a patient suffering from the relevant condition. The skilled person does not need to know how or why the invention works in order to replicate it. The result would be that the knowledge which made the identification of the new purpose inventive need not be disclosed at all.

20. The main problem about this result is that it would enable a patent to be obtained on a wholly speculative basis. Without some disclosure of how or why the known product can be expected to work in the new application, it would be possible to patent the manufacture of known compounds for the purpose of treating every conceivably relevant condition without having invented anything at all, in the hope that trial and error might in due course show that the product was efficacious in treating at least some of them. For that reason, both Arnold J and the Court of Appeal concluded that it was not enough simply to refer to a known compound and assert that it was efficacious for treating a specified condition. The patentee must disclose some reason for regarding this assertion as "plausible". In their view, this requirement was not exacting. The Court of Appeal (para 46) put the point as follows:

> "The EPO and domestic cases do, however, indicate that the requirement of plausibility is a low, threshold test. It is designed to prohibit speculative claiming, which would otherwise allow the armchair inventor a monopoly over a field of endeavour to which he has made no contribution. It is not designed to prohibit patents for good faith predictions which have some, albeit manifestly incomplete, basis. Such claims may turn out to be insufficient nonetheless if the prediction turns out to be untrue. A patent which accurately predicts that an invention will work is, however, not likely to be revoked on the ground that the prediction was based on the slimmest of evidence. Thus, the claims will easily be seen not to be speculative where the inventor provides a reasonably credible

> theory as to why the invention will or might work. The same is true where the data in the specification is such that the reader is encouraged to try the invention."

21. Warner-Lambert's primary case is that even this undemanding test is an impermissible addition to the text of the Patents Act and the European Patent Convention, and that the sole criterion of sufficiency is that the invention can be performed by the skilled person. Alternatively, they accept that some such test is necessary in order to exclude purely speculative claims, and to that extent they are prepared to add something to the literal language of sections 14(3) and 72(1)(c) of the Patents Act and EPC articles 83 and 138(1)(b). But they take issue with the courts below on two points. First, the courts below held that the patentee must show that his prediction of therapeutic efficacy was plausible in relation to everything falling within the scope of any claim if that claim was to be valid. Secondly, they held that the patentee may not demonstrate the plausibility of his prediction to the required standard by reference only to later published data. Mr Mitcheson QC, who appeared for Warner-Lambert, disputed both propositions.

22. The Court of Appeal's reference to "armchair inventors" suggests that what they meant by speculative claiming was claiming by persons who had done nothing new or inventive at all but had simply sought to patent abstract possibilities. That may well be a particular risk in the case of patents for new uses of known compounds, especially when they are commercially successful in their existing use. In reality, however, speculative claiming of this kind is simply one of a number of ways in which a patentee may attempt to claim a monopoly more extensive than anything which is justified by his contribution to the art. Other ways in which this can happen include claiming a monopoly wider than the disclosure in the patent can support. An over-broad claim will not necessarily be speculative. The inventor may really have invented something corresponding to the full breadth of the claim. Research may subsequently demonstrate this. But the claim will still exceed his contribution to the art if that contribution is not sufficiently disclosed in the patent.

23. The concept of plausibility originates in the case law of the EPO as a response to over-broad claims, in particular claims to whole classes of chemical compounds supported by a description which fails to show which compounds can be expected to work. The Technical Board of Appeal treats the condition of sufficiency under EPC article 83 as satisfied if it is possible to work the invention across the scope of the claim from the information in the specification, interpreted in the light of common general knowledge at the priority date. It addresses the broader question whether the disclosed contribution to the art is commensurate with the monopoly claimed under EPC article 56, in the context of inventive step. In that context, its case law requires the formulation of a problem which the claims of the patent could be said to solve: see T 939/92 *AGREVO/Triazole sulphonamides* [1996] EPOR 171. It imports a requirement that the patent should disclose not just what the invention

is and how to replicate it, but some reason for expecting that it will work. Plausibility was the standard to which the patentee was expected to demonstrate this.

24. Thus in *JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE/Growth differentiation factor-9* (T 1329/04) [2006] EPOR 8, the hypothetical problem calling for solution was whether a claimed polynucleotide was a member of the TGF-beta superfamily. The only evidence to support the contention that it was, consisted of material published after the priority date. The patent was held invalid for want of an inventive step. The Board observed at para 12:

> "The definition of an invention as being a contribution to the art, ie as solving a technical problem and not merely putting forward one, requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve. Therefore, even if supplementary post-published evidence may in the proper circumstances also be taken into consideration, it may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve."

See also the Board's observations to the same effect in *BRISTOL-MYERS SQUIBB/Dasatinib* (T 0488/16) (1 February 2017, unpublished), at para 4.9.

25. English law diverges from this approach, although the divergence is more a question of labels than of substance. It distinguishes between so-called "classical insufficiency" (where the skilled person is unable to perform the invention from the information disclosed in the specification) and so-called *Biogen* insufficiency (where the claim is said to be too broad, because it exceeds the disclosed contribution to the art). It deals with both under section 14(3), the statutory analogue of EPC article 83. The expression *Biogen* insufficiency is derived from the decision of the House of Lords in *Biogen Inc v Medeva Plc* [1997] RPC 1. The patent in suit in that case claimed a class of products, namely a molecule defined partly by the way that it had been made (by recombinant DNA). The trial judge and the EPO Technical Board of Appeal had found that the disclosure was sufficient to enable the invention to be performed across the whole scope of the claim, and the Appellate Committee proceeded on the basis that that was so. But the specification described only one method of making the molecule by recombinant DNA, whereas other methods were possible which owed nothing to the matters disclosed. The patent therefore claimed more than the inventor's contribution to the art warranted. The House of Lords imported into section 14(3) of the Act a concept similar to the former requirement of fair basis in section 32(1)(i) of the Patents Act 1949 ("that any claim of the complete specification is not fairly based on the matter disclosed in the specification"). It held that if the claim extended beyond the technical contribution

to the art disclosed in the patent, it failed for insufficiency independently of any objection based on want of an inventive step and notwithstanding that the skilled person could perform the invention across the whole scope of the claim. Lord Hoffmann, delivering the leading speech, said at p 50:

> "But the fact that the skilled man following the teaching of Biogen 1 would have been able to make HBcAg and HBsAg in bacterial cells, or indeed in any cells, does not conclude the matter. I think that in concentrating upon the question of whether Professor Murray's invention could, so to speak, deliver the goods across the full width of the patent or priority document, the courts and the EPO allowed their attention to be diverted from what seems to me in this particular case the critical issue. It is not whether the claimed invention could deliver the goods, but whether the claims cover other ways in which they might be delivered: ways which owe nothing to the teaching of the patent or any principle which it disclosed."

He went on to make the same point in the context of the objection of insufficiency. Adopting the statement of principle cited above from *EXXON/Fuel oils*, he pointed out, at p 54, that the purpose of requiring sufficiency of disclosure could not be limited to enabling the public to work the invention after the patent had expired:

> "Section 72(1)(c) of the 1977 is not only intended to ensure that the public can work the invention after expiration of the monopoly. It is also intended to give the court in revocation proceedings a jurisdiction which mirrors that of the Patent Office under section 14(3) or the EPO under article 83 of the EPC, namely, to hold a patent invalid on the substantive ground that, as the EPO said in *Exxon/Fuel Oils* (T 409/91) [1994] OJ EPO 653, para 3.3, the extent of the monopoly claimed exceeds the technical contribution to the art made by the invention as described in the specification."

Lord Hoffmann was not, in these observations, addressing the question of second use patents. But such patents raise a similar problem. If it is enough to disclose how to make a known compound and for what conditions, the patentee has acquired a monopoly without adding anything to the sum of knowledge. He will have satisfied the condition of sufficiency but without satisfying its purpose.

26. The answer to this anomaly in the case of Swiss-form patents was supplied by a series of decisions in which the EPO Technical Board of Appeal held that there

was to be implied into a purpose-limited claim an assertion of efficacy for the designated purpose, and that this was an intrinsic technical feature of the claim. This proposition was originally established in purpose-limited patents for non-medical uses. In two decisions published on the same date in 1989, G2/88 *MOBIL/Friction reducing additive* [1990] OJ EPO 93, at para 9, and G 6/88 *BAYER/Plant Growth Regulating Agent* [1990] OJ EPO 114, at para 7 the Board drew attention to the Protocol on the Interpretation of EPC article 69, which required a patent to be "interpreted as defining a position … which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties". From this they concluded that

> "… with such a claim, where a particular technical effect which underlies such use is described in the patent, having regard to the Protocol, the proper interpretation of the claim will require that a functional feature should be implied into the claim, as a technical feature; for example, that the compound actually achieves the particular effect."

The principle was first applied to patents for new medical uses in T 158/96 *PFIZER/Obsessive-compulsive disorder* (28 Oct 1998, unpublished), at para 3.1.

27. In *Prendergast's Applications* [2000] RPC 446, 448 Neuberger J arrived independently at the same conclusion. It followed that the specification must include some basis for supposing that the claim to therapeutic efficacy was true:

> "In relation to a 'Swiss-type' application, it appears to me that, in the absence of any practical evidence of the idea working (that is the idea of using a well-established drug for the treatment of a condition for which it has not so far been used), the absence of any evidence of the idea working involves the absence of a description. … [W]hether or not there is a description or an adequate description, for the purposes of section 14(5)(c) of the 1977 Act, must be judged by reference to the nature of the application. There is obvious force in the contention that, where you have a claim for the use of a known active ingredient in the preparation of a medicament for the treatment of a particular condition, the specification must provide, by way of description, enough material to enable the relevantly skilled man to say this medicament does treat the condition alleged, and that pure assertion is insufficient."

28. The implications of this approach for sufficiency were considered by the EPO Technical Board of Appeal in *SALK INSTITUTE FOR BIOLOGICAL STUDIES/AP-I complex* (T 609/02) (27 October 2004, unpublished). At para 9, the Board observed:

> "Where a therapeutic application is claimed in the form allowed by the Enlarged Board of Appeal in its decision G 5/83 (OJ EPO 1985, 64), ie in the form of the use of a substance or composition for the manufacture of a medicament for a defined therapeutic application, attaining the claimed therapeutic effect is a functional technical feature of the claim (see G 2/88 and G 6/88, OJ EPO 1993, 93 and 114, Headnote III. And point 9 of the reasons, for non-medical applications, see also T 158/96 of 28 October 1998, point 3.1 of the reasons). As a consequence, under article 83 EPC, unless this is already known to the skilled person at the priority date, the application must disclose the suitability of the product to be manufactured for the claimed therapeutic application."

29. The Board went on to mitigate this principle so as to reflect the fact that in the case of purpose-limited medical patents definitive evidence of therapeutic effect would not be available until clinical trials had been carried out. Since these would have to be disclosed, it was practically inevitable that the patent application would have to be made before any trials. This implied that sufficiency could be demonstrated by the disclosure of material supporting the claimed therapeutic effect which was less than definitive:

> "The patent system takes account of the intrinsic difficulties for a compound to be officially certified as a drug by not requiring an absolute proof that the compound is approved as a drug before it may be claimed as such. The Boards of Appeal have accepted that for a sufficient disclosure of a therapeutic application, it is not always necessary that results of applying the claimed composition in clinical trials, or at least to animals are reported. Yet, this does not mean that a simple verbal statement in a patent specification that compound X may be used to treat disease Y is enough to ensure sufficiency of disclosure in relation to a claim to a pharmaceutical. It is required that the patent provides some information in the form of, for example, experimental tests, to the avail that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se. Showing a pharmaceutical effect in vitro may be

> sufficient if for the skilled person this observed effect directly and unambiguously reflects such a therapeutic application (T 241/95, OJ EPO 2001, 103, point 4.1.2 of the reasons, see also T 158/96 of 28 October 1998, point 3.5.2 of the reasons) or, as decision T 158/96 also put it, if there is a 'clear and accepted established relationship' between the shown physiological activities and the disease (loc cit)."

After discussing the potential value of *in vitro* tests for this purpose, the Board observed, at para 10:

> "This means that the skilled person is made aware of the structure of the active ingredient proposed for the pharmaceutical composition as well as, in technical terms, of a definite link between the ingredient and the mechanism allegedly involved in the disease state. The presence of a cause/effect relationship is, thus, made plausible."

It was somewhat tentatively suggested to us by Mr Mitcheson that this principle did not justify the application of a plausibility test beyond the application stage, or authorise its use as a ground for revocation. But the correspondence between EPC articles 83 and 138 makes this kind of argument difficult to accept.

30. Mr Mitcheson's main submission under this head was a different one. This was that the subsequent case law of the EPO indicates that the *SALK* principle applies only where the therapeutic effect suggested in the patent is inherently implausible. The argument is that it is necessary for the patentee to disclose reasons for regarding the claimed therapeutic effect as plausible only when the skilled person reading the patent would be sceptical about it in the absence of such disclosure. This submission is consistent with some turns of phrase in the cases. But it would have been a strange thing for the Technical Board of Appeal to have meant. It would be inconsistent with the reason why plausibility of the claimed therapeutic effect is required, namely to support the implied claim to therapeutic efficacy and to justify the monopoly by reference to the patentee's contribution to the art. If Warner-Lambert's argument were sound, it would mean that if nothing was known either for or against the claimed therapeutic effect, no disclosure need be made in support of it.

31. The leading case relied on in the jurisprudence of the EPO is T 0578/06 *IPSEN/Pancreatic cells* (29 June 2011, unpublished). This concerned a compound for extending the functional life of pancreatic islet cells. The patent comprised no experimental data supporting the drug's claimed therapeutic effect, but it did contain

a technical explanation of its effect and an experimental methodology by which this could be verified: see para 11. The Board was concerned with the circumstances in which the specification could be sufficient without experimental data. It held, at paras 14-15:

> "14. The Boards of Appeal have indeed dealt with cases where, in the context of the assessment of inventive step, there could only be an invention if the application made it at least plausible that its teaching did indeed solve the problem it purported to solve and in which to establish plausibility the disclosure of experimental results in a patent application, or, under certain circumstances, by post-published evidence, was considered necessary (see decision T 716/08 of 19 August 2010, points 14 to 16 for a summary of the case law).
>
> 15. The board re-emphasises in this context however that this case law considers the establishment of plausibility only relevant when examining inventive step if the case at hand allows the substantiation of doubts about the suitability of the claimed invention to solve the technical problem addressed and when it is thus far from straightforward that the claimed invention solves the formulated problem."

This decision is authority for the proposition that plausibility can be demonstrated in the specification without experimental evidence, if there is no substantiated doubt about the theoretical case made for the efficacy of the invention. This is the only relevant proposition for which it is authority. As the Board observed in *INTERVET/Infectious salmon anaemia virus vaccine* (T 0716/08) (19 August 2010, unpublished), para 15, (the case cited in the passage quoted above from IPSEN), "common general knowledge at the priority date may be used to interpret the teaching in an application or a patent", but there must be something in the patent to interpret. This is no more than the Board had said in *SALK* itself.

32. These principles may be illustrated by the decisions of the Board in T 1437/07 *ALLERGAN/ Botulinum toxin for treating smooth muscle spasm* (26 October 2009, unpublished), and T 950/13 *BRISTOL MYERS SQUIBB/Dasatinib in the treatment of chronic myelogenous leukaemia* (3 February 2017, unpublished).

33. In *ALLERGAN*, it is unclear from the report what technical information was disclosed in support of the claim to therapeutic efficacy, except that it did not include any experimental data. The recital of the arguments shows that the sole ground on which the disclosure was said to be insufficient was that the absence of experimental

data was alone enough to make the claim to therapeutic efficacy "not credible". The Board dealt with this objection as follows:

> "38. The respondents argue that it was not credible that the therapeutic effect could be achieved because the treatment disclosed in Example 9 had not actually been carried out.
>
> 38.1 However, article 83 EPC stipulates that an invention must be disclosed 'in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art' (emphasis added by the board). Thus, article 83 EPC does not stipulate that a claimed invention must have actually been carried out by the applicant or the inventor. Moreover, according to rule 42(1)(e) EPC, even the presence of an example is not mandatory. Therefore, just because a patent discloses an effect which has not in reality been achieved, there is no reason - in the absence of convincing evidence that the effect cannot be achieved - for the board to doubt that the effect can be achieved. Thus, the respondents' argument does not convince the board."

The decision, like the decision in *IPSEN*, is authority for the proposition that experimental data are not essential to sufficiency unless it is being positively alleged with "convincing" supporting evidence that the invention does not work. In that event it may be necessary for the patentee to point to experimental data to rebut the allegation. But this does not mean that the specification is sufficient if there is neither experimental data nor any other reason to deduce from the specification that the claim to therapeutic efficacy is plausible. The decision is not authority for saying that the objector has the onus of showing that it is implausible. Sufficiency turns on what the patentee has disclosed. It must always be necessary for the patentee to demonstrate that he has included in the specification something that makes the claim to therapeutic efficacy plausible. Otherwise a mere assertion of efficacy would be enough.

34. The same point was made by the Board of Appeal in *BRISTOL MYERS SQUIBB*. The compound the subject of the patent was dasatinib for the treatment of chronic myelogenous leukaemia. The patent taught that dasatinib worked by inhibiting certain protein tyrosine kinases associated with chronic myelogenous leukaemia. No experimental data were disclosed in the specification. At para 3.6, the Board observed:

> "The disclosure of experimental results in the application is not always required to establish sufficiency, in particular if the

> application discloses a plausible technical concept and there are no substantiated doubts that the claimed concept can be put into practice."

The objection was that there were "substantial doubts" about the product's efficacy for the designated purpose in the absence of either (i) experimental data, or (ii) "a coherent theory which could explain such an effect", ie what the Board called a "plausible technical concept". The Board of Appeal upheld the patent because it disagreed on point (ii). It thought that there was a coherent theory. This was because it was common general knowledge in the art that the inhibition of certain kinases associated with chronic myelogenous leukaemia was an effective way to treat that condition. Dasatinib had significant functional and chemical affinities with another kinase inhibitor known to be effective. This was more than a mere assertion of efficacy. The patent disclosed a coherent theory to support it in the light of common general knowledge.

35. All of these judgments deal with highly fact-specific issues arising from objections or potential objections on the ground of insufficiency. When reading them, it is important not to miss the wood for the trees. The fundamental principle which they illustrate is that the patentee cannot claim a monopoly of a new use for an existing compound unless he not only makes but discloses a contribution to the art. None of them casts doubt on the proposition that the disclosure in the patent must demonstrate in the light of the common general knowledge at the priority date that the claimed therapeutic effect is plausible. On the contrary, they affirm it: see *ALLERGAN* at paras 26, 37, and *BRISTOL* at para 3.2.

36. The Court of Appeal's statement of the effect of the plausibility test has already been quoted (para 20 above). They considered that the threshold was not only low, but that the test could be satisfied by a "prediction … based on the slimmest of evidence" or one based on material which was "manifestly incomplete". Consistently with that approach, they considered (paras 40, 130) that the Board's observations in *SALK* laid down no general principle. I respectfully disagree. The principle is that the specification must disclose some reason for supposing that the implied assertion of efficacy in the claim is true. Plausibility is not a distinct condition of validity with a life of its own, but a standard against which that must be demonstrated. Its adoption is a mitigation of the principle in favour of patentability. It reflects the practical difficulty of demonstrating therapeutic efficacy to any higher standard at the stage when the patent application must in practice be made. The test is relatively undemanding. But it cannot be deprived of all meaning or reduced, as Floyd LJ's statement does, to little more than a test of good faith. Indeed, if the threshold were as low as he suggests, it would be unlikely to serve even the limited purpose that he assigns to it of barring speculative or armchair claims.

