WARNER-LAMBERT v ACTAVIS: THE SUPREME COURT'S JUDGMENT ON SECOND MEDICAL USE CLAIMS

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In a decision following a long series of judgments which raise a number of novel and interesting legal and commercial points, the Supreme Court has finally held[1] that Warner Lambert's second medical use patent for the use of pregabalin in the treatment of neuropathic pain is invalid on grounds of insufficiency.

The judges of the Supreme Court have provided clarification as to what degree of evidence of efficacy must be included in the patent specification to satisfy the statutory requirement of sufficiency. The judges also opined, *obiter*, as to the correct test for infringement of a second medical use patent drafted in the so-called 'Swiss form' – use of substance X for the preparation of a medicament for treating indication Y. The judges were unable to agree on this latter issue, and as second medical use patents are of increasing importance to the pharmaceutical industry, this is unlikely to be the last word on the subject.

In this article, rather than attempting to summarise each technical issue discussed by their Lordships, the authors will draw out and discuss the principles decided which are of general applicability to second medical use patents containing Swiss form claims. The authors also consider the applicability of the decision to patents containing second medical use product claims, which are now the only form in which new second medical use patents can be granted.

Background

The case concerns the pharmaceutical compound pregabalin, marketed by Warner-Lambert (part of the Pfizer group) as Lyrica. The drug is used for treatment of epilepsy, generalised anxiety disorder and neuropathic pain. Pregabalin itself was protected by a patent which expired in May 2013. The patent in dispute, EP(UK)0934061 ('the patent'), is concerned with the use of pregabalin for treatment of pain, particularly neuropathic pain. The drug is a best-seller for Warner-Lambert – in Arnold J's first judgment in respect of Warner Lambert's application for an interim injunction,[2] annual sales in the United Kingdom alone were said to be in excess of £200 million in 2013. According to the evidence submitted to the court, at least 50 per cent of those sales related to treatment of pain.

After expiry of the patent protecting pregabalin *per se*, Actavis obtained marketing authorisation to launch a generic pregabalin product (which it intended to sell under the name Lecaent). This dispute concerns whether Warner-Lambert can compel Actavis to take steps to ensure that Lecaent is not dispensed for the treatment of pain, in respect of which the patent applies.

Second Medical Use Patents

Given the enormous costs involved in developing new pharmaceutical compounds, the pharmaceutical industry has been active for many years in searching for new medical uses for known compounds. The advantages are obvious: known compounds will already have been tested for safety, and can therefore be brought to market for new uses far more quickly and cheaply than entirely new compounds.

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1) *Warner-Lambert Company LLC v Generics (UK) Ltd & Actavis Group PTC EHF* [2018] UKSC 56.

2) [2015] EWHC 72 (Pat).

Prior to the entry into force of the European Patent Convention 2000, the only means by which a second medical use of a known pharmaceutical could be patented was in the so-called 'Swiss form' ('use of substance X for the preparation of a medicament for treating indication Y'). Swiss form claims are purpose-limited process, not product, claims.

The EPC 2000 permitted the grant of purpose-limited product patents, and since 2011, patents with Swiss form claims are no longer granted by the EPO, that is, second use medical patents must now be applied for in EPC 2000 form. Patents containing Swiss form claims granted prior to that date will, however, continue in force for at least a further decade.

Pregabalin itself was initially used as an anticonvulsant and for treatment of certain anxiety disorders. Subsequently, it was discovered that it could be used in the treatment of neuropathic pain (see next section for an explanation of this term). The first three claims of the patent read:

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

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

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

Types of Pain

Lord Sumption sets out, at paragraph 6, a concise and readable explanation of the different types of pain, an understanding of which is necessary to understand the decision. In summary:

- Broadly speaking, pain falls into two categories, termed nociceptive and neuropathic pain.
- Nociceptive pain is experienced in response to stimuli including heat, mechanical pressure and chemicals. Such pain subsides upon treatment of the underlying cause.
- Inflammatory pain is a sub-category of nociceptive pain, caused by the body's response to an injury. Again, inflammatory pain subsides upon treatment of the underlying cause.
- Neuropathic pain results from damage to the nervous system itself. It can be peripheral (arising from damage or dysfunction of the peripheral nervous system) or central (arising from damage or dysfunction of the central nervous system).
- Neuropathic pain can last for years or even for life. Treatments for nociceptive/inflammatory pain are not normally effective for treatment of neuropathic pain.