37. Plausibility is not a term of art, and its content is inevitably influenced by the legal context. In the present context, the following points should be made. First, the proposition that a product is efficacious for the treatment of a given condition must be plausible. Second, it is not made plausible by a bare assertion to that effect, and the disclosure of a mere possibility that it will work is no better than a bare assertion. As Lord Hoffmann observed in *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc* [2008] RPC 28, para 28, "it is hard to see how the notion that something is worth trying or might have some effect can be described as an invention in respect of which anyone would be entitled to a monopoly". But, third, the claimed therapeutic effect may well be rendered plausible by a specification showing that something was worth trying for a reason, ie not just because there was an abstract possibility that it would work but because reasonable scientific grounds were disclosed for expecting that it might well work. The disclosure of those grounds marks the difference between a speculation and a contribution to the art. This is in substance what the Technical Board of Appeal has held in the context of article 56, when addressing the sufficiency of disclosure made in support of claims extending beyond the teaching of the patent. In my opinion, there is no reason to apply a lower standard of plausibility when the sufficiency of disclosure arises in the context of EPC articles 83 and 84 and their analogues in section 14 of the Patents Act. In both contexts, the test has the same purpose. Fourth, although the disclosure need not definitively prove the assertion that the product works for the designated purpose, there must be something that would cause the skilled person to think that there was a reasonable prospect that the assertion would prove to be true. Fifth, that reasonable prospect must be based on what the TBA in *SALK* (para 9) called "a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se." Sixth, in *SALK*, this point was made in the context of experimental data. But the effect on the disease process need not necessarily be demonstrated by experimental data. It can be demonstrated by *a priori* reasoning. For example, and it is no more than an example, the specification may point to some property of the product which would lead the skilled person to expect that it might well produce the claimed therapeutic effect; or to some unifying principle that relates the product or the proposed use to something else which would suggest as much to the skilled person. Seventh, sufficiency is a characteristic of the disclosure, and these matters must appear from the patent. The disclosure may be supplemented or explained by the common general knowledge of the skilled person. But it is not enough that the patentee can prove that the product can reasonably be expected to work in the designated use, if the skilled person would not derive this from the teaching of the patent.

38. I turn to Warner-Lambert's alternative arguments. In the light of the general principles which I have considered, they can be addressed quite briefly.

39. The first argument is that whatever standard of plausibility is applied, the Court of Appeal were wrong to say that it had to be demonstrated across the whole scope of the claim. In my opinion, they were not wrong. As I have said, plausibility is not a distinct condition of validity, but one element in the test of sufficiency. As such, its application is governed by the same principles which apply to sufficiency generally. In a case such as this, where the claim is said to exceed the disclosed contribution to the art, it is of the essence that the specification must justify the full extent of the claim to the requisite standard. Where a feature of the claim is an assertion of therapeutic efficacy for a given condition, a monopoly is being claimed for the process of manufacturing the compound for the treatment of that condition. This does not mean that it must work for all patients suffering from that condition, or work on every occasion when it is applied by way of treatment. But it does mean that where the condition identified embraces a number of different pathologies, and the claim is construed as asserting the efficacy of the product for each of them, the assertion must be plausible in relation to them all. It must, as Kitchin LJ put it in *Regeneron Pharmaceuticals Inc v Genentech Inc* [2013] RPC 28, para 100 -

> "be possible to make a reasonable prediction the invention will work with substantially everything falling within the scope of the claim or, put another way, the assertion that the invention will work across the scope of the claim must be plausible or credible."

40. Warner-Lambert's second argument is that the courts below were wrong to reject later published data as relevant. This submission also is contrary to the legal basis of this particular head of insufficiency. We know that pregabalin works for the treatment of both peripheral and central neuropathic pain, because like any other medicament on the market, it underwent demanding clinical trials after the priority date, the results of which were made public. On that basis it received marketing authorisation for all neuropathic pain. This is always the case for a commercially valuable medicament, and no other kind will be worth litigating about. The question is not whether it works but whether the contribution to the art consisting in the discovery that it can be expected to work has been sufficiently disclosed in the patent. The inherent difficulty of demonstrating this before clinical trials is taken into account in the modest standard (ie plausibility) which is applied to test it. This point was made by the EPO Technical Board of Appeal in *SALK*, at para 8:

> "Sufficiency of disclosure must be satisfied at the effective date of the patent, ie on the basis of the information in the patent application together with the common general knowledge then available to the skilled person. Acknowledging sufficiency of disclosure on the basis of relevant technical information produced only after this date would lead to granting a patent for a technical teaching which was achieved, and, thus, for an

> invention which was made, at a date later than the effective date of the patent. The general principle that the extent of monopoly conferred by a patent should correspond to, and be justified by, the technical contribution to the art, has to be kept in mind."

This does not mean that subsequent data is never admissible in a dispute about sufficiency, but the purpose for which it is admitted is strictly limited. Where the asserted therapeutic effect is plausible in the light of the disclosure in the patent, subsequent data may sometimes be admissible either to confirm that or else to refute a challenger's contention that it does not actually work: see, for example, *ASTRAZENECA/Omeprazole Na* (T 1677/11) (27 November 2012, unpublished), *MERCK, SHARP & DOHME/Pharmaceutical nanoparticulate composition of a Tachykinin receptor antagonist* (T 0210/11) (17 July 2014, unpublished). But it cannot be a substitute for sufficient disclosure in the specification. As the EPO Technical Board of Appeal observed in *JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE/Growth differentiation factor-9* (T 1329/04) [2006] EPOR 8 at para 12, (cited above), it cannot be a substitute for sufficient disclosure in the specification.

Application to the present case

41. In what follows, unless otherwise stated, references to paragraph numbers are to the judgment of Arnold J.

42. The empirical data disclosed in the patent in support of the claim to therapeutic efficacy consisted of references to a number of pre-clinical animal models used to test drugs for various kinds of pain. The following facts about these models are either agreed or found by the judge:

> 1. The most significant model was the rat paw formalin test. This involves the injection of a noxious agent (formalin) into a rat's paw. The rat is monitored for the next hour and the amount of time that it spends licking or biting the paw is recorded. There are two phases. The first phase, which lasts about ten minutes, models the acute nociceptive pain caused by the injection itself. The second phase, which lasts about 45 minutes, models inflammatory pain. Nonsteroidal anti-inflammatory drugs were not effective for neuropathic pain, but were known to be efficacious in the second phase. The Patent specification accordingly recorded that the test results showed that pregabalin was effective in treating inflammatory pain. At the trial Warner-Lambert contended that nonetheless it was common general knowledge that the second phase could also be predictive of efficacy in treating neuropathic pain. The judge found, at para 235, that the evidence did not establish this.

2. The carrageenin test also models inflammatory pain. Carrageenin, an inflammatory agent, is injected into the sole of a rat's paw and tests are carried out to determine the extent of thermal or mechanical hyperalgesia. The Patent specification recorded that test results showed that pregabalin was effective in treating inflammatory pain. There is nothing in the literature to suggest that the carrageenin test could be used to predict efficacy for neuropathic pain, either on its own or in conjunction with the rat paw formalin test.

3. The post-operative pain model tests for pain responses following surgery. The rat's paw's plantaris muscle is incised under anaesthetic. After 24 hours the rat is assessed for mechanical hyperalgesia and tactile allodynia. Both are referred to in the Patent as nociceptive responses. Nothing in the literature suggests that this model can be used to predict efficacy for neuropathic pain, either on its own or in conjunction with the rat paw formalin test.

4. The specification also refers to two well-known models for peripheral neuropathy, the Bennett model and the Kim and Chung model. However, no data are presented from either model.

It follows that the experimental data in the specification was predictive of efficacy for the treatment of inflammatory pain. But the specification does not claim that the experimental data presented makes it plausible that pregabalin is effective for the treatment of any kind of neuropathic pain.

43. In these circumstances, the specification supported Claim 3 only if it would have suggested to the skilled person that there was some unifying principle which made it plausible that pregabalin would also work with neuropathic pain. The judge had already found, at para 161, in the context of the challenge for obviousness, that the skilled person would not have considered that there was any reasonable basis for thinking that an anticonvulsant like pregabalin, known to be effective for the treatment of epilepsy, would for that reason alone be effective for treating neuropathic pain. Warner-Lambert identified the relevant unifying principle as central sensitisation, a phenomenon discovered by Professor Clifford Woolf, one of their expert witnesses at trial, and published by him in 1983. Central sensitisation was a well-known concept at the priority date. It refers to the sensitisation of neurons in the dorsal horn to peripheral painful stimuli. For present purposes it is unnecessary to describe the detailed physiological processes involved. Essentially, pain signals originating in injury at the periphery are transmitted to the spine and intensified, resulting in allodynia and secondary hyperalgesia. The experts were agreed that central sensitisation is common to inflammatory pain and peripheral neuropathic pain but was not known to be causative of either (para 191). Moreover,

there is no necessary correlation between allodynia and secondary hyperalgesia on the one hand and either central sensitisation or neuropathic pain on the other. The judge found (para 205) that allodynia and secondary hyperalgesia were present in a "large majority" of patients suffering from neuropathic pain, but there was a "significant minority" of cases in which they were not present. Moreover, although allodynia and secondary hyperalgesia involved central augmentation, in some cases this would be central sensitisation, in others not. Central sensitisation is not the only mechanism of central augmentation (para 61).

44. A significant part of the evidence at trial was concerned with the role of central sensitisation in the second phase of the rat paw formalin test. This, as I have pointed out, models inflammatory pain. The judge found (para 235) that it was not known to be predictive of efficacy for neuropathic pain. The evidence established that central sensitisation played a role in the pain experienced in the second phase. But the judge found that it was not generally understood to be a dominant role (paras 211, 213-214). By this I understand him to have meant (since this was the issue between the experts) that it amplified but did not cause the pain experienced in the second phase.

45. Against this background, the judge dealt first with central neuropathic pain. He rejected the suggestion that central sensitisation could serve as a unifying principle embracing it. This was because although central sensitisation was understood to contribute to inflammatory pain and peripheral neuropathic pain, both of which originate in the peripheral nervous system, it cannot contribute to central neuropathic pain, which has nothing to do with damage to the peripheral nerves (paras 193, 348). There was an issue at trial about the correct classification of fibromyalgia and phantom limb pain. They were said to be exceptions to this proposition. But the judge (para 194) was not satisfied that this was common general knowledge. These findings are fatal to the argument that central sensitisation can serve as a unifying principle embracing central neuropathic pain. The judge's reasons for rejecting that argument seem to me to be unanswerable.

46. The judge refused to allow Warner-Lambert to argue by way of alternative that the presence of hyperalgesia or allodynia itself served as a unifying principle embracing central neuropathic pain, because it had not been pleaded, advanced in evidence or put to the relevant witnesses. But in any event he considered (para 349) that the evidence did not support it, mainly because it was difficult to reconcile with the fact that nonsteroidal anti-inflammatory drugs were known to be effective for the treatment of inflammatory pain but not neuropathic pain.

47. Turning to peripheral neuropathic pain, which is the subject of Actavis and Mylan's cross-appeal, the judge evidently found this to be a difficult issue. He considered the evidence to be "finely balanced", but concluded on balance (para

351) that the specification enabled a plausible prediction to be made that pregabalin would be effective for treating peripheral neuropathic pain. His reasoning was as follows:

> "In addition to the general points made above, Warner-Lambert's case suffers from the problem that it has not been established that it was common general knowledge that the rat paw formalin test was predictive of efficacy for neuropathic pain. Moreover, as discussed above, Professor Woolf accepted that the carrageenin and post-operative pain models did not assist in this regard. Nevertheless, I have concluded on balance that, given that plausibility is a relatively low threshold, the data contained in the specification, when read with the common general knowledge, just make it plausible that pregabalin would be effective to treat peripheral neuropathic pain. This is because the common general knowledge as to (i) the involvement of central sensitisation (at least as an amplifying mechanism) in both inflammatory pain and peripheral neuropathic pain and (ii) the role played by central sensitisation in the rat paw formalin test would have suggested to the skilled team that it was possible that a drug which was effective for inflammatory pain, in particular as modelled by the second phase of the formalin test, would also be effective in peripheral neuropathic pain, although this would not necessarily be the case. This conclusion is supported by the evidence not only of Professor Woolf, but also of Dr Scadding and Professor Wood in cross-examination. Dr Scadding said that, when he read the Patent, he thought that it 'could be the case' that pregabalin would be effective for (peripheral) neuropathic pain, although a demonstration of that was missing. Professor Wood more or less accepted that it was a credible suggestion, although he made it clear that he would want to test it experimentally."

48. An appellate court should not normally interfere with conclusions of a trial judge which depend on his evaluation of a substantial body of expert evidence: see *Biogen Inc v Medeva Plc* [1997] RPC 1, 50 (Lord Hoffmann). I consider, however, that Actavis and Mylan are entitled to succeed on their cross-appeal, not because there was anything wrong with the judge's findings, but because those findings do not support his conclusion that the specification makes it plausible to predict that pregabalin will be efficacious for treating neuropathic pain. The question, it must be remembered, is not whether it is plausible but whether the specification discloses something that would make it so in the eyes of the skilled person.

49. The starting point was pointed out by the judge himself (para 255) in the context of the challenge based on obviousness. Because the only evidence of therapeutic efficacy presented in the specification is the results of the four animal models, the skilled person would understand that the patentee was relying on these as being predictive of efficacy. Those results were, however, predictive only of efficacy for inflammatory pain. The specification does not in terms claim more than this. No data are presented for the two recognised models of neuropathic pain, the Bennett model and the Kim and Chung model. There is no mention of central sensitisation, or indeed of any unifying principle that might embrace any condition other than inflammatory pain. This is an unpromising basis for a submission that there is a unifying principle which enables any kind of conclusion about efficacy for neuropathic pain to be derived from results of the animal models.

50. The judge's analysis of the implications for peripheral neuropathic pain of the data presented in the specification was based entirely on the common general knowledge that central sensitisation was "involved" in both inflammatory and peripheral neuropathic pain. The judge concluded from this that it was "possible" that a drug which the specification showed to be effective for the first would also be effective for the second, "although this would not necessarily be the case." In my opinion this is a logical non-sequitur. The reason for seeking a unifying principle embracing neuropathic as well as inflammatory pain is that the unifying principle may suggest a common cause or metabolic mechanism embracing both, whose operation may be affected by the drug. That might in turn suggest that a drug which was effective for one condition might also be effective for the other. The "involvement" of central sensitisation in both inflammatory and peripheral neuropathic pain does not prove or even suggest that they have a common cause. Indeed, it is clear that they do not. The involvement of central sensitisation in both inflammatory and peripheral neuropathic pain does suggest that there may be a common metabolic mechanism at work, at least in intensifying the pain. But neither the specification nor the common general knowledge of the art supplies any reason for supposing that pregabalin affects the operation of that mechanism or even that it might well do. In particular, there is nothing to suggest, even as a hypothesis, that pregabalin works with peripheral neuropathic pain by blocking central sensitisation.

51. The information presented in the specification about the rat paw formalin test does not assist on this point. The rat paw formalin test, as I have said, models inflammatory pain. It shows a diminution of pain in the second phase, associated with the administration of pregabalin. But in the absence of anything in the specification about the effect of pregabalin on the mechanism of pain, there is no reason to suppose that the diminution of pain is associated with its effect on central sensitisation as opposed to its effect on any other agent of inflammatory pain. The judge had found (paras 211, 214) that central sensitisation was not the dominant factor in the second phase of the test. If, notwithstanding the involvement of central sensitisation in both inflammatory and neuropathic pain, the rat paw formalin model

is not predictive of efficacy for neuropathic pain, I find it difficult to see how the model can assist in making such a prediction plausible. The judge was obviously conscious of the logical inconsistency, and believed that he had found a way of resolving it. With respect, I do not think that he had.

52. More generally, it cannot in my view be enough to justify a monopoly that it is "possible" a priori that a drug which was effective for inflammatory pain would also be effective for neuropathic pain, in the absence of any reason to suppose that the possibility had some scientific basis or that it was more than speculative. Everything is possible that is not impossible, but "not impossible" is very far from being an acceptable test for sufficiency. Plausibility may be easy to demonstrate, but it calls for more than that.

53. Floyd LJ said (para 133) that he was "fortified" in his conclusions by a further consideration, which the judge had not relied on, namely that

> "… it was established through the evidence that the skilled team would be encouraged by the data in the patent to carry out simple tests (which are themselves identified in the patent) to confirm the suitability of pregabalin for peripheral neuropathic pain. I would have thought, on the basis of that evidence (as I think the judge did) that the specification had thereby made a contribution to the art which would justify a claim to peripheral neuropathic pain."

The "simple tests" that Floyd LJ was referring to were the Bennett and the Kim and Chung tests for peripheral neuropathic pain; and the evidence that he had in mind was that of Dr Scadding, the expert clinician called by Actavis and Mylan: see paras 119-120 and 127. Dr Scadding had accepted that "the skilled person would be encouraged by the data in the patent to ask the neuroscientist to test pregabalin for neuropathic pain." Professor Wood, the expert neuroscientist called by Actavis and Mylan who would notionally have been asked to carry out these tests, gave more guarded answers when he was asked to deal with the point in cross-examination: Day 2, pp 265-269. His evidence, in summary, was that there were "no data whatever about neuropathic pain in the patent", but that he would be encouraged by the broad terms of the claims to try many tests, including the Bennett and the Kim and Chung tests. There were, he said, "many different pain mechanisms that can give apparently similar symptoms", for which there were different models, and it would be necessary to test for all of them. Some were difficult to test for. It was put to him that even the Bennett and the Kim and Chung tests would not provide definitive proof of efficacy, because it was a "step by step process". His final answers on this point fairly reflect the tenor of his evidence, so far as one can judge from the transcript:

> "A. … So one would just carry out an analysis of all these different models, to see where the drug had better utility than present medication.
>
> Q. The data in the patent would give you sufficient motivation to carry out further tests and step-by-step you would reach the stage where you have demonstrated that pregabalin was effective for the treatment of pain?
>
> A. It would certainly inspire you to analyse its activity in a broad range of pain models. Of course, this would be useful for the clinician attempting to exploit the drug in treating various different types of human pain. Animal models are not ideal, but they are always a useful pointer for the clinician.
>
> Q. A useful starting point?
>
> A. Absolutely."

I am conscious of the danger of an appellate court analysing extracts from a transcript of evidence on complex and inter-related technical questions, where so much depends on the impression that the witness's evidence as a whole has made on the trial judge. But in the absence of any discussion of this point by the judge, I feel unable to attach the same importance to it as Floyd LJ did. There is, however, a more fundamental objection to it, which is well brought out by the evidence which I have cited from Professor Wood. In classical insufficiency cases, where the question is whether the disclosure in the patent enables the skilled person to perform the invention, the skilled person may be assumed to supplement the disclosure by carrying out simple tests. In cases like this one, where the invention is novel but the objection of insufficiency is that the claim exceeds the disclosed contribution to the art, the role of hypothetical "simple tests" is necessarily more limited. As the EPO Technical Board of Appeal observed in *JOHNS HOPKINS*, at para 12, the specification can be said to contribute to the art if it solves a problem, but not if it merely poses one. Or as Lord Hoffmann observed in a passage that I have already quoted, the notion that something is "worth trying" cannot be enough without more to justify a monopoly. The specification in the present case says nothing about neuropathic pain of any kind. It says nothing about central sensitisation, which is said to provide a link between neuropathic and inflammatory pain. The mere fact that the skilled team, faced with an apparent discrepancy between the breadth of the claims and the absence of supporting data in the specification, would be encouraged to fill the gap by carrying out tests of its own, serves only to confirm the absence of any disclosed contribution to the art.

54. I conclude that Claim 3 of the patent and the other claims relating to neuropathic pain were invalid for insufficiency. The disclosure did not contribute any knowledge of the art capable of justifying a claim to a monopoly of the manufacture of pregabalin for the treatment of neuropathic pain of any kind.

Decisions in other jurisdictions

55. Mr Mitcheson reminded us more than once in the course of his submissions that if we were to hold Claim 3 insufficient we would be the only court to do so in the various jurisdictions party to the EPC. In issuing the Patent, the EPO had rejected the suggestion that it might be insufficient, albeit without giving detailed reasons. Warner-Lambert also rely on decisions of the courts of France, Germany and Sweden, all of which have subsequently upheld Claim 3 as sufficient. This is more than a forensic point. If courts in other jurisdictions have upheld Claim 3, that may serve as a reality check against my own, less favourable conclusions. Other things being equal, it would be unfortunate if different jurisdictions party to the EPC arrived at different conclusions concerning the same patent. However, other things are rarely equal, and the force of this point depends entirely on how far the factual and technical evidence before the foreign court was the same as the material before Arnold J, and how far their domestic statutes were comparable.

56. In France, the Tribunal de Grande Instance of Paris published its judgment on 8 July 2016. They appear to have had before them transcripts of at least part of the evidence given to Arnold J. They held that the Patent was sufficient because the occurrence of allodynia and hyperalgesia provided a unifying principle embracing both neuropathic and nociceptive pain. There are difficulties about this theory, as Arnold J pointed out (para 349), but for present purposes it is enough to say that this was the alternative argument which he refused to allow Warner-Lambert to run, a ruling which was not challenged before us.

57. In Germany, the Federal Patent Court ruled on 24 January 2017 that the Patent was invalid for lack of inventive step. It dealt only briefly with the objection of insufficiency, holding that it was "probable" that the disclosure was sufficient to enable the invention to be carried out. The court does not appear to have grappled with what in England would be called *Biogen* insufficiency. This judgment is also under appeal.