'Skinny Labels'

In order to market a pharmaceutical compound, marketing authorisation must first be obtained. A generic manufacturer, seeking to market a pharmaceutical compound after the period of patent protection for the compound itself has expired, is permitted, once the ten-year period of data exclusivity has expired, to rely upon the marketing authorisation of the originator's product. In doing so, the generic manufacturer is required to submit only data proving equivalence of the generic product, and not the full data that is normally required for authorisation of a new product. When relying on an existing authorisation, the generic manufacturer is also required to submit to the regulator product information (called the Summary of Product Characteristics or 'SmPC'), the package leaflet for patients and the labelling. When authorised, that same information is required to be included in the Patient Information Leaflet ('PIL').

The originator's SmPC and PIL may make reference to indications or dosage forms which are protected by subsequent patents, and if so the generic manufacturer is permitted to exclude such indications/dosage forms. The truncated SmPC/PIL in this scenario is referred to as a 'skinny label'. Skinny labels are therefore used by generic manufacturers to reduce the risk of infringing second medical use patents. Actavis's SmPC and PIL state that the conditions for which Lecaent is indicated are epilepsy and generalised anxiety disorder, for which patent protection has expired.

Case History

The dispute has a long and complex procedural history. Warner-Lambert initially applied, in late 2014, for an interim injunction requiring Actavis to take a number of steps to prevent Lecaent from being dispensed for treating pain. In a

series of three judgments,[3] Arnold J refused to grant such an interim injunction, on the grounds that (i) Warner-Lambert had no arguable case of infringement, and (ii) in any event, the balance of justice favoured refusal of the injunction. Arnold J did, however, order NHS England to issue appropriate guidance about prescribing pregabalin. The authors summarised those three judgments in an earlier article.[4]

On appeal, whereas the Court of Appeal disagreed with Arnold J's analysis of whether Warner-Lambert's cases of direct and indirect infringement were arguable, it upheld his decision not to grant an interim injunction.[5]

The trial of the action was then heard by Arnold J in June–July 2015, who held[6] that:

(i) none of the claims of the patent are obvious over any of the prior art relied upon by the defendants;

(ii) claims 1, 3, 4, 6, 13 and 14 of the patent are invalid on the ground of insufficiency; and

(iii) even if claims 1 and 3 had been valid, Actavis had not infringed those claims.

Arnold J also refused permission,[7] on grounds of abuse of process, for Warner-Lambert to make a post-trial amendment to claim 3 of the patent, which sought to limit the scope of the claim to peripheral neuropathic pain, and thus to exclude from its scope central neuropathic pain, which had been held to be vulnerable to the insufficiency attack (see section on 'sufficiency' below).

On appeal, Warner-Lambert's appeals against the findings of insufficiency and non-infringement were dismissed, as was the defendants' cross-appeal against Arnold J's finding that the patent did make a plausible claim that pregabalin was effective to treat peripheral (but not central) neuropathic pain.[8]

Issues in Dispute

The issues in dispute before the Supreme Court were summarised by Lord Sumption as:

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

(2) the sufficiency of the disclosure in the specification;

(3) whether Warner-Lambert's proposed post-trial amendments to the patent constituted an abuse of process; and

(4) the test for infringement of a patent for manufacture of a product for a limited use.

Construction

The issue of construction was addressed primarily in Lord Briggs' judgment. Claim 3 claims use of pregabalin 'for the preparation of a pharmaceutical composition for treating neuropathic pain'. The issue to be determined was whether, in this context, 'neuropathic pain' means all neuropathic pain, that is, including central neuropathic pain (termed the 'broad construction') or only peripheral neuropathic pain (termed the 'narrow construction'). Arnold J and the Court of Appeal both held that the broad construction was the correct one. As we shall explain, the construction was of importance in determining the issue of sufficiency.