58. In Sweden, the Stockholm District Court, sitting as a Patent Court, gave judgment on 12 August 2016. This decision is final. The District Court came closer than those of France and Germany to grappling with the issues before us, but it received expert evidence which was not before Arnold J. The court applied the classic sufficiency test, asking whether the claim was plausible across the whole

scope of the claim. It considered that the mere mention of Bennett and the Kim and Chung test made the assertion of efficacy for treating neuropathic pain plausible, but it did not distinguish for this purpose between central and peripheral neuropathic pain. The Court of Appeal in the present case disagreed, on the ground that these were tests for peripheral neuropathic pain which could not justify a claim to efficacy for all neuropathic pain. I also disagree, both for that reason and for the wider reasons which I have already given.

59. After the argument was completed, we were supplied with the recent decision of the Full Court of the Federal Court of Australia on 23 February 2018. Australia is not, of course party to the European Patent Convention, and the court expressed reservations about applying the case law of the EPO Technical Board of Appeal or decisions under the United Kingdom Patents Act 1977 in an Australian statutory context. The court analysed the question solely in terms of classical insufficiency. It was therefore concerned only with the question whether the invention could be performed by the skilled man on the basis of the disclosure in the patent.

60. None of these decisions cause me to doubt the conclusions that I have reached as a matter of English law, in the light of the evidence given and the facts found in these proceedings.

Infringement: general

61. Patent infringement is a statutory tort. Section 60 of the Patents Act 1977 (so far as is relevant) provides as follows:

> "60.(1) Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say -
>
> (a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;
>
> (b) where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the

consent of the proprietor would be an infringement of the patent;

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

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

62. Some general points should be made at the outset about section 60 of the Patents Act. First, although liability for infringement is often said to be strict, section 60 of the Patents Act distinguishes between those heads of infringement which require proof of a mental element and those which do not. In short, under section 60(1)(a) and (c), there is no mental element. Liability, as Lord Hoffmann observed in *Merrell Dow Pharmaceuticals Inc v HN Norton & Co Ltd* [1996] RPC 76, 92, is absolute. "It depends upon whether the act in question falls within the claims and pays no attention to the alleged infringer's state of mind." On the other hand, an allegation of infringement under section 60(1)(b) (at any rate by offering the process for use in the United Kingdom), or an allegation of indirect infringement under section 60(2), on the other hand, requires proof of knowledge. In both cases, the knowledge required is encapsulated in the phrase "when he knows, or it is obvious to a reasonable person in the circumstances …". Secondly, section 60 uses a consistent conceptual approach to the relationship between the words product, process and invention. Invention is a class with only two members, product and process, and the invention in question is the subject matter of one or more claims in the patent. Thus, for the purposes of section 60, phrases about using the process, product or invention, or working the invention or putting the invention into effect need to be understood and applied by reference to the claim (or claims) in the patent alleged to be infringed.

Direct infringement: section 60(1)(c)

63. It is common ground that Swiss-form claims are purpose-limited process claims. Claim 3 of the patent in suit is not a product claim, because the product is not novel. It is a process claim because it protects the process of "preparation" (or manufacture) of a medicament containing pregabalin. It is purpose-limited because it only protects that process so far as it is undertaken "for" treating neuropathic pain. The monopoly claimed is a monopoly of preparation or manufacture of the product for the designated purpose. It is not a monopoly of the subsequent use of the product for that purpose. This is the basis on which Claim 3 is consistent with the prohibition of patents for methods of treatment or diagnosis. It follows that Warner-Lambert's allegation of direct infringement is and must be based on section 60(1)(c).

64. Section 60(1)(c) is concerned with cases where a product is obtained directly by means of the patented process. Infringement occurs whenever a person disposes of that product, offers to dispose of it, uses or imports it, or keeps it, whether for disposal or otherwise. The infringer may be, but need not be, the same as the person who makes the product. The section also applies to anyone in the downstream generic market, including wholesalers and pharmacists. Liability is strict. Provided only that the product has been obtained directly by means of the process, it extends to subsequent dealings with all and every such product irrespective of knowledge.

65. The current regime in the United Kingdom for the prescribing and dispensing of medicines is described in admirable detail by the judge, but the following summary will suffice. Unless there is good reason to do otherwise, doctors usually prescribe generically, by reference to the international non-proprietary name of the drug (the "INN"), rather than by brand or proprietary name. Thus, doctors would usually prescribe pregabalin rather than either Lyrica or Lecaent, regardless of whether they were treating a condition for which the original patent had expired, such as epilepsy, or a condition such as neuropathic pain for which patent protection still subsisted. Doctors do not usually include on their prescriptions any description of the condition (or "indication") being treated. Pharmacists are free to respond to generic prescriptions by dispensing either a branded or a generic product. Generic products are usually much cheaper than the branded product and, for that and other reasons, pharmacists have an incentive to dispense generic products where possible. They usually do so without knowing the indication for which the drug has been prescribed. Many prescriptions are collected by someone other than the patient. Patients may not know precisely the indication to which the prescription relates, in particular if they are using several drugs to address a combination of indications. It is usually impracticable for the busy pharmacist to contact the busy doctor to find out the indication for which pregabalin was prescribed. The result is that the pharmacist will not know whether the prescription addresses an indication which is patent-protected. The manufacturer and the supplier of generic pregabalin is even further removed from any actual knowledge of the use for which his product is being

prescribed. He knows only what can be inferred from published statistics about the market for different uses of pregabalin, and his own share of that market.

66. Because doctors commonly prescribe generically and the pharmacist generally does not usually know what indication is being treated, the use of "skinny labels" specifying the purpose of the generic product cannot reliably prevent the pharmacist from dispensing the generic product for a patent-protected use. Dispensing pharmacists know that Lyrica and Lecaent are identical, and the same dosage regime can be used for all indications for which pregabalin has received marketing authorisation. In March 2015, shortly after Lecaent came onto the market, the judge gave directions as a result of which the NHS in England, Wales and Northern Ireland (but not apparently in Scotland) issued guidance to doctors to prescribe Lyrica rather than pregabalin for neuropathic pain, and to pharmacists to dispense Lyrica in response to a prescription for generic pregabalin if told that the prescription was for the treatment of pain. It is by no means clear that it will always be appropriate to meet problems arising in relation to second medical use patents by guidance of this kind. Mr Silverleaf QC for the Secretary of State told us on instructions that the established conventions about prescribing generically had evolved for good reason, and could not lightly be discarded. In particular the use of INNs rather than proprietary names in prescription records served as clear and valuable guidance to other practitioners taking over the care of patients from the prescribing doctor. There was some evidence before the judge at the trial that his guidance had been effective in limiting the scale of the problem. What is, however, clear is that whatever steps are taken to limit the leakage of generic pregabalin into the patent-protected market, it is foreseeable that some generic pregabalin will be supplied in good faith by pharmacists to meet prescriptions which are intended by the prescribing doctors for the treatment of neuropathic pain.

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

was therefore enough to support a case of infringement of Claim 3 under section 60(1)(c) that it was foreseeable to the manufacturer that a more than *de minimis* amount of it would in due course be used for the treatment of neuropathic pain.

68. The Court of Appeal broadly accepted Warner-Lambert's submission subject to two qualifications. First, the downstream use for treating pain had to be intentional rather than accidental. By this they meant only that patients would receive the drug for treating their pain, rather than for example for treating epilepsy, with a coincidentally beneficial effect upon pain from which they happened also to suffer. The second qualification was more important. Floyd LJ held that the requisite mental element could be negatived if the manufacturer had taken all reasonable steps to prevent the downstream use of his drug for treating pain. At para 208 Floyd LJ said this:

> "The intention will be negatived where the manufacturer has taken all reasonable steps within his power to prevent the consequences occurring. In such circumstances his true objective is a lawful one, and one would be entitled to say that the foreseen consequences were not intended, but were an unintended incident of his otherwise lawful activity."

69. In his judgments on the application for an interim injunction [2015] EWCA Civ 556 (at paras 74-92) and the substantive appeal (paras 190-191), Floyd LJ considered another possibility, which he called (not entirely accurately) the "only packaging will do" approach. This approach, which he associated with the case law of the German courts, treats the question whether a product was manufactured "for" a designated purpose as depending only on whether there was some outward manifestation of that purpose in the manufacture itself, including any information about its purpose contained in the accompanying label or patient information leaflet. He rejected it because he considered that it gave insufficient protection to the patentee.

70. Before us, Warner-Lambert maintained their primary case, but adopted the Court of Appeal's qualified version of it as a fall-back. The Secretary of State, and other interveners with a stake in the market for treating the non-patented use, supported Actavis' case. No one adopted the "only packaging will do" approach. But after the hearing, the parties addressed it in writing, at the invitation of the court. Actavis adopted it by way of alternative to their primary case that the test required proof of subjective targeting. Warner-Lambert and the Secretary of State maintained their respective original positions.

71. It is clearly correct that this issue depends not on the meaning of section 60(1)(c) of the Patents Act but on the construction of the relevant claims in the patent. The question is what, as a matter of construction, does it mean to claim in a patent the use of pregabalin for the preparation of a medicament "for" treating neuropathic pain. In my view, most of the difficulty in answering this question arises from the view of both courts below that Claim 3 (and any other purpose-limited claim in Swiss-form) includes a mental element, namely the intention of the manufacturer, as part of the definition of the monopoly. This view is perhaps invited by the common use of the phrase "purpose-limited" to describe a claim in Swiss-form. The expression is convenient, but it elides a number of different concepts, not all of which involve a mental element. I think that a test for infringement which depended on intention, whether objective or subjective, would be contrary to principle and productive of arbitrary and absurd results.

72. It is first necessary to say something about the distinction between subjective and objective intention, which is legally fundamental. Subjective intention is a state of mind, ascertained as a matter of fact. A person may subjectively intend X if, for whatever reason, he deliberately does an act which is liable to bring X about, desiring it to happen. The degree of probability of X occurring may be relevant to the question whether it should be inferred as a fact that such a desire existed, but that is a question of proof and not of principle. Objective intention by comparison is not so much a matter of fact as an artificial construct for attributing legal responsibility. A person is taken to intend the ordinary and natural consequences of his acts. He objectively intends those consequences if they were foreseeable to a reasonable person, whether or not they were actually foreseen by him. Policy considerations may determine the degree of probability with which the consequence must be foreseeable if legal responsibility is to be attributed on that basis.

73. The first point to be made applies to any test of infringement based on intention, whether subjective or objective. A Swiss-form patent protects the process of manufacture of a product for the treatment of the designated condition. The hypothesis is that some of a generic manufacturer's output will be prescribed or dispensed for the treatment of the patent-protected indication and that the manufacturer intends this, subjectively or objectively. But it is not suggested that different parts of his output can be appropriated at the manufacturing stage to distinct therapeutic uses. If the manufacturer's intention is the touchstone, then the only intention that can realistically be attributed to him is that his output will be applied to the treatment of neuropathic pain as well as seizure disorders. If that intention is proved, the entire output will be tainted, including that part of it which is in fact prescribed and dispensed for the treatment of seizure disorders for which patent protection has expired. It will all have been "prepared" with the relevant intention on the part of the manufacturer. It follows that a distributor supplying or a pharmacist dispensing generic pregabalin will be dealing in a product obtained by means of a patented process within the meaning of section 60(1)(c) of the Act, and

will incur liability for infringement even if it has been prescribed for epilepsy rather than pain, because of the manufacturer's intention that it should be used for either or both. The interventions in the present appeal show that pharmacists are well aware of this risk. Their only safe course will be to refuse to deal with the generic product at all. This will in turn impact on generic manufacturers. They will be dissuaded from producing generic drugs even for treating the original indication which is no longer entitled to patent protection.

74. I deal first with the hypothesis that the test is subjective intention.

75. First, a patent is a public document. It is autonomous, in the sense that it is supposed to define exhaustively what the product or process is which is the subject of the legal monopoly. For the scope of the monopoly to be dependent on some extraneous fact not ascertainable from the patent but dependent on the state of mind of the manufacturer, is an extraordinary concept. It is not easy to see how it could be said to comply with the requirement of section 14(5)(a) of the Act that the claim in the patent application should "define the matter for which the applicant seeks protection". The same is true of the corresponding provision of EPC article 84. It is fair to say that a person can infringe a patent under section 60(1)(c) by handling a product obtained by the patented process, although it is not apparent from the product that it was obtained by the patented process. But that cannot be a reason for piling Pelion upon Ossa by holding that the patent need not even exhaustively define what the process is.

76. Secondly, if subjective intention is relevant, then liability under section 60(1)(c) extends to a person who infringes a purpose-limited patent by virtue not of his own intentions but of the intention of someone else, namely the generic manufacturer. I know of no other legal context in which the wrongfulness of an act can depend on the state of mind of someone other than the actor, to which the actor is not necessarily privy.

77. Thirdly, subjective intention implies choice. This is in particular true of the form of intention proposed by Actavis as relevant, namely "targeting" the patent-protected market. What the manufacturer of the generic product must intend is its use for the patent-protected purpose by prescribing physicians and dispensing pharmacists. Their practices are outside his control. He cannot meaningfully be said to choose that they will prescribe or dispense pregabalin for the treatment of pain merely by manufacturing it. A hope that they will do so is not the same as an intention.

78. Fourthly, the practical problems of applying a test based on subjective intention are striking. Suppose that the generic manufacturer makes pregabalin

intending it to be used for (inter alia) the treatment of pain, but that objective is not achieved? Does the mere intention taint the entire production run, even if it is all used for conditions such as epilepsy for which patent protection has expired? Suppose that the manufacturer makes more of the product than he believes can be sold for the treatment of seizure disorders or takes active steps to encourage its use for the treatment of pain. Is the liability of the importer, wholesaler or pharmacist to depend on whether the manufacturer resolved to take those steps at the time of manufacture or afterwards? No rational scheme of law could depend on such considerations as these. And all of this of course assumes that the manufacturer's state of mind can be proved. In the great majority of cases it would have to be inferred from his overt acts. In practice, the most that one can usually say is that use for the patent-protected purpose is an objectively foreseeable consequence of the manufacture of the product for distribution and sale. I turn therefore to Warner-Lambert's hypothesis that that is the test.

79. The foreseeability test has the merit of being objective, but there is in my view little else to commend it. Foreseeability is, as I have pointed out, a device for attributing legal responsibility to the person who should have foreseen the objectionable consequences of his acts, whether or not he actually did so. Its use as the basis for attributing legal responsibility to someone else seems to me to be entirely arbitrary. There are other difficulties about it. Since it is common ground that some more than *de minimis* leakage of generic pregabalin into the market for treating neuropathic pain is foreseeable whatever reasonable steps are taken, the simple foreseeability test means that all stocks of generic pregabalin will have been manufactured by use of the patented process regardless of the manufacturer's subjective intention. Consequently, any subsequent dealing with those stocks by importers, distributors or pharmacists will constitute infringements under section 60(1)(c). The result would be to give the patentee a *de facto* extension of the expired patent for the original use until the expiry of the patent for the new one.

80. Warner-Lambert recognised that this was likely to be an unacceptable result, and submitted that it could be mitigated by a flexible approach to remedies. Injunctions could be refused, they suggested, and financial recovery limited by confining the patentee to an account of the infringer's profits, based upon an assessment of the proportion of generic pregabalin dealt with by any infringer which is actually used for the treatment of pain. These concessions to reality may have been forensically necessary, but in my view they are no more satisfactory than the unqualified foreseeability test. First, they assume that dealers in generic pregabalin going about a lawful business of supplying it for its non-patented use are infringers. But they are entitled to conduct their trade lawfully, as no doubt most would wish to. The courts cannot properly adopt a solution that makes that impossible. Secondly, while the court may be able to withhold an injunction as a matter of discretion, damages are not a discretionary remedy. The patentee has, in principle, a right to elect between damages and an account of profits. They are alternative remedies, but

the choice is not the court's. Thirdly, an election by the patentee for damages would expose the infringer to liability for the loss of the patentee's profit margin on lost sales of the branded product. That will generally be much higher than the profit margin on the generic product, since it has to cover the patentee's research costs.

81. Warner-Lambert's alternative case is that the foreseeability test should be applied subject to the qualification proposed by the Court of Appeal, namely that the infringer had taken all reasonable steps to prevent leakage of generic pregabalin into the market for the patented use. The problem about this is while there are steps available to a manufacturer to limit the scale of the leakage of generic pregabalin into the market for the patent-protected use, there are no reasonable steps which will eliminate it entirely. Although the Court of Appeal described the taking of steps by the manufacturer as sufficient to negative intention to manufacture pregabalin for the patent-protected purpose, it will not in fact negative it if the test of intention is foreseeability. This is because the manufacturer will be taken to intend the foreseeable leakage notwithstanding the steps taken to reduce its scale. In reality, what the Court of Appeal has proposed is not a way of negativing intention. It is a non-statutory defence to infringement. Such a defence may or may not be desirable. But Parliament has not provided for one, and it is not the function of the courts to invent non-statutory defences to statutory torts. Least of all is it their function to invent a non-statutory defence to a statutory tort of strict liability, which is subject to limited express statutory defences none of which applies. It is right to add that the Court of Appeal's compromise is likely to be legally uncertain and practically unworkable. How are distributors or pharmacists to know what steps have been taken by the manufacturer to prevent leakage, or whether they will be regarded by the court as reasonable? Warner-Lambert do not suggest that the reasonable steps required of the generic manufacturer will be limited to skinny labelling or some other precaution visible to users of the generic product.

82. The claims fall to be interpreted, in accordance with the Protocol on the interpretation of article 69 EPC, on a basis which "combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties." What is fair or reasonable for these purposes falls to be considered in the light of the central objectives of this area of law. It is possible to identify four such objectives. They are:

> 1. To provide reasonable protection to the second medical use patentee, so as to reward and to incentivise the complex and expensive processes of research and testing necessary to bring these valuable uses to the market. That protection needs, as far as is consistent with competing policy objectives, to protect the patentee against the invasion of his monopoly by competitors.

2. To allow the public the benefit of the product for its original therapeutic use, unconstrained by any patent rights once the patent covering that use has expired. As Sir Donald Nicholls VC famously observed in *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* [1995] RPC 233, 238, "patents exist today to reward and thereby encourage inventors; they are not intended to make it possible to take out of public use processes or products already made available to the public." The patentee has had the reward of his invention for the original use and should not obtain, by a side wind, an effective continuing monopoly in relation to the original use after the expiry of the patent protection for it.

3. To provide reasonable legal certainty for those engaged in the manufacture, marketing and prescribing of the generic drug for the non-patented use, that their conduct is lawful. This policy objective is expressly recognised by the Protocol and, without it, the second objective is unlikely to be achievable.

4. To protect the autonomy of clinical judgments. The prohibition in EPC article 52(4) (now article 53(c)) and section 4(2) of the Patents Act) of patents for methods of treatment or diagnosis has been described by the EPO Technical Board of Appeal as securing that medical and veterinary practitioners are "free to use their skills and knowledge of the best available treatments to achieve the utmost benefit for their patients uninhibited by any worry that some treatment might be covered by a patent": G 0001/07 *MEDI-PHYSICS/Treatment by surgery* [2010] EPOR 25 at para 3.3.6.

83. The foreseeability test, in either its qualified or unqualified form, would achieve objective 1 but frustrate objectives 2, 3 and 4. The subjective targeting test would probably achieve a reasonable balance between objectives 1 and 2, but it would not serve objectives 3 and 4. I conclude that the intention of the manufacturer, whether subjective or objective, is irrelevant to the question of infringement.

84. In my opinion, in a purpose-limited process claim, the badge of purpose is the physical characteristics of the product as it emerges from the relevant process, including its formulation and dosage, packaging and labelling and the patient information leaflet which in EU (and other) countries will identify the conditions for whose treatment the product is intended. I shall call this, for want of a better phrase, the "outward presentation" test. I adopt it for the following reasons. First, it provides an objective test, which is not dependent on proof of the internal cogitations of the manufacturer. The patient information leaflet is not just a public statement of the use for which the product is made, but one which is directly addressed to the potential user, ie to those persons whose acts are potentially within section 60(1)(c), namely importers, distributors, pharmacists and patients. Accordingly, it avoids the

unacceptable anomalies associated with a test based on the manufacturer's subjective intention. Secondly, as the EPO has recognised (see para 26 above), in a purpose-limited claim, the designated purpose is an inherent characteristic of the invention. The outward presentation test is consistent with this notion. A test based on intention is not. This is because the manufacturer's state of mind in exploiting the process is not a characteristic of the invention. It is a characteristic of the inventor, coming into being after (usually long after) the invention has been made and the patent granted. Likewise, the market conditions which may make some consequence of manufacture objectively foreseeable are not a characteristic of the invention. They arise from subsequent facts. Third, the outward presentation test properly reflects the critical feature of Swiss-form patents, namely that the patent is for the process of manufacture, not for the subsequent use that may be made of the product. The physical presentation of the product is generally part of the process of manufacture. Subsequent activities of the manufacturer in marketing the product are not. Fourth, it provides legal certainty, in particular for those downstream of the manufacturer who deal in the product. Fifth, and critically, it strikes a fair balance between the public interest in rewarding the invention by allowing the patentee to exploit his monopoly and the public interest in the free use of the invention for therapeutic uses which do not have, or no longer have, patent protection. In my opinion, it satisfies all four policy objectives governing the interpretation of patent claims which I summarised at para 82 above. Finally, the outward presentation test derives some support from the case law of the EPO Technical Board of Appeal. The Board does not of course deal with infringement claims, but it has construed purpose-limited claims as referring to the purpose identified by reference to the characteristics of the product. In T 1673/11 *GENZYME/Treatment of Pompe's disease* [2016] EPOR 33, the patent claimed use of human acid alpha glucosidase in the manufacture of a medicament for the treatment of infantile Pompe's disease. In opposition proceedings, the Board (para 9.1) defined the scope of the claim as limited to

> "the manufactured medicament which contains as an active substance human acid alpha glucosidase in the 100-110 kD form *and which is packaged and/or provided with instructions for use in the treatment of infantile Pompe's disease*." (Emphasis added)

85. "Outward presentation" is a rough paraphrase of the German "sinnfällige Herrichtung" which is the major part of the test of infringement applied to purpose-limited patent claims by the German courts: see *Antivirusmittel* (Case X ZR 51/86) (Bundesgerichthof, 16 June 1987), (1987) GRUR 794, at para 18; *Chronische Hepatitis C - Behandlung/Ribavirin I* (Case 4a O 145/12) (Landgericht Düsseldorf, 24 February 2004); *Chronische Hepatitis C - Behandlung/Ribavirin II* (Case 4a O 145/12) (Landgericht Düsseldorf, 14 March 2013); *Cistus Incanus* (Case I-2 U 53/11) (Oberlandesgericht Düsseldorf, 31 January 2013). This is why Floyd LJ

associated what he called the "only packaging will do" test with German law. It is, however, important to guard against the over-ready transfer of concepts from one legal system to another, in which the legal context may be different. For the purpose of determining infringement, German law does not distinguish between product and process claims in the clear-cut way that the United Kingdom Patents Act does. In either case, the monopoly claimed may be treated as extending to the use made of the product after its manufacture: *Patentgesetz*, section 9 and *Dexmedetomidin* (Case I-2 U 30/17) (Oberlandesgericht Düsseldorf, 1 March 2018), (BeckRS 2018, 2410, at paras 41-43). Moreover, many of the anomalies considered above are avoided in German law by the limitation of monetary remedies for infringement to cases of deliberate or negligent infringement, although negligence will readily be assumed: *Patentgesetz*, section 139(2). This background explains why the German courts, while applying an objective test, have been prepared on appropriate facts to find infringement of purpose-limited claims on a wider basis than the mere presentation of the product: see *Östrogenblocker* (Case I-2 W 6/17) (Oberlandesgericht Düsseldorf, 5 May 2017) at para 39, and *Dexmedetomidin* (Case I-2 U 30/17) (Oberlandesgericht Düsseldorf, 1 March 2018) at para 44.

86. However, whether or not it is soundly based on German law, Floyd LJ's objection to the "only packaging will do" test deserves to be considered on its merits. His main point was that once it was accepted (as it was, by both parties before him) that there was a mental element in a purpose-limited claim, there was no reason to limit the evidence of the manufacturer's intention to the physical presentation of the product. As he pointed out (para 191), "packaging may be a means of demonstrating the necessary mental element, whatever that is, but it cannot possibly be the only means of doing so." I accept that there is force in this point, which is one reason why I reject the importation of a mental element in the claim. It falls away if the mental element is discarded. More pertinent is Floyd LJ's objection that an outward presentation test gives insufficient protection to the patentee. One can imagine circumstances in which the labelling and the patient information leaflet of a generic manufacturer might be regarded as a charade. He might, for example, manufacture pregabalin with the intention of supplying an unexceptionable label and patient information leaflet but then encouraging dealers and pharmacists to supply it for the treatment of pain. To the extent that this is a realistic scenario, the outward presentation test may be imperfect. But I cannot regard the existence of such imperfections as decisive, for two reasons. In the first place, the patentee's interest, although important, is not the only consideration. As I have pointed out by reference to the Protocol on the interpretation of EPC article 69, the interpretation of a claim requires the court to take account both the reasonable protection to which the patentee is entitled and the need for legal certainty for third parties. Broader policy objectives, including the public interest in the free exploitation of a product for a patent-expired use, are also relevant. This may involve, as it does in this case, a compromise between opposing and incommensurate factors. It may be thought anomalous that the manufacturer of the generic product should be free of liability if he markets it for a patent-protected use provided that he labels it as being for a non-

protected use. But to my mind it is a far greater anomaly that in a "charade" case the generic manufacturer's intention exposes to liability not just himself but any pharmacist who handles his product even if he scrupulously supplies it only for a non-protected use. Secondly, the imperfect nature of the protection conferred by an outward presentation test arises, as it seems to me, from a limitation inherent in a Swiss-form patent. A person's exposure to liability for infringement depends on the purpose for which the patent-protected product was manufactured. The patentee's protection is therefore necessarily incomplete. A test which treated the claim as extending to the promotion of the product after its manufacture appears on the face of it to ignore this limitation. There is no perfect solution to this problem in the absence of a general defence of good faith available to third parties, such as exists in Germany in the case of claims to monetary remedies. But we are not in a position to add such a defence to the UK Patents Act. I consider that the outward presentation test is less imperfect than any other. The evidence does not enable us to say how serious the problem identified by Floyd LJ really is. The legislation was not drafted with purpose-limited products in mind, and if it proves to be serious it must be for the legislature to address it.

Indirect infringement: section 60(2)

87. Warner-Lambert's alternative case of infringement, based on section 60(2) can be shortly dealt with. Section 60(2) is concerned with indirect infringement, ie with cases where a person incurs liability for infringement by knowingly supplying to a primary infringer the means of putting the invention into effect. There is a mental element in indirect infringement, for knowledge is expressly required. But it is unnecessary on this appeal to explore what that entails. Lecaent is manufactured by Balkanpharma in Bulgaria to the order of Actavis, which then imports and markets it in the United Kingdom. This case has proceeded at all levels on the basis that Actavis can be treated as if they were the manufacturer. The infringement case under section 60(2) is that, in supplying Lecaent in the United Kingdom, Actavis are knowingly "supply[ing] in the United Kingdom a person … with … means, relating to an essential element of the invention, for putting the invention into effect". The argument is that "the invention" is the use of pregabalin to treat neuropathic pain, and that it is "put into effect" when a pharmacist dispenses a pack of Lecaent against a prescription written by a doctor for neuropathic pain. Therefore by supplying Lecaent (directly or indirectly) to pharmacists Actavis supply them with the means for putting the invention into effect.

88. The short answer to this is that the invention protected by Claim 3 is the manufacture of pregabalin for the designated use, and not the subsequent use of the product for treating patients. This is what the Court of Appeal decided, correctly in my view, in *Menashe Business Mercantile Ltd v William Hill Organisation Ltd* [2003] 1 WLR 1462: see para 24 (Aldous LJ). It was the ground on which the judge struck out the indirect infringement claim on the interlocutory application of

Actavis. It was re-instated by the Court of Appeal as arguable. At trial, Arnold J held that the argument was bad. In the Court of Appeal, Floyd LJ adhered to his earlier view. He accepted that *Menashe* was authority for the proposition that the "invention" in section 60(2) was the process identified in the relevant claim. But he considered that the "preparation" referred to in the claims might still not be put fully into effect until the pharmacist had dispensed the medicament and affixed a sticker with the patient's name on it. He warned against the danger of translating section 60(2) into infringement limited to acts upstream of manufacture. In my view Arnold J was right about this. The whole purpose of the Swiss-form for purpose-limited medical use claims is to avoid the problem of lack of novelty associated with product claims and the statutory provision which makes a method of treatment unpatentable. It is well understood that the degree of protection available from a Swiss-form claim may be more limited than that available from standard product claims. These essential features of purpose-limited patents are fatal to any attempt to construe Claim 3 as extending to steps taken by the pharmacist.

Disposal

89. For these reasons, I would dismiss Warner-Lambert's appeal and allow the cross-appeal of Actavis and Mylan on insufficiency.

LORD BRIGGS:

Overview

90. I am grateful to Lord Sumption for his introduction to this difficult appeal. In bare outline, and adopting his classification of the issues, I consider that the Court of Appeal was correct on the issues as to construction, amendment and abuse of process, for reasons which I shall shortly give. I agree with Lord Sumption's reasons for concluding that both the judge and the Court of Appeal were wrong on the issue of sufficiency. But I have reached a different conclusion from his on the issue about infringement. We both agree that the Court of Appeal's test for infringement was wrong, as is the test proposed by the appellants. For the reasons given below I have concluded that the judge and the respondents in their primary case were broadly right, on the test for infringement of a patent for a purpose-limited process claim.

Construction

91. Claim 3 claims "use of [pregabalin] for the preparation of a pharmaceutical composition for treating neuropathic pain". The question is whether "neuropathic pain" in its context means all neuropathic pain, including central neuropathic pain

(as Actavis and Mylan contend), or only peripheral neuropathic pain (as Warner-Lambert say). I will call these the broad and narrow constructions respectively. Both the judge and the Court of Appeal decided without, it seems, much difficulty, in favour of the broad construction. I agree with them.

92. There is no issue about the basic principles of construction. Section 125(1) of the Patents Act 1977 provides that the claim must be:

> "interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly."

Section 125(3) provides that:

> "the Protocol on the Interpretation of article 69 of the European Patent Convention (which article contains a provision corresponding to subsection (1) above) shall, as for the time being in force, apply for the purposes of subsection (1) above as it applies for the purposes of that article."

The Protocol provides:

> "Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and the drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties."

The Claims must be construed in their context in the patent as a whole, including its summary and detailed description and the teaching which it discloses. A course must be steered between the Scylla of slavish literalism and the Charybdis of pure purposiveness, a task which recent English cases about construction generally

suggest requires a constant hand on the tiller. The object is to interpret them as they would be understood by a person skilled in the art, with all the common general knowledge available to such a person as at the priority date.

93. The only substantial difference between the parties about the principles of construction arose from Lord Pannick QC's submission on behalf of Warner-Lambert that patents should be construed on the principle of validating construction. In other words, where possible, a construction should be preferred which results in the relevant claim be treated as valid (*ut res magis valeat quam pereat*). The principle is well established as applied to the construction of contracts and subordinate legislation. But there is some English authority for its application to patents. In *Parkinson v Simon* (1895) 12 RPC 403, which was decided long before the Protocol was adopted, Lord Davey observed, at p 411.

> "if the language of a claim be ambiguous, and if it be fairly capable of two constructions, the court would be disposed to adopt that construction which would uphold the patent, and not that which would render it invalid."

94. More recently, the same point was made by Neuberger J in *Kirin-Amgen Inc v Roche Diagnostics GMBH* [2002] RPC 1, para 286. There is also substantial support for it in other common law jurisdictions. It was adopted by the Supreme Court of the United States in *Turrill v Michigan Southern Railroad Co* (1863) 68 US (1 Wall) 491 and *Klein v Russell* (1873) 86 US (19 Wall) 433. And more recently by the Full Court of the Federal Court of Australia in *H Lundbeck A/S v Alphapham pty Ltd* (2009) 177 FCR 151. Emmett J observed in that case, at para 52:

> "A specification must be given a purposive rather than a purely literal construction and must be construed in a practical common-sense manner, avoiding a too technical or narrow construction in favour of a construction under which the invention will work, as against one according to which it may not work."

In *Letourneau v Clearbrook Iron Works Ltd* (2005) FC 1229 in the Federal Court of Canada there are dicta to much the same effect, at para 38.

95. Nonetheless, in my opinion, validating construction will not usually have a significant place in modern patent law. The main problems about it were well stated by Sedley LJ (with whom Aldous LJ agreed) in *Smithkline Beecham plc's Patent* [2003] RPC 49, at para 103.

> "Because the law has historically been suspicious of monopolies for well-known reasons of public policy, there is no useful analogy between a patent and a deed or a written contract. The latter two will have been drafted for a purpose which, assuming it not to be illegal or contrary to public policy, the law will do what it properly can to uphold. A patent, by publicising an invention, makes it the patentee's sole property for 20 years, so that the patentee's immediate interests are in opposition to those of the rest of the world. It is in society's longer-term interests that, by setting the two things in balance, genuine innovation should be protected and rewarded without stifling further invention. Lord Davey's approach, and any analogue of it, would reward opaque drafting as objectionably as the infringers' defence in cases like *Edison Phonograph* seeks out opacity where, on a fair-minded reading, there is none. The Convention and Protocol place such exercises off limits in a way which, it seems to me, our law well understands and which sits comfortably with the wording and intent of section 125(1)."

96. Lord Davey's statement in *Parkinson v Simon* was a thing of its time. Validating construction was developed as a principle of interpretation during the 19th century as a counter-weight to strict grammatical construction at a time when the latter was otherwise the dominant rule. Its importance in modern times has been greatly diminished by the emergence of purposive construction, as applied to contracts and legislation as well as to patents: see *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183, HL(E). Validating construction is now often mentioned as if it were but one aspect of that modern approach. It is also right to remember that until 1919 the court's power to amend a patent was extremely limited and that it did not assume its present wide form until 1977. In Lord Davey's time and for many years thereafter, it was natural to apply to patents the same principle of validating construction which applied to contracts and delegated legislation, neither of which could be saved except by striking out severable provisions (the so-called "blue pencil test").

97. The principles of construction embodied in the European Patent Convention will not necessarily correspond to those applied in the law of the United States and other common law countries. The Protocol strikes a careful balance between the conflicting interests involved: between literal and purposive construction, between maintaining competition and rewarding invention, and between fair protection for the proprietor and reasonable legal certainty for potential competitors. The latter consideration is reinforced by the express requirements of clarity and definition in section 14(5)(a) and (b) of the Patents Act 1977 and the corresponding provisions

of EPC article 84. A presumption in favour of validity would cut across the legal policies underlying patent protection in all of these respects.

98. These considerations apply to all patents, but they are perhaps particularly important in relation to second medical use patents. There is a positive public interest in the active ingredient becoming available to be used freely for the original use after the patent for that use has expired, because that is the *quid pro quo* for the prior 20 years monopoly granted to the patentee. It follows that there is a particular need for legal certainty in fixing the dividing line between the original use and the new one. There are therefore sound reasons of policy for requiring clarity in the claims of patents of this kind. None of this means that claims are to be construed with a predisposition to find fault, or the description read with a mind that is not willing to learn. But it does require that an issue as to the construction of a claim should be addressed, as far as possible, by deciding what it really does mean, rather than by too easily accepting that there is ambiguity, and resolving it by inventing a meaning which saves the claim from invalidity.

99. I turn to the meaning of Claim 3. Warner-Lambert argues for the narrow construction on the following main grounds:

> 1. There was no settled usage among those skilled in the art at the priority date as between the broad and the narrow meaning, so that its meaning in the context of the Patent has to be derived from its detailed contents.
>
> 2. The specification, particularly in paragraphs 3 and 6, points to the narrower construction, both as a matter of definition and because it cites examples of peripheral neuropathic pain only, making no mention of the main examples of central neuropathic pain, so that the phrase neuropathic pain in Claim 3 should be construed *eiusdem generis*.
>
> 3. In the event that (1) and (2) leave the meaning ambiguous, the validating principle should be applied, in favour of the narrow construction.

100. Ground (1) is correct up to a point. It is common ground that the skilled team would at the relevant time have known of the definition of neuropathic pain by the International Association for the Study of Pain ("IASP") in its publication *The Classification of Chronic Pain* as including both peripheral and central neuropathic pain. The note to the definition ("Peripheral neuropathic pain occurs when the lesion or dysfunction affects the peripheral nervous system. Central pain may be retained as the term when the lesion or dysfunction affects the central nervous system.") shows that the distinction between the two was well understood. This is not

inconsistent with the evidence given by some but not all of the experts that a skilled team might use the phrase "neuropathic pain" in a broader or narrower sense, depending upon the context. Given the distinction between the two kinds of neuropathic pain, and the need for precision in the drafting of the Claims, the use in Claim 3 of the global expression is significant.

101. Ground (2) calls for a careful examination of paragraphs 3 and 6 of the description against the background of the full list of claims. Paragraphs 3 and 6 of the description are in the following terms:

> "[0003] The instant invention is a method of using a compound identified below in the treatment of pain, especially for treatment of chronic pain disorders. Such disorders include, but are not limited to, inflammatory pain, postoperative pain, osteoarthritis pain associated with metastatic cancer, trigeminal neuralgia, acute herpetic and postherpetic neuralgia, diabetic neuropathy, causalgia, brachial plexus avulsion, occipital neuralgia, reflex sympathetic dystrophy, fibromyalgia, gout, phantom limb pain, burn pain, and other forms of neuralgic, neuropathic, and idiopathic pain syndromes.
>
> [0006] The instant invention is a method of using (S)-3-aminomethyl-5-methylhexanoic acid or a pharmaceutically acceptable salt thereof as an analgesic in the treatment of pain as listed above. Pain such as inflammatory pain, neuropathic pain, cancer pain, postoperative pain, and idiopathic pain which is pain of unknown so origin, for example, phantom limb pain are included especially. Neuropathic pain is caused by injury or infection of peripheral sensory nerves. It includes, but is not limited to pain from peripheral nerve trauma, herpes virus infection, diabetes mellitus, causalgia, plexus avulsion, neuroma, limb amputation, and vasculitis. Neuropathic pain is also caused by nerve damage from chronic alcoholism, human immunodeficiency virus infection, hypothyroidism, uraemia, or vitamin deficiencies. Neuropathic pain includes, but is not limited to pain caused by nerve injury such as, for example, the pain diabetics suffer from."

102. The full list of claims is as follows:

“1. Use of (S)-3-(aminomethyl)-5-methylhexanoic acid or a pharmaceutically acceptable salt thereof for the preparation of a pharmaceutical composition for treating pain.

2. Use according to Claim 1 wherein the pain is inflammatory pain.

3. Use according to Claim 1 wherein the pain is neuropathic pain.

4. Use according to Claim 1 wherein the pain is cancer pain.

5. Use according to Claim 1 wherein the pain is postoperative pain.

6. Use according to Claim 1 wherein the pain is phantom limb pain.

7. Use according to Claim 1 wherein the pain is burn pain.

8. Use according to Claim 1 wherein the pain is gout pain.

9. Use according to Claim 1 wherein the pain is osteoarthritic pain.

10. Use according to Claim 1 wherein the pain is trigeminal neuralgia pain.

11. Use according to Claim 1 wherein the pain is acute herpetic and postherpetic pain.

12. Use according to Claim 1 wherein the pain is causalgia pain.

13. Use according to Claim 1 wherein the pain is idiopathic pain.

> 14. Use according to Claim 1, wherein the pain is fibromyalgia pain."

103. Warner-Lambert argues that the third sentence of paragraph 6 of the description is a definition of neuropathic pain as peripheral pain, because it identifies the peripheral sensory nerves as the location of its cause. They say that such of the long list of particular types of pain in paragraphs 3 and 6 as can be fitted within neuropathic pain are all examples of peripheral neuropathic pain. They point out that the two best known types of central neuropathic pain, namely stroke and multiple sclerosis, are not mentioned anywhere in the description or the claims.

104. These points are also correct, up to a point. However, I do not accept that the third sentence of paragraph 6 of the description is a general definition of neuropathic pain for the purposes of the remainder of the patent, or that paragraphs 3 and 6 as a whole implicitly limit the invention to peripheral neuropathic pain. My reasons are as follows:

> 1. The starting point is paragraph 3 of the description, which contains the summary of the invention. The list of conditions to be found there is expressly described as non-exclusive ("include, but are not limited to"). Paragraph 6 of the specification is an expansion of paragraph 3. It is headed "Detailed Description" and describes an invention for the treatment of "pain", as listed above.
>
> 2. Although the third sentence of paragraph 6 would support the narrow definition if read on its own, it is in fact one of three descriptions of the causes of neuropathic pain in paragraph 6. Its function is simply to introduce the next sentence which contains illustrative examples of peripheral neuropathic pain. The second place where neuropathic pain is described includes vitamin deficiencies, which can cause both central and peripheral neuropathic pain. The third is deliberately expressed in non-exclusive terms ("includes, but is not limited to"). It is correct that there is no express reference to pain from strokes or multiple sclerosis, but these are by no means the only types of central neuropathic pain.
>
> 3. Claim 3 appears in a list of claims which begin at the broadest level of generality and then descends by stages to the more particular. Claim 1 covers all pain, without exception. Claims 2 and 3 then divide pain into two classes of pain which cover substantially the whole field except for idiopathic pain, the subject matter of Claim 13. Thus Claim 2 covers all kinds of inflammatory pain while Claim 3 covers all kinds of neuropathic pain. All the remaining

claims, apart from Claim 13, relate to more narrowly defined types of pain which fall within either of Claim 2 or Claim 3.