Warner-Lambert, arguing for the narrow construction, advanced the argument that patents should be construed on the principle of validating construction, that is, where possible, a construction should be preferred which results in the relevant claim being treated as valid. Lord Briggs expressed considerable scepticism as to whether that principle, derived from the law of contracts and applied historically to patents in English law, has any applicability to patent construction in the modern era. He pointed out that European patent construction is governed by the Protocol to the EPC, which seeks to balance the competing interests of patentees and third parties. In Lord Briggs' view, in relation to second medical use patents in particular, the need for clarity in the scope of claims is the decisive factor. At paragraph 98 he said:

> *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*

3) [2015] EWHC 72 (Pat); [2015] EWHC 223 (Pat); [2015] EWHC 485 (Pat).

4) [2014] BSLR 14(3), 107–114.

5) [2015] EWCA Civ 556.

6) [2016] RPC 3.

7) [2015] EWHC 3370 (Pat).

8) [2016] EWCA Civ 1006.

> *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.*

Reviewing the grounds on which Warner-Lambert argued that the term 'neuropathic pain' is ambiguous, he held:

> *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.*

The other judges agreed with this aspect of Lord Briggs' judgment (Lord Mance with some reservations), and accordingly the (broad) construction adopted by Arnold J was upheld.

Sufficiency

The key matter in dispute in relation to sufficiency was whether or not it was plausible from the specification of the patent that pregabalin is effective for the treatment of neuropathic pain. At first sight, that question is somewhat surprising, given that neither the EPC nor the Patents Act 1977 contain any express requirement of plausibility, whether in relation to sufficiency or otherwise. The requirement of plausibility is instead a judge/EPO-made rule. Lord Sumption provides an explanation of the policy considerations underpinning the requirement – to avoid the risk of 'armchair inventors' speculatively patenting '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'.

The requirement of plausibility was first laid down in a series of EPO decisions[9] in relation to inventive step – a patentee must not only disclose the invention and details of how it may be implemented, but must also provide plausible reasons as to why it can be expected to work. In subsequent decisions of the EPO[10] and the English courts,[11] the requirement of plausibility has been imported into the law of sufficiency in respect of second medical use patents, including Swiss form patents.

Drawing together the various threads from the case law, and rejecting Warner-Lambert's contention that the requirement to establish plausibility applies only where the therapeutic effect suggested in the patent is inherently implausible, Lord Sumption (writing for the majority) stated the following principles:

(1) The proposition that a product is efficacious for the treatment of a given condition must be plausible.

(2) A bare assertion to that effect will not suffice, and nor will the disclosure of a mere possibility that it will work.

(3) A claimed therapeutic effect may potentially be rendered plausible by a specification showing that something was worth trying for a reason, that is, 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.

(4) 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.

(5) That reasonable prospect must be based on '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'.

(6) The effect on the disease process can potentially be demonstrated by *a priori* reasoning, rather than experimental evidence.

9) Including *JOHN HOPKINS UNIVERSITY SCHOOL OF MEDICINE/Growth differentiation factor-9* (T–1329/04) and *BRISTOL-MYERS SQUIBB/Dasatinib* (T–0488/16).

10) *SALK INSTITUTE FOR BIOLOGICAL STUDIES/AP-I complex* (T–609/02).

11) *Prendergast's Applications* [2000] RPC 446.

(7) Whereas the disclosure may be supplemented or explained by the common general knowledge of the skilled person, the skilled person must be able to derive the above from the disclosure of the patent.

(8) Plausibility has to be demonstrated across the whole scope of the claim.

(9) Whereas data published after the date of the patent application may be admissible either to *confirm* plausibility as disclosed in a patent, or to refute a contention that it does not work, subsequent data cannot be used to establish plausibility (and hence sufficiency) in the absence of sufficient disclosure in the specification.

Applying the above principles to the patent, Lord Sumption noted that the experimental data in the specification of the patent related only to animal models in respect of inflammatory pain. In light of principle 6 above, he held that 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'. Arnold J, having heard the expert evidence, had rejected the notion that there was any such unifying principle embracing *central* neuropathic pain, and Lord Sumption regarded the judge's reasoning in this regard as 'unanswerable'.