4. The descriptions in paragraphs 3 and 6 of the specification have to be read as addressing all the claims, rather than focussing on particular claims by way of narrowing their scope. They repeatedly use words of inclusion rather than exclusion. Bearing in mind that the skilled team would have been aware that a well-known published classification of neuropathic pain was a broad one which included both central and peripheral elements, they would not be prompted by the language of paragraphs 3 and 6 to look for some sign that neuropathic pain was being used in a narrower sense than it appears to have in the hierarchy of the Claims.

5. Paragraphs 3 and 6 are in my view an example of torrential drafting designed to make the widest possible assertions of the utility of pregabalin for pain relief, ahead of a set of claims deliberately designed to go first for the broadest classes of use monopoly, (Claims 1 to 3), with more narrowly drawn fall-back claims (Claim 4 and following) if the broad classes should prove invalid.

105. Turning to Warner-Lambert's Ground 3, even if the validating principle has some limited role to play in construing a patent, I would not have regarded Claim 3 as an occasion for applying it, because Claim 3 is not in my view ambiguous. Ambiguity is the necessary condition for applying an interpretative presumption of this kind. The principle does not authorise the construction of the patent so as to create an ambiguity which can then be resolved in favour of validity.

106. In the result, I arrive at the same conclusion as the courts below, even if their emphasis on particular points may not be identical to mine. The judge may have been wrong, as the Court of Appeal said he was, to describe fibromyalgia and phantom limb pain as types of central neuropathic pain, but this does not undermine the central thrust of his analysis of the construction of Claim 3.

Amendment and abuse of process

107. Arnold J handed down his trial judgment on 10 September 2015. Warner-Lambert responded to their failure on sufficiency in relation to central neuropathic pain by applying on 1 October 2015 to amend Claim 3 by adding to the end the words "caused by injury or infection of peripheral sensory nerves". Following previous Court of Appeal guidance that applications to amend a patent should be decided by analogy with the principles applicable to the amendment of pleadings,

the judge refused the application. He concluded that it would give rise to issues (of clarity, added matter and sufficiency) requiring a further trial, that this could have been avoided by an application to amend (if necessary in conditional terms) before or even during the trial. He thought that it was an abuse of process to leave the application until after the handing down of judgment. The Court of Appeal agreed.

108. Warner-Lambert challenge this decision before us on three main grounds. First, they submitted that the assimilation of the principles governing the amendment of a patent to those governing the amendment of pleadings wrongly denied the patentee the benefit of the right to amend conferred by section 75 of the Act and article 138(3) of the EPC. Secondly, it is said that Claim 3 had been found to be partially valid, so that an amendment should have been allowed as of course, to bring it into line with the judge's decision on validity. Thirdly, it is submitted that the judge's decision, even applying English procedural jurisprudence concerning the amendment of pleadings, involved a disproportionate penalty, because any prejudice to Actavis and Mylan of having to participate in a second trial could be addressed by an appropriate order for costs. Given our majority conclusion that the patent is insufficient for want of support in the specification for the efficacy of pregabalin for treating any neuropathic pain, it will be apparent that the proposed amendment will not save Claim 3. However, the matter having been argued, I think it right to deal with it.

109. Warner-Lambert's first ground raises an important question of law. If they are right, it would be necessary to overrule a number of decisions of the Court of Appeal. There was originally no power in England to amend a patent. A discretionary power of the court to allow amendment of a patent by way of disclaimer in an action for infringement or proceeding for revocation was first introduced by section 21 of the Patents and Designs Act 1907. The power was subsequently extended by the Patents and Designs Act 1919 to include amendment by way of correction or explanation. The power thus conferred was continued by the Patents Act 1949.

110. Meanwhile the EPC, in its original form, introduced a provision for amendment, in article 138(2):

> "(2) If the grounds for revocation only affect the European patent in part, revocation shall be pronounced in the form of a corresponding limitation of the said patent. If the national law so allows, the limitation may be effected in the form of an amendment to the claims, the description or the drawings."

Its language reflected the fact that, at that time (in 1973) some contracting states did, but others did not, provide for amendment of patents.

111. Section 75(1) of the Patents Act 1977, responding to the EPC and its ratification by the United Kingdom, continued a discretionary power of amendment in the following terms:

> "In any proceedings before the court or the comptroller in which the validity of a patent is put in issue the court or, as the case may be, the comptroller may, subject to section 76 below, allow the proprietor of the patent to amend the specification of the patent in such manner, and subject to such terms as to advertising the proposed amendment and as to costs, expenses ·or otherwise, as the court or comptroller thinks fit."

112. The EPC 2000 modernised the convention provision for amendment by adding article 138(2) and (3) as follows:

> "(2) If the grounds for revocation affect the European patent only in part, the patent shall be limited by a corresponding amendment of the claims and revoked in part.
>
> (3) In proceedings before the competent court or authority relating to the validity of the European patent, the proprietor of the patent shall have the right to limit the patent by amending the claims. The patent as thus limited shall form the basis for the proceedings."

113. Section 75 of the Patents Act 1977 was then amended by the Patents Act 2004 by the introduction of a new subsection (5):

> "(5) In considering whether or not to allow an amendment proposed under this section, the court or the comptroller shall have regard to any relevant principles applicable under the European Patent Convention."

The main change wrought by the EPC 2000 was that amendment was no longer subject to the presence or absence of the necessary power in national law. The amended Convention provided for a Europe-wide right to amend. The question is whether that change was intended not merely to require all contracting states to have

a power of amendment, or went one stage further, elevating what had previously been a discretionary power in the national court into a right enjoyed by patentees, unqualified by any discretion afforded to national courts by their own law.

114. To that question the Court of Appeal has thus far provided a clear answer. In *Nikken Kosakusho Works v Pioneer Trading Co* [2005] EWCA Civ 906, [2006] FSR 4, it drew a sharp distinction between (a) pre-trial patent amendments, (b) post-trial patent amendments to delete claims which had been found invalid, and (c) post-trial patent amendments designed to set up a new claim which had not been adjudicated upon at trial. If a type (c) amendment would provoke a validity challenge which required a further trial then, generally, both the principle in *Henderson v Henderson* (1843) 3 Hare 100 and the Overriding Objective in the Civil Procedure Rules would militate against giving permission to amend, if the new claim could have been put forward by amendment in time for the first trial.

115. In *Nokia GmbH v IPCom GmbH & Co KG* [2011] EWCA Civ 6; [2011] FSR 15, the Court of Appeal took the opportunity to consider whether either *Johnson v Gore Wood & Co* [2002] 2 AC 1 or article 138(3) of the EPC (as amended in 2000) required the principles laid down in the *Nikken* case ("the *Nikken* principles") to be reconsidered. Jacob LJ held, at paras 108-109 that there was nothing in *Johnson v Gore Wood* inconsistent with the *Nikken* principles. Although the test was one of abuse of process and the onus on the person alleging abuse, vexing a defendant with two trials about the same patent by means of a post-trial amendment was prima facie abusive, if the amendment could have been made in time for all issues about the patent to be adjudicated upon at a single trial. As for article 138(3), the creation of a right to amend was simply designed to ensure that all contracting states provided for amendment of patents. It was not designed to override the national law of each state about the timing, grant or refusal of amendments, and certainly not to legitimise what would otherwise be the abuse of a contracting state's process: see paras 127-129.

116. *Nikken* and *Nokia* were followed and applied both by the judge and by the Court of Appeal in the present case. Faced with submissions that several European states took a more relaxed view about amendment after a trial at first instance, Arnold J said this [2015] EWHC 3370 (Pat); [2016] RPC 16, para 23:

> "Secondly, and more fundamentally, any assessment of abuse of process must depend upon the procedural rules applicable in the relevant jurisdiction, which will reflect the procedural philosophy applicable in that jurisdiction. But the EPC Contracting States differ not merely in their procedural rules, but also in their procedural philosophies. Thus there are different conceptions of procedural economy. The traditional

> English conception is that it requires the first instance court to adjudicate upon all essential points in dispute, certainly all points that require findings of fact or evaluation. In that way, if there is an appeal, the Court of Appeal is in a position to deal with any issues of law that may then arise and dispose of the case without either a re-hearing or remitting it to the first instance court. By contrast, there are many civil law jurisdictions where the view is taken that the correct approach to procedural economy is for the first instance court only to decide the issues which are sufficient to enable that court to dispose of the case, and to leave other issues undecided."

In the following two paragraphs he made similar observations about differing procedural philosophies at the appellate level.

117. An approach which treats procedural issues about amendment in national patent proceedings as turning upon national procedural law and philosophy is not just an English eccentricity. In *High Point SARL v KPN BV* (15 September 2017) 16/00878 ECLI:NL:HR:2017:2363 the Hoge Raad of the Netherlands held, at [4.1.6-4.1.7] that EPC article 138(3) was designed only to ensure that all contracting states made sure that their national laws made provision for amendment of patents, with no objective to achieve greater harmonisation than that. Procedural requirements for that purpose remained a matter for the national law of each state. Cross-reference to passages in the Advocate General's Opinion cited by the court show that in reaching that conclusion it had in mind the application of the abuse principle by the judge in this very case, following *Nokia.*

118. It is of course open to this court to adopt a different position on this question than either the series of decisions in the Court of Appeal, or the views of the Supreme Court of the Netherlands. But I can see no good reason why we should do. First, no authority to the contrary, here or elsewhere in Europe, was cited to us. Secondly, I find the analysis of Arnold J of the reasons why different contracting states should have different procedural rules and principles about amendment, cited above, to be compelling. Thirdly, nothing in the language of article 138 suggests that the Court of Appeal and the Supreme Court of the Netherlands have got its purpose and effect wrong. Finally, matters of procedure are pre-eminently a matter for the Court of Appeal, and this court is slow to interfere in a consistent development of procedural principle by that court unless persuaded that it is clearly wrong.

119. I can deal briefly with the second ground, namely that this was an amendment to a partly valid patent. That is literally true, even given our conclusions on insufficiency, since the claims relating to different types of inflammatory pain have survived. But it misses the point of the *Nikken* principles. They distinguish between

(i) amendments merely to delete claims and related material which have been found to be invalid, and (ii) amendments designed to make good a claim not thus far advanced in the amended form. The proposed amendment of Claim 3 is not to excise parts found to be invalid. The whole of Claim 3 was held invalid. Furthermore it is common ground that it would require a further trial to test the validity of the amended Claim 3.

120. The submission that the refusal was disproportionate, even applying the *Nikken* principles and *Johnson v Gore Wood*, was based on the assumption (shared by the judge) that a further trial need not take longer than two days, that the cost of this would be modest compared with the value of the amended Claim 3, that an order for costs would deal with any prejudice to Actavis and Mylan, and that the amendment, even if late, was a response to a late raising by Actavis and Mylan, shortly before trial, of an invalidity argument based upon the absence of sufficiency in a claim for central neuropathic pain. These are essentially case management points, and all of them were deployed before the judge and the Court of Appeal. Both courts reached the same conclusion in rejecting them. Both courts consisted of judges experienced in the trial of patent cases, three of whom had, in turn, been the judge in charge of the specialist Patents Court. In those circumstances this court would interfere only if the courts below had erred in law, left significant matters out of account, taken into account irrelevant matters, or gone clearly wrong. The submissions made to this court came nowhere near surmounting those steep hurdles. It is plain, as the judge held, that the occasion to consider whether to make an amendment to Claim 3 (which could have been conditional on that claim being found otherwise invalid) occurred at the very latest when Actavis and Mylan raised their plausibility case about central neuropathic pain shortly before trial. Instead Warner-Lambert chose to run a case for a narrow construction of Claim 3, to meet exactly the same potential problem. There was ample material upon which the judge and the Court of Appeal could properly have concluded that the attempt to make a post-trial amendment was an abuse of process, and no basis upon which this court could properly interfere, harsh though the consequences might have been if the cross-appeal had failed.

Infringement

121. Infringement was originally alleged in relation to Claims 1 and 3. There has been no attempt to challenge the finding of invalidity in relation to Claim 1. The consistent decisions of the courts below, with which this court agrees, that Claim 3 is invalid and cannot be saved by amendment, mean that the issues about infringement are therefore of no consequence in relation to the Patent. Nonetheless they have been fully and fiercely argued at all levels, and a significant disagreement about the tests for infringement of second medical use patents has divided the courts below. The Secretary of State for Health has intervened in writing and by counsel, and there have been no less than nine written interventions by other stakeholders,

large and small, for all of which I wish to express the court's gratitude. The submissions of the parties and the interveners raise an important and difficult question of law, likely to be applicable to all Swiss-form patents. The answer may have consequences for all purpose-limited claims, but that will have to be decided in future cases, as they arise. Although Swiss-form claims are now a closed class (because they have been replaced for the future by purpose-limited product claims under article 54(5) of the EPC 2000) there are sufficient still in force for the issues as to infringement to have potentially wide-ranging consequences. I therefore propose to deal with the infringement issues in full, on the assumption (contrary to what we have concluded) that Claim 3 is valid in relation to all forms of neuropathic pain.

122. Infringement of a patent is, in the UK, a statutory tort. Both the scope of the tort (ie the conduct of the defendant sufficient to constitute him an infringer) and the nature and extent of the remedies available to the patentee against the infringer are aspects of the national law of each contracting state. Nonetheless the question whether there has been an infringement may, and does in this case, depend critically upon the construction of the relevant claims in the patent, for which purpose Section 125(3) of the Act incorporates reference to the Protocol, as already described in the Construction section of this judgment.

123. The need to strike a fair balance between the need to incentivise and reward inventors on the one hand and the need to provide legal certainty for third parties, to enable them to pursue lawful competition on the other, gives rise to particular difficulties in relation to alleged infringement of Swiss-form second medical use patents, to such an extent that the parties were substantially agreed that there is no ideal solution. The choice lies between defining infringement so widely that manufacturers will be dissuaded from producing generic drugs even to fulfil the original (no longer patented) use, and defining it so narrowly that patentees are inadequately protected from the invasion of their newly patented second use by generic manufacturers. Warner-Lambert contends for a wide definition which it says can be tempered by the court taking a restrained approach to remedies. Actavis say that any inadequacies for patentees in what they submit is the correct narrower definition are the necessary consequence of the judicial fudge which has enabled Swiss-form claims to thrive at all, and must be endured if the generic market for the original use, which is itself an important public good, is not to be killed off altogether. Actavis assert that the modern replacement EPC 2000 patents for second medical use will cure most of the problems associated with the Swiss-form in the longer term. Whether that is right remains to be seen.

124. The starting point is (again) the express terms of Claim 3:

> "use of [pregabalin] for the preparation of a pharmaceutical composition for treating neuropathic pain."

It is now common ground, at least between the parties, that this is a purpose-limited process claim. It is a process claim because it protects the process of manufacture of a medicament containing pregabalin. It is purpose-limited because it only protects that process if it is undertaken for the purpose of treating neuropathic pain. The purpose limitation lies at the heart of the claim, because the use of pregabalin in the manufacture of a medicament lacked novelty at the priority date. It is the discovery that pregabalin-based medicaments treat neuropathic pain which was alleged to be (and must for this analysis be assumed to be) the relevant contribution to the art.

125. It was also common ground until the end of the hearing in this court that a purpose limitation of this kind necessarily imports some kind of mental element, actual or imputed. It was assumed that doing something for a particular purpose inevitably does. The question whether the manufacturer is an infringer begins by asking for what purpose is he using pregabalin for the preparation of a medicament. In outline, the rival contenders for the requisite mental element on the part of the manufacturer were foreseeability and intention. Warner-Lambert and the Court of Appeal favoured foreseeability. Actavis and the judge favoured intention.

126. More recently, and in response to a request from the court for further written submissions, Actavis has suggested, in the alternative, that the search for a mental element should be abandoned, in favour of a test of purpose which depends entirely upon the physical characteristics of the product as it emerged from the manufacturing process, including any information about its purpose contained in the accompanying label or patient information leaflet, an approach described by Floyd LJ in the Court of Appeal as "only packaging will do". As will appear, it derives from the jurisprudence of the German courts, where it is labelled "*sinnfällige Herrichtung*", usually translated into English patent jargon as "manifest making-up". But these are little more than headings for more detailed concepts. Before unwrapping them, it is necessary first to lay out both the context and the statutory definition of infringement.

127. The context consists of the current regime within the UK for the prescribing and dispensing of medicines. It is described in admirable detail by the judge, and I am content to adopt, without repeating, Lord Sumption's summary of it.

128. The end result is that the use of labelling on a generic form of pregabalin stating that it is not for the prevention of pain will not in fact prevent it being dispensed for that purpose, because the pharmacist does not generally know what is the condition for which pregabalin has been prescribed, and the generic

manufacturer can be in no better position. Furthermore, as Lord Sumption explains, recent NHS guidance does not constitute a satisfactory long-term precedent for resolving the problem, even though it may have been of real assistance in this case.

129. The statutory tort of patent infringement is defined by section 60 of the Patents Act 1977 (so far as is relevant) as follows:

> "60.(1) Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say -
>
> (a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;
>
> (b) where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent;
>
> (c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.
>
> (2) Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom."

130. Warner-Lambert pursues its infringement case under section 60(1)(c) and, separately, under section 60(2). Each needs to be addressed separately but, at the outset, it is convenient to make some observations about section 60, viewed as a whole. First, although liability for infringement is generally said to be strict, the section makes a clear distinction between those parts of the multi-headed definition of infringement which do, and which do not, require proof of a mental element. In short, the definitions in section 60(1)(a) and (c) do not, but section 60(1)(b) does, at least in relation to offer of the process for use in the UK, and 60(2) does as well. In both the latter definitions the knowledge requirement is the same, encapsulated in the phrase "when he knows, or it is obvious to a reasonable person in the circumstances …".

131. Secondly, section 60 appears to use a consistent conceptual approach to the relationship between the words product, process and invention. It is clear from section 60, read as a whole, that invention is a class with only two members, product and process, and that the invention is the subject matter of one or more claims in the patent. Phrases about using the process, product or invention, or working the invention or putting the invention into effect need to be understood and applied by reference to the claim (or claims) in the patent alleged to be infringed. Thus, while it may be appropriate in other circumstances to refer to the invention, or to putting the invention into effect, in wider or narrower terms than as set out above, it is not appropriate to do so in the context of section 60.

132. Turning to section 60(1)(c), this focuses upon a product obtained directly by means of the patented process. Infringement then occurs, as in section 60(1)(a), whenever a person disposes of that product, offers to dispose of it, uses or imports it, or keeps it, whether for disposal or otherwise. Under section 60(1)(c) the infringer may be, but need not be, the same as the person who makes the product. Liability for the prohibited conduct is strict, provided only that the product has been obtained directly by means of the process, and it then extends to dealings with all and every such product. By contrast with section 60(1)(a), the infringement liability for making the product obtained from the patented process is not addressed by section 60(1)(c). That liability must arise, if at all, from section 60(1)(b), which includes a necessary mental element, when using the process to make the product.

133. But what if the patented process is, according to the relevant claim, one which itself involves a mental element? In the language of section 60(1)(c) a product will not be "obtained directly by means of that process" if the required mental element is inapplicable to the manufacturer, all the more so if, as with Swiss-form claims, it is the manufacture or "preparation" of the medicament that is sought to be protected. It would appear to follow that if A keeps or disposes of a product manufactured by B without B having the requisite mental element, then A will not infringe even if his intention is to use or dispose of the product with a view to its being used for the purpose identified in the claim. Similarly, A in the above example will not escape

liability for infringement if B manufactured the product for the purpose identified in the claim, however innocent A may be of B's state of mind, and regardless of the use to which A puts the product. This is precisely because section 60(1)(c) imposes strict liability, and is therefore blind to A's state of mind. It was not suggested that any of the exceptions in section 60(5)ff could be prayed in aid by A. In short, the question whether dealings with the product after its manufacture give rise to infringement depends entirely on whether the product itself was tainted at the time of manufacture by having been obtained by a process (and therefore in this context for a purpose) within the claim.

134. It may well be doubted whether section 60(1)(c) can have been formulated with purpose-limited process claims in mind. It appears to place an unrealistic burden on those wishing to deal in good faith with the relevant product downstream of the manufacturer, such as importers, distributors and dispensing pharmacists, because it may be impossible for the dealer to form any reliable view about the manufacturer's state of mind. Furthermore the dealer will not escape liability by distributing or dispensing the product only for indications outside the claim, such as for indications for which earlier patent protection has expired. Their only safe course, as emphasised by many of the intervening stakeholders, will be to refuse to deal with the generic product at all.

135. Section 60(2) does not distinguish between product and process inventions. It applies equally to both. But recognition that the "invention" is something circumscribed by the scope of the claim means that the critical phrase "putting the invention into effect" is likewise constrained. If, as here, the claim is to protect the process of manufacture, then the invention is fully put into effect once the process of manufacture is complete. The claim cannot include dispensing pursuant to a prescription or treating, as part of the process, because those activities cannot be patented. In short, Swiss-form claims have been deliberately formulated so as to be limited to manufacture, to avoid falling foul of that restriction. The conduct prohibited by section 60(2) is supplying or offering to supply something to someone not entitled to "work the invention". I think it plain that, in relation to process claims which are limited to manufacture, section 60(2) is concerned with activity upstream of manufacture, whereas section 60(1)(c) is concerned with conduct downstream of manufacture. These may conveniently be labelled respectively as "supplying the means" and "dealing in the product", provided that those phrases are used for convenience rather than by way of definition. Manufacture itself is caught only by section 60(1)(b), by the phrase "uses the process".

136. It is convenient to address Warner-Lambert's case under section 60(2) first, because I think that it is susceptible to the relatively easy answer which Lord Sumption provides at the end of his judgment, with which I fully agree. In particular it does not depend upon the answer to the very difficult question about the requisite mental element in a purpose-limited process claim.

137. I can therefore return to the issues about mental element which arise from the infringement case under section 60(1)(c). I have explained my view that this has nothing to do with the question whether section 60(1)(c) itself imposes a mental element as a requirement for infringement liability. It plainly does not. The real question is: what, if any, mental element is built into this purpose-limited process claim? That is a question of construction of the claim, not a question about UK patent infringement law. I have summarised the rival contentions of intention, foreseeability and (now) no mental element at all, but it is necessary to describe them, and their potential consequences, in more detail.

138. Warner-Lambert originally submitted that it was enough to bring manufacture of a drug containing pregabalin within Claim 3 if it was foreseeable to the manufacturer that a more than *de minimis* amount of it would in due course be used for the treatment of neuropathic pain. The Court of Appeal broadly accepted this submission, subject to two qualifications. First, the downstream use for treating pain had to be intentional rather than accidental. By this it meant only that patients would receive the drug for treating their pain, rather than for example for treating epilepsy, with a coincidentally beneficial effect upon pain from which they happened also to suffer.

139. The second qualification is more important. Floyd LJ held that the requisite mental element could be negatived if the manufacturer had taken all reasonable steps to prevent the downstream use of his drug for treating pain. I refer to "pain" because the Court of Appeal was proceeding on the hypothetical assumption that both Claims 1 and 3 were valid. At para 208 he said this, at para 44:

> "The intention will be negatived where the manufacturer has taken all reasonable steps within his power to prevent the consequences occurring. In such circumstances his true objective is a lawful one, and one would be entitled to say that the foreseen consequences were not intended, but were an unintended incident of his otherwise lawful activity."

140. Before this court Warner-Lambert adhered to their pure foreseeability submission, using the Court of Appeal's more nuanced approach as a fall-back. On their primary case the taking of reasonable steps might be relevant to remedies but, if leakage of Actavis' generic product into the market for relieving neuropathic pain was still foreseeable after the taking of all reasonable steps to prevent it, infringement would still be the consequence.

141. Actavis' submission was that the requisite mental element is intention, by which they mean that it must be shown that the manufacturer was targeting the drug

for use in treating pain. The Secretary of State, and many of the other interveners with a stake in the market for treating the non-patented use, supported Actavis' case, pointing out that Warner-Lambert's case would cast the net so widely and unpredictably for dealers in, including dispensers of, generic forms of pregabalin that they would be deterred from having anything to do with it, even for the non-patented indications.

142. In written submissions responsive to the court's request following the hearing Warner-Lambert and the Secretary of State maintained their previous positions, both rejecting the abandonment of any mental element as conceptually wrong, and because it loaded the policy balance unjustly against the Swiss-form patentee. Actavis added a "no mental element" alternative to its original position, without expressing a clear preference for either, on the basis that both intention and "manifest making-up" reflected the requirement to identify the purpose limitation equally well.

143. The parties drew from three main sources in advancing their competing cases. The first was English authority on the meaning of intention in the law of tort. The second was European authority on Swiss-form patents. The third was policy considerations.

144. The English common law of tort uses the concept of intention in a spectrum of different ways, depending upon context. *Fish & Fish v Sea Shepherd UK* [2015] AC 1229 was a case about the liability of joint tortfeasors. This court held that there had to be demonstrated a common design by the persons alleged to be liable to do, or to secure the doing of, the acts which constituted the tort. Dissenting, but not on this point, Lord Sumption said this, at para 44:

> "Intent in the law of tort is commonly relevant as a control mechanism limiting the ambit of a person's obligation to safeguard the rights of others, where this would constrict his freedom to engage in activities which are otherwise lawful. The economic torts are a classic illustration of this. The cases on joint torts have had to grapple with the same problem, and intent performs the same role. What the authorities, taken as a whole, demonstrate is that the additional element which is required to establish liability, over and above mere knowledge that an otherwise lawful act will assist the tort, is a shared intention that it should do so."

145. In *OBG Ltd v Allan* [2008] AC 1, a case about the economic torts of procuring a breach of contract and causing loss by unlawful means, Lord Hoffmann said this, about the first of those torts, at paras 42-43:

> "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* 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'."

Later, at para 62, he applied the same test to the second of those torts.

146. By contrast, in *Bourgoin SA v Ministry of Agriculture, Fisheries and Food* [1986] QB 716; [1985] 3 WLR 1027, Oliver LJ said, at 777H:

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

That was a case about breach of statutory duty and misfeasance in public office. Oliver LJ's dictum was approved by the House of Lords in *Three Rivers District*

Council v Governor and Company of the Bank of England [2003] 2 AC 1, which was also a case about misfeasance in public office.

147. I do not derive from this source any compelling guidance for the identification by way of construction of the mental element in a purpose-limited process claim, for the following reasons. First, the search is not here for the requisite element in a tort at all. The tort of infringement created by section 60(1)(c) does not require any mental element. Rather the search is for the mental element, if any, by which what would otherwise be an invalid process claim is limited by the requirement that the manufacture be for a purpose. It defines the scope of the monopoly claimed, not (separately at least), the state of mind of the infringer.

148. Secondly, all the various and different types of "intention" set out by the English authorities are context dependent. They apply in different ways to different torts. Even if this had been a search for the mental element required of an infringer (otherwise than because of the limited scope of the claim) the English authorities give no guidance about where patent infringement lies on the spectrum which they describe.

149. The Court of Appeal conducted its own review of the relevant European authorities about infringement of Swiss-form patents, first during the interim appeal in May 2015 and again during the appeal from the trial judgment, in October 2016. Floyd LJ concluded, correctly in my view, that they provide no clear or settled answer to the problem. But they do tend to show that a broad foreseeability test of the kind proposed by Warner-Lambert has not found favour. In summary, the German courts have concluded that the patentee will only be able to show that an alleged infringer's process is "for" the patented use if there is some outward manifestation of that purpose in the presentation of the manufactured product, for example in its packaging: see the decision of the German Federal Court of Justice in *Carvedilol II* (Case X ZR 236/01) (decision of 19 December 2006); the decision of the Landgericht Dusseldorf in *Chronic Hepatitis C Treatment* (Case 4a O 145/12) (decision of 14 March 2013); the decision of the Oberlandesgericht Dusseldorf in *Cistus* (Case I-2 U 53/11) (decision of 31 January 2013); and the decision of the Landgericht Hamburg in *Warner-Lambert Co LLC v Aliud Pharma GmbH* (Case 327 O 140/15) (decision of 2 April 2015). Floyd LJ called it the "only packaging will do" approach. He noted that the recent decision of the EPO in T 1673/11 *GENZYME/Treatment of Pompe's disease* [2016] EPOR 33 appeared to follow the German lead. The underlying rationale of those decisions appears to be that the "purpose" designated by a Swiss-form patent was an inherent property of the product which emerged from the manufacturing process, rather than something to be found in the mind-set of the manufacturer. In recent written submissions Warner-Lambert point out that the latest decisions of the German courts have modified this rigorous focus upon the packaging by admitting proof of infringement by reference to foreseeability, for example in *Östrogenblocker* (Case I-2 W 6/17) (5 May 2017),

para 39, and *Dexmedetomidin* (Case I-2 U 30/17) (1 March 2018), (BeckRS 2018, 2410, paras 42-44).

150. The Spanish courts have taken a slightly more generous approach to patentees, looking for some authorisation or encouragement by the manufacturer directed at strengthening the use of the product for the patented indication: see the decision of the Madrid Court of Appeal in *Wyeth v Arafarma Group SA* (Case C-539/07) (16 April 2008).

151. In France, Floyd LJ detected a still more flexible approach in the preliminary decision of the Tribunal de Grande Instance dated 26 October 2015 *in Warner-Lambert Co LLC v SAS Sandoz* (Case 15/58725), Vice Presiding Judge Marie-Christine Courboulay, whereby the court was prepared to take fully into account steps taken by the defendant generic manufacturer to discourage the use of its product for the patented indication. That was a case about this very Patent. The report of the full merits hearing in the same case, in August 2016 (Case 16/57469) dismissing the infringement claim, was made available to this court. I do not think that it really addresses the question as to the mental element built into the purpose limitation of the claims in this Patent, as a question of construction of the claim.

152. In a helpful appendix to its printed case, Warner-Lambert note that the courts of the Netherlands have tended successively to follow the differing leads given by Arnold J and then by the Court of Appeal in this case. They do not therefore provide significant independent guidance.

153. I have not carried out my own intense review of the European authorities on this point, because counsel did not suggest that either the summary of them, or the conclusion that they provided no clear answer, as set out by Floyd LJ, was wrong. There appears to be a spectrum of differing approaches to the question of the relevant mental element built into a purpose-limitation in a process claim. It may well be that the courts in different contracting states will reach solutions which differ because the particular aspects of their national law on infringement, and the structure of their relevant markets, mean that striking a fair balance between protection of patentees and legal certainty for the lawful activities of third parties produces a different result in each jurisdiction. That may be unfortunate, since the construction of claims in a European patent ought to be consistent across all contracting states, but there is nothing which this court can do about it, save to proceed with due regard to the decisions of those states' courts.

154. We were pressed by counsel for Warner-Lambert with dicta about knowledge and intention in the joint judgment of Jacob and Etherton LJJ in *Grimme Landmaschinenfabrik GmbH & Co KG v Scott* [2010] EWCA Civ 1110; [2011] FSR

7, at paras 112-114. That was an infringement claim under section 60(2), which has its own built-in knowledge requirement. The patent in issue was for a product rather than a process, and was neither medical nor in Swiss-form. It therefore provides no assistance in the present context.

155. Policy considerations formed a, if not the, main plank in the submissions both of the parties and of the interveners. I have already summarised the main battle-lines above. Policy is, to an extent, a perfectly legitimate factor to be taken into account on what is, for the reasons explained, essentially a question of construction of the purpose limitation in Claim 3. Policy considerations inevitably underlie the striking of the balance required by the Protocol. In my view, the central policy objectives are:

> 1. Providing reasonable protection to the second medical use patentee, both to reward and to incentivise the complex and expensive processes of research and testing necessary to bring these valuable uses to fruition. That protection needs, as far as is consistent with competing policy objectives, to protect the patentee against the invasion of his monopoly by competitors.
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> 2. Protecting the public against the loss of the patent-free use of the relevant drug for treating the indications for which it was originally developed. This means that the patentee for the new use should not obtain, by a side wind, an effective continuing monopoly in relation to the old use, after the expiry of the patent protection for it. This policy objective preserves for the public the enjoyment of the *quid pro quo* for the grant of the now expired monopoly for the original use, in the form of very much cheaper generic forms of the drug becoming available for those uses.
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> 3. Providing reasonable legal certainty for those engaged in the manufacture, marketing and prescribing of the generic drug for the non-patented use, that their conduct is lawful. This policy objective is expressly recognised by the Protocol and, without it, the second objective is unlikely to be achievable.

156. I am satisfied by the evidence, and by the submissions of the parties and the interveners, that the simple foreseeability test primarily contended for by Warner-Lambert would prioritise the first policy objective at an unacceptable cost to the achievement of the second objective. This is because, it being common ground that some more than *de minimis* leakage of generic pregabalin into the market for treating neuropathic pain is foreseeable regardless of the taking of all reasonable steps within the generic manufacturers' power to prevent it, all stocks of their generic forms of pregabalin will have been manufactured by use of the patented process, such that

any subsequent dealing with those stocks will constitute infringement under section 60(1)(c). For as long as doctors prescribe pregabalin for pain generically, without specifying that the relief of pain is the purpose of the prescription, pharmacists will always risk dispensing a generic form of pregabalin for pain, unless they confine themselves to dispensing Lyrica to meet all pregabalin prescriptions. That is why some leakage is foreseeable.

157. The result is that pharmacists would have to desist from dispensing generic pregabalin at all, if they wish to avoid infringement. This is not merely because of the risk of dispensing the generic product for pain, but, as I have explained above, because all dealings in a generic product (including prescription) will be an infringement under section 60(1)(c), even if the pharmacist knows that the prescription is for treating a non-patented indication. If foreseeability is the test, then all generic pregabalin will be tainted product from the point of manufacture, such that any dealing with it will be an infringement.

158. A fair balance between competing policy objectives is not struck by preferring the complete achievement of one by a construction which completely prevents the achievement of the others. Accordingly I consider that policy considerations are strongly opposed to Warner-Lambert's main case. In partial recognition of this difficulty counsel for Warner-Lambert submitted that the adverse effect of a simple foreseeability test could be mitigated by a flexible approach of the court towards remedies. Injunctions could be refused, and patentees confined to an account of the infringer's profits, based upon an assessment of the proportion of generic pregabalin dealt with by any infringer which is actually used for the treatment of pain.

159. I consider that there are a number of insuperable objections to this approach. First, it tacitly assumes that dealers in generic pregabalin going about a lawful business of seeking to supply the market for its non-patented use are infringers. The prospect that they would be subjected only to a modest financial sanction is simply no answer to a person who wishes to conduct a lawful trade or profession. Nor would it provide any protection at all from the cost, stress and uncertainty of the litigation of infringement claims. Secondly, while the court may be able to withhold an injunction as a matter of discretion, the patentee has, in principle, a right to elect between damages and an account of profits. They are not alternative discretionary remedies, between which the court is free to choose. Thirdly, an election by the patentee for damages would expose the infringer to the patentee's much larger lost profit margin per pack than the profit typically made by a manufacturer of, or dealer in, a generic product. Fourthly, the patentee's loss of profit would not be limited to sales lost for the treatment of pain, but to sales lost for all treatment because, as I have explained, sales or dispensing of tainted generic product for non-patented treatment would also be acts of infringement. The result therefore is that policy considerations firmly militate against Warner-Lambert's primary case.

160. Warner-Lambert's secondary case, namely foreseeability tempered by negativing intent by the taking of all reasonable steps, is the compromise solution preferred by the Court of Appeal. While it may go some way towards avoiding the destruction of the second policy objective, at acceptable cost to the achievement of the first, it also faces serious objections, both in principle and practice. First, if the basic test for the requisite mental element is foreseeability, it is simply not the case that the taking of all reasonable steps by the generic manufacturer to prevent leakage into the market for the patented use will necessarily make that leakage unforeseeable. It does not appear to do so at present. Leakage does appear to have been substantially reduced during the period before the trial, but this appears to have been attributable mainly to steps taken by the NHS, at the behest of the court on the application of Warner-Lambert, to encourage doctors and pharmacists to prescribe and dispense Lyrica rather than a generic alternative for pain. Although the Court of Appeal described the taking of steps by the manufacturer as sufficient to negative intention to manufacture pregabalin for the patented purpose, in the context of foreseeability it sounds more like the erection of a non-statutory defence to infringement. However desirable, that is not the function of the court in the context of a statutory tort.

161. The main practical objection to this apparent compromise between policy objectives 1 and 2 is that it is achieved, if at all, at the expense of objective 3, namely legal certainty for dealers in, and dispensers of, generic pregabalin. How are they to know what steps have been taken by the manufacturer to prevent leakage, or whether the steps taken will eventually be regarded by the court as reasonable? Warner-Lambert do not suggest that the reasonable steps requirement will be satisfied merely by skinny labelling, or limited to things visible to all users of the generic package. As noted above, if the mental element test for the purpose limitation gives rise to serious legal uncertainty among dealers and dispensers of the generic drug as to whether the product is or is not tainted by having been manufactured within the scope of the claim in the patent, they will be likely to decline to use the generic drug at all, in order to avoid the risk of infringement.

162. I have considered whether the difficulties in finding an appropriate solution to the infringement issue ought to be regarded as flowing from the parties' original concession (now withdrawn by Actavis) that the purpose limitation in this Patent (and in any Swiss-form claim) necessarily involves some kind of mental element. The German approach, of treating the purpose of the manufacture of a product as inherent in the physical characteristics of the product, and decisively determined by the form of its presentation in fully manufactured form, well serves the policy objective of providing legal certainty for the market, and mitigates the rigour of the strict liability imposed in the UK upon dealers by section 60(1)(c). Its weakness, on an assumption that a mental element is required, is that it cannot realistically be the only way of proving infringement, namely the manufacture of the product for the patented use. The latest German cases, as described above, appear to acknowledge

that weakness by introducing an alternative basis for proving infringement, based upon the mental element of foreseeability.

163. Following the hearing we considered whether an alternative approach would be to abandon the search for an appropriate mental element altogether. It would treat the identification of the purpose for which the product was manufactured as conclusively determined by a review of the fully manufactured product, including its packaging, labelling and enclosed patient instructions, upon the conceptual basis that the relevant purpose was an aspect of the physical characteristics of the product emerging from the manufacturing process. It would place the downstream dealer in a generic product (importer, distributer or pharmacist) in as good a position as the court to determine whether the product was tainted by an illegitimate purpose in its manufacture, and therefore to be avoided for fear of liability under section 60(1)(c). It would maximise legal certainty, and the use of the generic products for the non-patented indications. It would have the powerful advantage of avoiding the unusual (perhaps even unique) legal result of penalising a class of users as infringers by reference only to the state of mind of other persons (the manufacturers) of which that class could not reliably be aware.

164. We were of course conscious of the fact that this solution was not proposed either by the parties or by any of the interveners, and that we could not properly adopt it without calling for further submissions, in particular from Warner-Lambert, because it would deprive Swiss-form patentees even of the protection afforded by their ability to prove the requisite intent on the part of the manufacturer by evidence other than that constituted by the appearance and content of the fully manufactured product. In the event no party other than Actavis favoured that solution, and even they regarded it only as an alternative to their primary case, based upon intention. The Secretary of State considered that it did not strike the appropriate policy balance.

165. I have, not without some reluctance, come to the conclusion that this is not an available alternative. My reasons follow. First and foremost, I think that the original concession that the purpose limitation in a Swiss-form claim necessarily involves a mental element of some kind on the part of the manufacturer was rightly made. When we speak of someone making something "for" a particular use, and conclude as we must that "for" means something more than "suitable for", it must point to something in the mind of the manufacturer. Even if the manufacturer is a corporation using a factory entirely staffed by robots, if the manufacturing process is only protected by the patent if it is carried out for a particular purpose, the requirement to identify a mental element on the part of the manufacturer is simply inescapable. The court is well versed in identifying the governing mind of a corporation and, when the need arises, will no doubt be able to do the same for robots.

166. By contrast I do not think that treating the purpose for which something is manufactured as inherent in the physical characteristics of the resulting product, truly reflects the role which the purpose limitation plays in defining the monopoly created by a Swiss-form patent. The fact is that, in its essentials, the Pregabalin-based medicament sought to be protected by the Patent has exactly the same physical characteristics as Pregabalin-based medicaments used to treat epilepsy and GAD.

167. That is not to say that the form in which the product of a manufacturing process is presented to the market will not often, or indeed usually, be decisive evidence, one way or the other, of the manufacturer's intended purpose, leaving aside the occasional cases where other evidence may prove that the presentation is in fact a charade. Subjective intent is routinely proved by objective evidence of conduct.