Arnold J had, though, held that the experimental data in the specification enabled a plausible prediction to be made that pregabalin would be effective for treating *peripheral* neuropathic pain. Specifically, the judge had found as fact that it was common general knowledge that a phenomenon known as 'central sensitisation' was involved in both inflammatory and peripheral neuropathic pain. The judge then concluded that it was 'possible … although this would not necessarily be the case' that a drug shown to be effective against inflammatory pain would also be effective against peripheral neuropathic pain.

Whilst mindful of the *Biogen* principle[12] – that 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 – Lord Sumption did overturn Arnold J (and the Court of Appeal), on the grounds that the judge's findings of fact did not support the conclusion he reached. In Lord Sumption's view, Arnold J's conclusion was a 'logical non-sequitur':

> *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. (paragraph 52)*

Lord Sumption therefore concluded that claim 3 was invalid for insufficiency irrespective of the type of neuropathic pain. Consequently, even had the term 'neuropathic pain' been construed as applying only to 'peripheral neuropathic pain', claim 3 would still have been invalid.

Infringement

Given the findings of invalidity of the key claims, the discussion of the law of infringement is *obiter*. Nonetheless, it is of interest, particularly as it is the first occasion on which infringement of Swiss form claims has been considered at this level.

The main discussion in the judgments was in relation to the direct infringement claim under section 60(1)(c) of the Patents Act 1977. That provision states that a patent is infringed by a defendant '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'. The judges were unanimous that that provision potentially applied not only to manufacturers of generic medicaments, but also to entities further down the chain, including importers, distributors, wholesalers and dispensing pharmacists.

12) *Biogen Inc v Medeva Plc* [1997] RPC 1.

The five judges fell broadly into two 'camps'. Lords Sumption and Reed, rejecting any subjective or mental element in the test, proposed an 'outward presentation' test. The only relevant matter in this approach 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'. Only if, objectively speaking, that outward presentation shows that the product is intended for the patented indication(s) will infringement be made out.

Lords Hodge and Briggs instead adopted a subjective test – where it can be established that the manufacturer subjectively intended to target the patented indication(s), there will be infringement. Lord Mance adopted the middle ground – whereas his preferred starting point was the 'outward presentation' test, he '*prefer[red] 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*'.

Warner-Lambert also claimed indirect infringement pursuant to section 60(2) of the Patents Act, which provides that a patent is infringed where a defendant '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'.

The judges unanimously held that section 60(2) was inapplicable to post-manufacture activities relating to Swiss form patents, on the grounds that the invention is the manufacture of pregabalin for the designated use, and not its subsequent use for treating patients. As Lord Briggs explained at paragraph 135:

> *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.*

Post-trial Amendment

Arnold J had held that Warner-Lambert's attempt, post-trial, to amend claim 3 to limit it to peripheral neuropathic pain, would give rise to further issues of clarity, added matter and sufficiency, thereby necessitating a further trial. This could have been avoided by an application to amend before or even during the trial, and it was an abuse of process to leave the application until after trial.

Given the majority decision that claim 3 was invalid for insufficiency, even in relation to peripheral neuropathic pain, the application to amend could not have succeeded in any event. However, Lord Briggs (with whom all the other judges agreed) did provide his reasoning as to why Arnold J's refusal was correct. Lord Briggs confirmed that the right to amend a patent, laid down in the EPC, is subject to English procedural law and is therefore not an unfettered right. The Court of Appeal's decision in *Nikken*,[13] which held that a post-trial amendment which would necessitate a further trial contravened the principle in *Henderson v Henderson*[14] and was therefore an abuse of process, was upheld as a correct statement of English law.

Discussion

Their Lordships took the trouble to provide fully reasoned judgments even on *obiter* issues, which merit close reading, and the authors therefore provide only their brief observations on each of the issues determined.

There are various canons of construction, potentially applicable to construing contracts, statutes, patents and so on. In many cases, one or more of the canons can be useful in resolving ambiguities. Although Lord Briggs was sceptical as to the applicability of the validating construction to patent law, he did not rule it out altogether in appropriate cases.

13) *Nikken Kosakusho Works v Pioneer Trading Co* [2005] EWCA Civ 906.

14) (1843) 3 Hare 100.

Certainly, the authors can envisage scenarios, involving genuine ambiguities in claim language, where the validating construction might be helpful in construing a patent.