168. Secondly, I do not consider it safe to conclude that the apparent German lead in this direction can simply be followed in this different jurisdiction. I agree with Lord Sumption's analysis of the way in which German law differs from UK law in making a less significant distinction between purpose and product claims. I have not been able to agree with Lord Mance's analysis, which seems to me to follow the German lead in treating the purpose as limiting the product, by focusing solely on the way it is packaged and marketed, while at the same time acknowledging that, in English law, the patent protects the process. I agree that it does, but the purpose limits the process which is protected. We know nothing about the particular features of the German systems for prescribing and dispensing medicines, about its regime for patent infringement, or about the market conditions within which a fair balance has to be struck. The fact that German, French, Spanish and Dutch courts have all taken different approaches to this issue strongly suggests that differing legal, market and structural factors within each jurisdiction have been influential, and perhaps even decisive, but we have no sufficient knowledge of those factors, save within the UK.

169. Thirdly, it is striking that neither Actavis nor those interveners with an interest in maximising generic use for non-patented purposes together with legal certainty have put forward this more rigorous solution to their difficulties at any stage in this litigation, until prompted by this court to consider whether to do so, after the hearing. This may be simply because they all acknowledged that some mental element is implicit in a purpose limitation, or because they recognised that it would not strike a fair balance between their interests and those of patentees.

170. Fourthly, I think that this solution would not indeed strike a fair balance. The Court of Appeal regarded the "only packaging will do" solution as plainly affording inadequate protection for patentees. At para 191 Floyd LJ said:

> "These matters arise as a matter of interpretation of the word 'for'. The parties are agreed that the word imports a mental element. Packaging may be a means of demonstrating the necessary mental element, whatever that is, but it cannot possibly be the only means of doing so."

There is force in this objection. A generic manufacturer might well demonstrate the requisite purpose by flooding the market for pregabalin beyond the sector of it which treats the non-patented indication, or by covertly encouraging dealers and pharmacists to use it for the treatment of pain, regardless of what appears on the label. Or a smoking-gun internal document might reveal that the manufacturer's packaging for the non-patented use was just a charade, because its corporate purpose was indeed to profit by its distribution and use for the patented indications. All these forms of evidence might prove the requisite intent, even if the packaging did not.

171. Finally, the principal driver towards this alternative is the concern that section 60(1)(c), in conjunction with Swiss-form patents, imposes draconian strict liability on dealers in generic products, without giving them the ability to find out whether the manufacturer has an intention that taints its products in their hands. It is tempting to try to fashion an answer to this difficulty by creating some sort of bona fide purchaser defence for dealers in the generic drug, downstream of the manufacturer, so that they could avoid liability for infringement under section 60(1)(c) unless they were on notice of the true (infringing) purpose of the manufacturer, in cases where it was not revealed by the packaging. It would fill a lacuna in legislation which cannot have been drafted with purpose-limited product claims in mind. But that would be another illegitimate attempt to create a non-statutory defence to a statutory tort. Nonetheless the sense of injustice engendered by that acknowledgment of the potential for unfairness of UK legislation about infringement ought not to lead to straining the essential meaning of a purpose limitation beyond its proper limits, by what is really a legal fiction that it involves no mental element of any kind.

172. The so-called subjective intent test favoured by Actavis would I think accommodate all forensic means whereby a purpose of the generic manufacturer to serve (and profit from) the market for neuropathic pain could be proved, including but not limited to the packaging on the product. Anything from which the court could properly find that the manufacturer had such a purpose could be relied upon, including targeted disclosure, during litigation, of documentary records of the manufacturer's decision-making processes. I call it a "so-called" subjective test because a person's intention is as much a matter of fact as the state of his digestion, and this is true of corporate persons as much as of individuals. It may be proved objectively by words, conduct and even inactivity, and the court is well versed in treating a decision not to enquire about something suspected as probative of blind-eye knowledge.

173. I acknowledge that this solution is a compromise like any other. It certainly falls short of providing complete protection to patentees from the invasion of their monopoly. It appears that it would not cause the complete destruction of the generic market for pregabalin for the treatment of the non-patented indications, although exposure of pharmacists to strict liability where the manufacturer is proved to have had the requisite intent may still discourage some pharmacists from using the generic product. The departure from the German "only packaging will do" solution by permitting any means of proof of the manufacturer's purpose (but well short of mere foreseeability) will provide less than perfect legal certainty for those who deal in and dispense the generic versions of pregabalin. Nonetheless, as I have said, the packaging, labelling and patient instruction leaflets will in most cases be the best evidence of the manufacturer's intention. But the Proviso requires only the striking of a fair balance.

174. It was submitted for Actavis that to the extent that their proposed test for the mental element fell short of providing full protection to patentees, this should be regarded as a necessary consequence of the judicial fudge constituted by the recognition of Swiss-form patents in the first place. There is something in this point, but it does not absolve the court from seeking a construction of the purpose limitation which strikes as fair a balance as possible. Nor do policy considerations mean that the court can do otherwise than choose between available meanings of the claim as a matter of construction. The claim cannot just be re-written. But I consider that a test for the manufacturer's purpose based upon determining his intent, in the manner described above, is well within the ambit of legitimate construction. That is the construction which I consider to be correct.

Conclusion

175. I would therefore dismiss the appeal, and allow the cross appeal.

LORD HODGE:

176. I agree with Lord Sumption and Lord Briggs on the construction of Claim 3 for the reasons which they give. I also agree with them that Arnold J was entitled to refuse to allow Warner-Lambert to amend that claim after he had handed down his trial judgment on 10 September 2015, again for the reasons they give. I therefore would dismiss Warner-Lambert's appeal.

177. There are only two matters on which I wish to add any comment. The first is the test for insufficiency in the context of Swiss-form patents, and in particular the meaning of the plausibility test which has been developed to take account of the

inability of the applicant for such a patent to establish the claimed therapeutic effect of the medicament by clinical trials before applying for the patent. The second relates to the test for direct infringement under section 60(1)(c) of the Patents Act 1977.

Sufficiency: the plausibility test

178. The general principle that the extent of a patent monopoly defined by the claims should correspond to, and be justified by, the applicant's technical contribution to the art underpins the requirement of sufficiency of disclosure. It justifies the existence of the boundary between an educated and educating prediction of efficacy for the designated therapeutic purpose on the one hand and mere speculation on the other, which is addressed by the plausibility test which the EPO Technical Board of Appeal ("the Board") has developed in a series of decisions. But the general principle tells one little about where the plausibility test draws that boundary. It is necessary to look to those decisions to discover that boundary.

179. There are four principal decisions of the Board - SALK (27 October 2004), *ALLERGAN* (26 October 2009), *IPSEN* (29 June 2011) and *BRISTOL MYERS SQUIBB* (3 February 2017) - which assist in this exercise. I agree with Lord Sumption (paras 33-34) that those decisions do not place an onus on an objector to show that the implied assertion of therapeutic efficacy is implausible. I also agree with his view (paras 35-37) (a) that the patentee must disclose in its patent, when read in the light of the common general knowledge, the contribution to the art which justifies his monopoly and, to that end, (b) that the specification must disclose some scientific reason for thinking that the medicament might well have the claimed therapeutic effect.

180. Where I differ from Lord Sumption is that, in agreement with Lord Mance, who has analysed the three cases of *ALLERGAN*, *IPSEN* and *BRISTOL MYERS SQUIBB*, I do not interpret those principles as requiring the patentee to demonstrate within its patent a prima facie case of therapeutic efficacy.

181. In my view the recent decisions of the Board (a) require that the therapeutic effect of the medication appears plausible from the data in the patent interpreted in the light of the common general knowledge, (b) do not require that the patent discloses experimental evidence to demonstrate that plausibility unless there is an allegation, supported by sufficient evidence, that the invention does not work, but (c) allow the plausibility to be reinforced by considering evidence which post-dates the patent (although later-published data are not admissible if they alone render the therapeutic effect plausible), (d) take account of the ease with which the therapeutic effect can be ascertained using straightforward tests which are known in the prior

art, and (e) where the data in the specification have made the claimed therapeutic effect plausible, place a burden on an objector to substantiate doubt that the desired effect can be achieved.

182. Adopting the lower standard of plausibility which the recent decisions support, I am inclined to think that Arnold J, who heard and analysed the expert evidence on this matter, including that of Professor Woolf, Dr Scadding and Professor Wood, did not err in his evaluation of that evidence when he concluded that Warner-Lambert had done just enough to satisfy the plausibility test in relation to peripheral neuropathic pain. The result of the rat paw formalin test demonstrated that pregabalin reduced inflammatory pain at phase 2. There was expert evidence which treated as credible the suggestion that the efficacy of pregabalin in reducing pain which that test revealed would not be confined to inflammatory pain and that the medication would also be effective in relation to peripheral neuropathic pain. As Arnold J stated (para 351), it was common general knowledge that central sensitisation was involved (at least as an amplifying mechanism) both in relation to inflammatory pain and in relation to peripheral neuropathic pain and that it played a role in the rat paw formalin test. The patent had not demonstrated that pregabalin had an effect on central sensitisation and a prima facie case had not been made out. But the plausibility test does not require that standard.

183. The patent's contribution to the art, which Arnold J found, was not only the demonstration that pregabalin reduced inflammatory pain but also, because of the involvement of central sensitisation which was common general knowledge, a credible assertion that the drug would also reduce peripheral neuropathic pain. In my view it was not necessary, in order to overcome the relatively low hurdle of plausibility, for the patent to demonstrate by experiment or by scientific theory, that pregabalin blocked or reduced central sensitisation. In agreement with Lord Mance, I do not see the example which the Board gave in para 9 of SALK, which Lord Sumption quotes at para 29 and founds on in his fifth point in para 37, as establishing a sine qua non of plausibility.

184. I would add that the patent also identified the Bennett and Kim tests, which were straightforward tests and were available to the reader of the patent to test the claims that pregabalin was effective to treat peripheral neuropathic pain. The teaching could be tested without undue burden. Subsequent tests established the efficacy of pregabalin in treating pain, including peripheral neuropathic pain. That later evidence is, as I have said, not admissible if there were no data from which one could make predictions about the efficacy of the medication in relation to peripheral neuropathic pain: T 1329/04 *JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE/Growth differentiation factor* [2006] EPOR 8, para 12. But the plausibility test allows the court to have regard to such later evidence to make good the prediction if there is some basis for the prediction in the patent. Floyd LJ in the leading judgment in the Court of Appeal (para 133) treated the outcome of these

tests as fortifying the judge's conclusion that the patent had contained a plausible prediction. I agree.

185. I would therefore have dismissed the cross appeal and have upheld Claims 10, 11 and 12.

Infringement

186. I agree that Warner-Lambert have no claim under section 60(2) of the Patents Act 1977 for the reasons which both Lord Sumption and Lord Briggs give.

187. The difficulty in finding a satisfactory answer to the interpretation of Claim 3 in the context of an infringement claim under section 60(1)(c) is the result of the shoe-horning of the judge-made law, namely the Swiss-form claims, into a statutory scheme in section 60 of the Patents Act which was not framed with such purpose-limited process claims in mind. The problems so caused are particularly acute in relation to prescribed medicaments as section 60(1)(c) imposes strict liability on suppliers and pharmacists who may have no reliable knowledge of the intention of the generic manufacturer and who operate in a context in which doctors, for sound therapeutic reasons, normally prescribe drugs generically but also do not usually specify the medical condition or conditions which the medicament is intended to treat.

188. I agree that the test of foreseeability which Warner-Lambert promote and the qualified version of foreseeability which the Court of Appeal favoured should not be adopted for the reasons which both Lord Sumption and Lord Briggs advance. The disagreement between Lord Sumption and Lord Briggs is whether, as Lord Sumption advocates, to adopt an approach, which has (at least until recently) found favour in the German courts, confining evidence of the purpose of an alleged infringing manufacturer's process to the outward manifestation of that purpose on the product itself, including its packaging, labelling or in an accompanying patient information leaflet, or, as Lord Briggs suggests, to assess that manufacturer's actual intention in producing the medicament by taking account also of other manifestations of that manufacturer's purpose. The approach of the German courts has the serious disadvantage of giving inadequate protection to the patentee of the Swiss-form patent against a generic manufacturer who uses "skinny labels" and patient information as a charade behind which it exploits the second use market. The approach which Lord Briggs favours may expose dealers in the generic product and dispensing pharmacists to strict liability for infringement as a result of matters over which they may have neither knowledge nor control. Both approaches are far from perfect. I confess to having been strongly attracted by the tidiness and consistency with the principles of tort law which Lord Sumption's approach involves. That

approach also reduces the risk that suppliers and pharmacists will decline to deal in generic products after a patent has expired if there is a second medical use patent. But in my view Lord Briggs' approach creates a fairer balance between the central policy objectives which he sets out in para 160 of his judgment. Principally for that reason but also for the other reasons which he advances, I agree with Lord Briggs' judgment on this matter. If, on this approach, section 60(1)(c) were to cause serious problems to operators in the downstream market for generic products or to pharmacists, which in turn cause them to refuse to handle such generic products, it will be for the legislature to address those problems.

LORD MANCE:

189. I have read with benefit the judgments that have been prepared by Lord Sumption and Lord Briggs.

Construction

190. I would myself have been tempted by Warner-Lambert's case that, on a true construction of the patent, Claim 3 should be understood as limited to peripheral neuropathic pain. I would have been impressed by the statement in para 6 of the description that "Neuropathic pain is caused by injury or infection of peripheral sensory nerves", by the instances given which are of peripheral neuropathic pain and by the absence of any reference to any obvious instances of central neuropathic pain, such as pain from strokes and multiple sclerosis. I would also question whether the point made in para 104(3) of Lord Briggs' judgment is entirely sound. Claim 2 (use for inflammatory pain) and Claim 3 (use for neuropathic pain) are not sub-divisions covering the whole territory of Claim 1 (use for treating pain), since Claim 2 is itself commonly (but not I think necessarily) associated with an unmentioned category viz nociceptive pain. However, interpretation involves ascertaining the meaning of the claims as they would be understood by a person skilled in the art, in accordance with the principles set out in paras 92 to 98 of Lord Brigg's judgment, with which I am in agreement. The points made by Lord Briggs in para 104(4) and (5) of his judgment also have some force. All my colleagues are persuaded that the skilled person would understand Claim 3 as extending to central as well as peripheral neuropathic pain. Their reasonable opinion carries weight. I am not in the circumstances prepared to press my reservations to a conclusion that they are wrong.

Amendment and disposition of appeal

191. I also agree with Lord Sumption and Lord Briggs, for the reasons they give, that Arnold J was, in the circumstances of this case, entitled to refuse to allow

Warner-Lambert to amend Claim 3 after he had handed down judgment. It follows that I agree that Warner-Lambert's appeal fails.

Sufficiency or plausibility and its application

192. Where I do feel it necessary to disagree with the approach taken in Lord Sumption's judgment is in relation to the concept or test of sufficiency adopted in paras 26 to 37 in reaching it. This is a point of general importance. Swiss-form claims for the manufacture of a known compound for a novel use are a construct of courts, which was aimed at meeting a commercial need, but was not envisaged by the language of the European Patent Convention (before its 2000 amendment came into force) or of the United Kingdom statutory scheme. Sufficiency or plausibility, in the sense presently relevant, is a court-invented pre-condition to validity. It has been constructed by courts, principally to attach some limit to the Swiss-form claims for manufacture of compounds for uses which could otherwise be presented on a purely speculative basis. In the circumstances, there is every reason why the pre-condition should be narrowly understood, and should represent a low threshold to overcome.

193. In my view, Lord Sumption's analysis imposes too high a threshold, and imposes a burden on a patentee which the case law of the Board of Appeal of the European Patent Office does not justify. I prefer the approach advocated by Mr Mitcheson, but rejected by Lord Sumption in para 30 of his judgment. The case law of the Board of Appeal of the European Patent Office also seems to me to establish a reasonably clear position, which cannot be dismissed as "some turns of phrase" (para 30 of Lord Sumption's judgment).

194. Taking the cases discussed in paras 31 to 34 of Lord Sumption's judgment:

1. T 1437/07 *ALLERGAN* (26/10/09): The relevant paragraphs in the judgment read:

> "38. The respondents argue that it was not credible that the therapeutic effect could be achieved because the treatment disclosed in Example 9 had not actually been carried out.
>
> 38.1 However, article 83 EPC stipulates that an invention must be disclosed 'in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art' (emphasis added by the board). Thus, article 83 EPC does not stipulate that a claimed invention must have actually been carried out by

> the applicant or the inventor. Moreover, according to rule 42(1)(e) EPC, even the presence of an example is not mandatory. Therefore, just because a patent discloses an effect which has not in reality been achieved, there is no reason - in the absence of convincing evidence that the effect cannot be achieved - for the board to doubt that the effect can be achieved. Thus, the respondents' argument does not convince the board."

Again, it is notable that the Board of Appeal was prepared to proceed on the basis that a claimed effect was sufficiently disclosed in the absence of convincing evidence that it could not be achieved.

2. T 0578/06 *IPSEN* (29/6/11): Lord Sumption, after quoting paras 14 and 15 of the judgment in *IPSEN*, concludes:

> "This decision is authority for the proposition that plausibility can be demonstrated in the specification without experimental evidence, if there is no substantiated doubt about the theoretical case made for the efficacy of the invention. This is the only relevant proposition for which it is authority."

That is not in my opinion a correct paraphrase of paras 14 and 15 in, or supported by a full reading of, *IPSEN*. In para 15 the board took pains to "re-emphasise" that the case law

> "considers the establishment of plausibility only relevant when examining inventive step if the case at hand allows the substantiation of doubts about the suitability of the claimed invention to solve the technical problem addressed and when it is thus far from straightforward that the claimed invention solves the formulated problem."

Para 13 in *IPSEN* is also relevant:

> "The board notes that the EPC requires no experimental proof for patentability and considers that the disclosure of experimental data or results in the application as filed and/or post-published evidence is not always required to establish that the claimed subject-matter solves the objective technical problem. This is in particular true in the absence of any formulated substantiated doubt as is the case here."

Paras 20 to 23 of the judgment in *IPSEN* underline this, by making clear that the onus is on the objector to demonstrate that there are doubts.

3. T 950/13 *BRISTOL MYERS SQUIBB* (3/2/17): (a) This is the most recent of all decisions, and particularly significant for that reason and because it examines the scope of T 609/02 *SALK INSTITUTE FOR BIOLOGICAL STUDIES*, relied upon in paras 28 to 29 of Lord Sumption's judgment. Again, in my opinion, the draft undervalues its significance. The principal claims in *BRISTOL MYERS SQUIBB* related to a compound of a formula for dasatinib or a salt thereof "for the manufacture of a medicament for the oral treatment of cancer, wherein the cancer is chronic myelogenous leukaemia (CML)" (Claim 1) or "for use in the oral treatment of cancer, wherein the cancer is [CML]" (Claim 4). Lord Sumption in para 34 explains *BRISTOL MYERS SQUIBB* as a case where

> "Dasatinib had significant functional and chemical affinities with another kinase inhibitor [viz imatinib] known to be effective."

4. However, the objection was that the "functional affinity" was no more than an assertion that dasatinib functioned in the same way as imatinib. See in particular the patentee's case on "Sufficiency of disclosure" set out in paragraph IX and the opponent's case set out in paragraph X. Ultimately, it appears that, although this was true, the possibility that dasatinib would function in the same way as imatinib and the ease with which this could be ascertained using methods known in the state of the art, supported by post-published documents combined to make Claims 1 and 4 plausible. A further claim that dasatinib went further than imatinib, and operated as an inhibitor in imatinib-resistant situations was however insufficiently plausible.

5. The Board of Appeal approached *BRISTOL MYERS SQUIBB* on the basis that it was commonly known in the art that the single causative abnormality in CML was the BRC-ABL oncogene, the protein of which was a tyrosine kinase responsible for the malignant transformation, that CML could be treated by inhibiting the BRC-ABL kinase and that imatinib did this and had been approved for the treatment of CML (paras 3.4 and 3.5). The application contained no "experimental evidence for dasatinib's BRC-ABL inhibitory activity", but

> "the disclosure of experimental results in the application is not always required to establish sufficiency, in particular if the application discloses a plausible technical concept and there are

> no substantiated doubts that the claimed concept can be put into practice." (para 3.6)

6. The application certainly drew an analogy between imatinib and dasatinib (para 3.6), but the Board of Appeal's reasoning shows that the furthest the application went in this regard was to point out that there was evidence that "dasatinib inhibited certain protein tyrosine kinases" ("PTKs") other than the BRC-ABL kinase, that it was "not uncommon for a protein kinase inhibitor to inhibit more than one [PTK]" and that "this can be explained by the fact that in all [PTKs] the ATP binding site and the transfer domains are to a certain extent similar" (para 3.8). The Board of Appeal placed weight on the fact that assays and methods of testing to establish the activity of dasatinib as an inhibitor of PTKs, including BRC-ABL were known in the art (para 3.8). The teaching that dasatinib was suitable for the treatment of CML was not rendered implausible by the fact that "it may not have been obvious in view of the prior art" (para 3.8). Further, at para 3.10.4, in these circumstances:

> "… post-published documents may be used as evidence that the invention was indeed reproducible without undue burden."

7. The Board of Appeal drew a careful distinction between the position in *BRISTOL MYERS SQUIBB* and the position in the earlier case of *SALK*. It pointed out (para 3.9.1) that the Board of Appeal in *SALK*, at para 11, had summarised the situation as one where the claimed subject-matter

> "covers limitless and untried downstream developments in relation to yet to be demonstrated molecular mechanisms. In the board's judgment, it amounts to no more than an invitation to set up further research programs for which no guidance is forthcoming."

In contrast, the Board said, the position in BRISTOL MYERS SQUIBB was that

> "a structurally well-defined compound and a plausible concept for its suitability in the treatment of CML has been disclosed."

Similarly, in rejecting the opponent's case that the skilled person was left to guess whether dasatinib exhibited any PTK inhibitory activity, let alone against BCR-ABL kinase, the Board pointed out, at para 3.10.2, that this

> "disregards that the present application clearly teaches that dasatinib is suitable in the treatment of CML, which is tantamount to dasatinib being a BRC-ABL kinase inhibitor. … Hence, ... the skilled person was not left to guess, which of the various PTKs was inhibited by dasatinib. Accordingly, no further 'research programme' was necessary in order to carry out the invention. The allegedly observed failure of some compounds according to formula I to inhibit the protein kinase Lck … or the poor or reduced oral absorption properties of other compounds falling within the scope of formula I is irrelevant in this context. Equally irrelevant is the low activity of dasatinib on certain other PTKs such as HER1 or HER2 kinase.
>
> The [opponent's] arguments may have been relevant, if the application had been limited to the general disclosure relied on by the [opponent], ie the provision of an extremely broadly defined group of compounds for the treatment of a plethora of diseases or disorders based on the inhibition of different types of PTKs with no further guidance at all as to which compounds inhibits [sic] which PTK. However, as set out above this is presently not the case."

> 8. In summary, being told that there was a functional analogy between dasatinib and imatinib in that they both inhibited BRC-ABL kinase was sufficient information for the skilled reader to consider dasatinib's suitability in the treatment of CML to be a plausible teaching.

195. For these reasons, I consider that it puts the test too high to suggest that "the specification must disclose some reason for supposing that the implied assertion of efficacy in the claim is true" (Lord Sumption's judgment, para 36). That amounts on its face to, or certainly risks being read as, a requirement that the plausibility of the claim must appear to be established prima facie through scientifically cogent reasoning or experimental evidence set out in the specification. Admittedly, Lord Sumption goes on in para 36 to suggest that the test is "relatively undemanding". But he continues in para 37 to say that it is sufficient if the specification "would cause the skilled person to think that there was a reasonable prospect that the assertion would prove to be true", and then that "[the] reasonable prospect must be based on what the [Board of Appeal] in *SALK* (para 9) called 'a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se". It also explains that, in so far as no experimental data is produced, it can be:

> "demonstrated by *a priori* reasoning. For example, …, the specification may point to some property of the product which would lead the skilled person to expect that it might well produce the claimed therapeutic effect; or to some unifying principle that relates the product or the proposed use to something else which would suggest as much to the skilled person."

Despite the use of phrases such as "reasonable prospect" and "might well produce", there is a real risk that the test as described by Lord Sumption would amount to, or be understood as, involving a requirement to establish a *prima facie case* on the material contained in the specification. In my opinion, the authorities analysed above do not put the standard so high. They certainly reject speculative or wide-ranging unsubstantiated claims. But they accept as sufficient a tailored claim which appears scientifically possible, even though it cannot be said to be even prima facie established, without for example testing or assays according to the state of the art. Only if a person skilled in the art would have significant doubts about the workability of the invention would it, in such a case, fail for insufficiency of disclosure.

196. I therefore consider that Lord Sumption's judgment puts the test of sufficiency of disclosure too high. I agree with the way in which Lord Hodge puts the position in para 181 of his judgment. I am also persuaded that, applying the correct test, Arnold J cannot be said to have erred in concluding there was enough material "just [to] make it plausible that pregabalin would be effective to treat peripheral neuropathic pain" (para 351). My reasons correspond with those given more fully by Lord Hodge in paras 182 to 184 of his judgment, which I have had the benefit of reading since writing a first draft of my own.

Infringement

197. I turn finally to infringement. I need add nothing to what Lord Sumption and Lord Briggs have said on indirect infringement under section 60(2) of the Patents Act 1977. They are agreed that the prescription, dispensing or use of generic pregabalin to treat neuropathic pain does not "put into effect" the patented invention, or involve any supply to doctors, pharmacists or others of the means of putting it into effect. The patented invention is, under English law, the process completed by manufacture of the composition for the patent-protected use. Any subsequent use is not itself patented.

198. On the subject of direct infringement under section 60(1)(c), the other members of the court are however equally divided. Lord Sumption, with whom Lord

Reed agrees, is on the one side and Lord Briggs and Lord Hodge are on the other. I am the "swing" voice, and it is with some unwillingness that I pronounce on the issue at all. All our remarks on it will be obiter, and it is often better to leave a truly contentious and difficult issue to a case where it matters. I also confess that my own view has swung between the two sides.

199. Nevertheless, I will, in the circumstances, express my present conclusions. The issue has been fully argued, and it may at least diminish, though I fear not exclude, the prospect of further litigation if some indication is given to resolve the split of views exposed in this court. The issue remains relevant to old-style Swiss-patent cases - though it will not arise in the same form, and we will not be addressing the position, under article 54(5) of the European Patent Convention. Patentability under article 54(5) is of a product (a "substance or composition") for any specific use, whereas English law regards patentability under a Swiss-form patent as attaching to a process, namely the process of manufacture of a product for a specific purpose.

200. Both sides agree that the issue whether infringement of a Swiss-form patent involves any and if so what mental element depends on the construction of such a patent. Claim 3, which it is in this connection relevant to consider, relates to:

> "use of [pregabalin] for the preparation of a pharmaceutical composition for treating neuropathic pain."

201. The second word "for" must under such a claim relate to one of two different subjects. First, it may attach to the process consisting of the "use of pregabalin for the preparation of" the composition or product. Alternatively, it may attach to the pharmaceutical composition or product, as prepared, presented and put on the market. Whichever approach is taken, some relevance will attach to how the pharmaceutical composition is presented and put on the market. But, if one reads the claim in the first way, it is natural to enquire into the subjective intention of the manufacturer in preparing the composition. If one reads it in the second, it is natural to focus on objective appearances or characteristics, and in particular on the way in which the composition is prepared, presented and marketed.

202. In deciding what protection a Swiss-form patent offers and what will constitute infringement, it is appropriate to consider the implications of each interpretation, against the background of the legislative aim of striking a fair balance between the opposing desiderata of incentivising and rewarding inventors and enabling manufacturers to compete lawfully and pharmacists and end users to carry on their affairs without incurring unbargained for liabilities against which they cannot sensibly protect themselves. The risk that anyone will actually pursue any

liability claim against any particular pharmacist and/or end user may be slight in any individual case. But, if liability exists, some may well be pursued, to demonstrate the risks of dealing in generic goods, and all will be affected by the resulting deterrent effect. In any event, one would not as a matter of principle expect the law to involve uncovenanted and unavoidable liabilities.

203. Each way of reading the claim identified in para 201 gives rise to questions. What is meant by subjective intention? And what circumstances would fall to be considered, in order to ascertain how a product is prepared, presented and marketed? As to subjective intention, Lord Sumption and Lord Briggs agree that mere foreseeability that some generic pregabalin would be used for treating neuropathic pain could not suffice to render the maker of the composition an infringer. A Swiss-form patent entitles the maker to prepare the composition for the new purpose identified in it. The subsequent use of the composition involves persons outside the maker's control. Lord Sumption and Lord Briggs also agree in rejecting the Court of Appeal's solution of adding a qualification, so that foreseeability would suffice, if a generic manufacturer failed to take reasonable steps to prevent intentional use of the generic pregabalin by "downstream" prescribers or users for the treatment of neuropathic pain. I have nothing to add to their agreement on these points.

204. So, if subjective intention is the test, it must be found in something more positive than foreseeability, that is in some form of design or desire on the part of the manufacturer. It seems unsatisfactory that patent infringement should depend on investigation of a subjective intention, internal to the manufacturer. That would also leave open the possibility of entirely blameless pharmacists and end users being liable under section 60(1)(c) for, say, disposal or use of generic pregabalin made by a manufacturer, whose subjective intentions the pharmacist and user would have had no means of gauging.

205. It is true that section 60(1)(c) of the Patents Act 1977 has inherent in it the possibility of unwitting liability of a third party for disposing of, offering to dispose of, or using or importing a product made by a manufacturer by an infringing process. But the thinking behind section 60(1)(c) was certainly not focused on the later invented Swiss-form patent. Rather it was, one supposes, assumed that the process by which a product was made would generally be obvious or easily ascertainable.

206. In the case of a Swiss-form patent, it would be far from obvious or easily ascertainable whether there had been infringement, if the test were whether manufacture ("use for the preparation") of the composition had taken place by the manufacturer with the subjective intention that the composition be used for the specific purpose identified in the claim (ie here, "for treating neuropathic pain"). Further, if subjective intention were the test, what would this mean? Suppose that a manufacturer were deliberately to make more pregabalin than could be required for

patent-free uses, there would be no means of saying whether any particular batch would be used for patented or for patent-free use. Would this mean that all manufactured batches infringed? So it would seem. These and other consequences are discussed by Lord Sumption and, I understand, recognised by Lord Briggs (see his para 171). They are to my mind powerful reasons for rejecting subjective intention as the test in any form.

207. What then of a test focused on the way in which the pharmaceutical composition is prepared, presented and marketed? This must include in particular its packaging and the instructions given for its use, since the actual pharmaceutical composition is by definition identical to that produced by the patented process which it is said to infringe. Again, it is necessary to consider what such a test would mean. Here, some guidance is, in my view, available from German authority, identified by Lord Sumption in para 85 and by Lord Briggs in para 149. The German authority must be read with the understanding that a Swiss-form patent is under German law regarded as protecting a purpose-limited product, not (as under English law) a purpose-limited process. Accordingly, the protection is treated as arising under section 9(1) of the German Patentgesetz, the German equivalent of section 60(1)(a) of the Patents Act 1977 (rather than under section 60(1)(c)): see *Pemetrexed* (Case No X ZR 29/15) (14 June 2016) in the Bundesgerichtshof ("BGH"), para 84, *Östrogenblocker* (Case I-2/W 6/17) in the Düsseldorf Oberlandesgericht ("OLG"), para 38 and *Dexmedetomidin* (Case I-2 U 30/17) (Düsseldorf OLG) (1 March 2018), (BeckRS 2018, 2410, paras 41 to 43).

208. Swiss-form patents are therefore treated in Germany on the same basis as the ordinary patents of a product for a specific use (where such patents are otherwise permissible) which were considered in *Antivirusmittel* (Case X ZR 51/86) (16 June 1987) (BGH): see the reference made to *Antivirusmittel* in the Swiss-form patent case of *Chronic Hepatitis C Treatment* (Case 4a O 145/12) (14 March 2013) (Düsseldorf OLG), paras 51 to 54.

209. Since the German analysis treats a Swiss-form patent as protecting a product, rather than a process, it follows that third parties disposing of or using a generic product for the patented use are potentially exposed to liability under article 9(1) of the Patentgesetz: see also Chapter A, para 342 of Kühnen, *Handbuch der Patentverletzung*, 10th ed (2017), a work extensively cited in *Dexmedetomidin*. However, under article 139(2) of the German Patentgesetz, damages for patent infringement are only available against a person who has deliberately or negligently committed the infringement. German law could not therefore expose a doctor, pharmacist or end user to potential liability to damages in the way that section 60(1)(c) of the English Act would on Warner-Lambert's case. (Such a person could however still be injuncted against further infringement under article 139(1) of the German Patentgesetz.)

210. If the protection sought by a Swiss-form claim is treated, as English law treats it, as arising under section 60(1)(c), but is, at the same time, seen as operating in the second way identified in para 201 above (ie as attaching to the pharmaceutical composition as prepared, presented and marketed), then, despite the differences identified above, the German approach appears to me capable of illuminating what it would mean. Essentially, a Swiss-form claim would, under English law, still be understood as protecting a process, but the scope of the protection would depend not on the subjective intention with which the process was undertaken, but on the objective characteristics of the resulting composition or product, judged by reference to the way in which it was packaged and marketed.

211. The German authorities originally took a narrow view of what that could embrace, speaking in *Chronic Hepatitis C Treatment, Cistus* (Case I-2 U 53/11) (31 January 2103) (Düsseldorf OLG) and *Warner-Lambert Co LLC v Aliud Pharma GmbH* (Case 327 O 140/15) (2 April 2015) (Hamburg OLG) of *sinnfällige Herrichtung*, ie manifest outward presentation. This approach was echoed by the Technical Board of Appeal in *GENZYME/Treatment of Pompe's disease* [2016] EPOR 33, where the Board distinguished purpose-limited product claims from Swiss-form process claims, treating the latter (contrary to the view taken by the German courts) as falling within article 64(2) of the European Patent Convention (which equates with section 60(1)(c) of the Patents Act 1977). The distinction it drew was that the former offered protection whenever the patented product was used for the patented purpose, whereas the latter offered protection only in respect of a product which was produced by the patented process and was, in the instant case, "packaged and/or provided with instructions for use in the treatment of infantile Pompe's disease" (para 9.1). In drawing this general distinction, the Board of Appeal was not however concerned with the precise limitations of the requirement under a Swiss-form claim that, to achieve protection, the product produced by the process should be "for" the patented use.

212. As Lord Sumption and Lord Briggs point out, the more recent German authorities, *Östrogenblocker* and *Dexmedetomidin*, take a broader view of the protection generated by a Swiss-form patent. They do not focus on the external presentation (including the instructions for its use) of the allegedly infringing product, but rather on its inherent suitability for the patented use. However, they underline an additional requirement of any infringement, viz that the distributor

> "needs to take advantage of circumstances which - in a similar way to an active obvious preparation - ensure that the purpose-related therapeutic use of the preparation offered or sold actually takes place."

and

> "The latter requires a sufficient and not just occasional use according to the patent in suit, as well as the supplier's respective knowledge, or at least its bad faith ignorance thereof:"

See *Östrogenblocker* para 39 and *Dexmedetomidin* (BeckRS 2018, 2410, para 44). The example given in the latter case is use in practice of the generic product for the patent-protected indication to a considerable extent "in most cases due to a corresponding prescription by a doctor", in circumstances of which its supplier is or should have been aware, and which it "still exploits … for itself by supplying its distributors": para 44. The limitation relating to knowledge, bad faith taking advantage or exploitation, introduced in para 39 of *Östrogenblocker* and para 44 of *Dexmedetomidin*, appears as a pre-condition to any infringement, rather than as a reflection of the general limitation of damages claims provided by article 139(2) of the Patentgesetz, to which I have referred in para 209 above.

213. In my view, the preferable starting point under English law is to view a Swiss-form claim in the second way identified in para 201 above. In other words, it protects the process of manufacturing a composition or product, which, as prepared, presented and put on the market, can be said objectively to be "for" the patent-protected use. A process leading to a composition or product, which does not make clear that its permitted use is limited will infringe. In the light of submissions received from counsel on this judgment as circulated in draft in the usual way before issue, I prefer however to leave open whether there might be some circumstances in which a generic manufacturer could or should be expected to go further, by a notice positively excluding the patent-protected use. All I would say in relation to the present case is that (i) although the parties appear, now, to differ on whether this would be either permissible or permitted, this is only the result of a very belated objection by Warner-Lambert to a note filed by Actavis at the court's request as long ago as 23 February 2018 and (ii) at trial and in the admittedly slightly different context of the steps that Actavis should reasonably have taken to avoid being treated as intending to infringe, Warner-Lambert did not even pursue any suggestion that such steps should have included the attachment of a notice recording, for example, that the generic product was not authorised, and was not to be used, for the treatment of neuropathic pain: see Arnold J's judgment, paras 526-527 and 586-589. That is a very unpromising basis for any suggestion by Warner-Lambert that such a notice could or should have been given on the facts of this case, in order to avoid a conclusion that the generic product Lecaent was "for" the patent-protected use of countering neuropathic pain.

214. The delicate and difficult question is how far surrounding circumstances or general knowledge may be relevant, if in their light it is obvious or easily ascertainable that the process results in a product which, despite packaging and instructions making clear that it is for the non-patent-protected use, is destined for

such use. For reasons already given, neither foreseeability nor subjective intention can be accepted as appropriate tests of liability.

215. The recent German authorities do not appear to give any direct answer to the question what a manufacturer is supposed to do, if it acquires the awareness of a "practice" of the sort mentioned in para 212 above. *Dexmedetomidin* (BeckRS 2018, 2410, para 44) says that it will be justified to hold it liable if "it still exploits this practice for itself by supplying its distributors". If that means that it must stop manufacturing and supplying any generic product, it involves an extreme solution which is too favourable to the patent-holder, since it excludes competition by the generic product even in patent-free areas of use. Another possibility is to read the German authorities as implying tacitly that the generic manufacturer should take (presumably, reasonable) steps to ensure that pharmacists and end users do not use the generic product for patented use. That would equate with the Court of Appeal's approach in this case, which constructs a pre-condition to legitimate manufacture and trade for which no basis, in my view, exists.

216. There is however a further possibility, which appears to have the support of paras 351 and 353 of Kühnen's work already cited, namely that, since a generic manufacturer has no contractual relationship with and cannot give directions to a third party such as a doctor prescribing drugs, the most that can be expected of such a manufacturer is that it makes clear on the product that it is not for the patent-protected use. It would seem to me also appropriate under English law to hold a generic manufacturer responsible in similar circumstances, if it was not made clear, in one way or another, that the product resulting from its manufacturing process was for the non-patent-protected use. However, although the context was again somewhat different, I note here the rejection by Arnold J, in paras 443-447 of his judgment, of Warner-Lambert's submission that Actavis must be taken to have foreseen the use of Lecaent for the treatment of neuropathic pain because of the inclusion of warnings as to adverse effects if it was so used or because of "blue box" wording to the effect that it might be prescribed to treat other conditions not listed in the leaflet.

217. Because context is all in the law, I also think that we should be careful about committing ourselves in obiter remarks in relation to other extreme cases not now before us. It may be going too far in favour of generic manufacturers to suggest as an absolute rule that a generic product, prepared, presented and put on the market, must always be viewed in isolation by reference only to its own packaging and instructions, and without regard to the realities or of the market for which it is prepared and into which it is being released. Take a situation where the circumstances make it obvious that a product, ostensibly limited in its permitted use by its packaging and instructions, was in fact destined for wider use; suppose that the manufacturer were to point out in separate studies, reports or advertisements that the composition resulting from its manufacturing process was pharmaceutically

identical with that made by a manufacturer operating under a Swiss-form patent; or suppose a generic manufacturer were to produce and supply quantities of the pharmaceutical composition for a distributor in a context which only made sense if they were destined for the patent-protected use. Even then, the question could arise whether it was sufficient that this was obvious as between the generic manufacturer and its buyer or whether it would also have to be obvious more generally, and in particular to persons dealing in or using the composition down the chain in view of their potential exposure in the event of any infringement by the manufacturer. The wide and unqualified grasp of section 60(1)(c) (see para 205 above) might leave third parties with some exposure in a remote situation such as I am currently postulating.

218. I prefer to say no more, and to leave open, the position in this type of remote situation. Normally, a generic manufacturer, and it follows others such as doctors, pharmacists and end users, should be protected from infringement of a Swiss-form patent if the manufacturer ensures that the generic product resulting from its manufacturing process is produced, prepared and marketed with a clear limitation to patent-free uses. As Kühnen observes, a generic manufacturer cannot control the activities of doctors, pharmacists and end users, with which it is in no contractual relationship. The protection afforded by a Swiss-form patent, analysed as protecting a process in the way that English law analyses it, is valuable, but necessarily limited.