The first step, however, in patent law at least, is to decide whether the meaning of the words in the claims can be determined from the specification and the common general knowledge. If the meaning is clear, a canon of construction such as the validating principle is simply inapplicable. The authors therefore agree with the general approach adopted by Lord Briggs, in refusing to 'engineer' an ambiguity in order to use a canon of construction to arrive at a strained construction.

With regard to sufficiency, it is now clear that the requirement of plausibility is firmly entrenched in the EPO and the English courts. Whereas Lord Sumption held that there is no requirement for the specification to provide *definitive* evidence of efficacy, or even experimental evidence at all, he refused to ignore altogether the requirement to provide some reason – experimental evidence, theoretical justification, or otherwise – which the skilled person would consider is a plausible reason to suppose that the claimed therapeutic effect is true. The authors consider that Lord Sumption drew the line at a sensible point, balancing policy factors (such as the need to prevent speculative patenting and to ensure that the patent monopoly is justified by the technical contribution to the art) and practical considerations (such as the need to apply for patent protection at an early stage, before definitive evidence of efficacy may be available).

Whereas Lord Sumption's analysis was not supported by all the judges – Lords Mance and Hodge dissented on this issue – it is not clear (to these authors at least) whether the latter two judges did in fact have a substantive disagreement with the majority. Lord Hodge said (at paragraph 180): 'I do not interpret [the case law] as requiring the patentee to demonstrate within its patent a prima facie case of therapeutic efficacy'. However, he went on in the next paragraph to say that there is a requirement 'that the therapeutic effect of the medication appears plausible from the data in the patent interpreted in the light of the common general knowledge [but no requirement] 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'.

The authors are unable to distinguish any difference between that analysis and the principles set out by Lord Sumption. It may be the case that Lords Mance and Hodge simply considered, contrary to the majority, that Arnold J's conclusion in respect of peripheral neuropathic pain was supported by his findings of fact. In any case, the majority view is binding, and it is now the law that plausibility must be positively demonstrated by the specification in patents containing Swiss form claims.

As to infringement, it is unfortunate, but not altogether surprising, that no common ground could be found as to the applicable test. The relevance of a mental element to direct patent infringement is not immediately obvious, given that infringement under section 60(1)(c) is a tort of strict liability. The reason for the mental element is the structure of Swiss form patent claims themselves – the preparation of the pharmaceutical composition must be 'for' treating the claimed indication. It is the meaning of the word 'for', in this context, which gives rise to the judges' different approaches.

Whereas Lord Sumption's test – the outward presentation must objectively show that the product is intended for the patented indication – has the benefit of simplicity, it could (as he acknowledged) lead to unfairness. It is easy to envisage a situation in which a generic manufacturer pays lip service to the rules by producing fully compliant packaging and information, but actively seeks, behind the scenes, to promote the use of its product for patented indications. Such bad faith activities would not be caught by the 'outward presentation' test.

The subjective test proposed by Lords Hodge and Briggs would catch the above, but would also be likely to have a chilling effect on the market, as a party further down the chain would not necessarily be privy to the manufacturer's state of mind. Even if Lord Sumption overstated matters slightly when he said (at paragraph 76) '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',[15] the authors certainly agree that it is preferable, where possible, to avoid such a scenario arising.

15) The authors would point by way of analogy to Community unregistered design infringement, where copying is a necessary part of the tort, but the liability of actors further down the chain, who may have no knowledge of the manufacturer's creation process, is strict.

The answer, in the authors' opinion, lies in a test which distinguishes between the manufacturer and parties further down the chain. The subjective test, for example, could apply to the manufacturer, and the 'outward presentation' test to parties further down the chain. Such a solution would require legislation – the judges quite rightly ruled out creating 'non-statutory defences to statutory torts'.[16] Whether or not Parliament will find the time for such legislation seems doubtful, given the other matters which seem likely to monopolise its attention for the foreseeable future.

Would the Outcome be the Same for a Second Use Patent under Article 54(5)?

Since the EPC 2000 came into force in December 2007, it has been possible pursuant to Article 54(5) to apply for a patent in relation to a second medical use in the form 'product X for treating indication Y'. As stated above, Swiss form claims are no longer permitted for new patent applications, although patents containing Swiss form claims are likely to be in force for at least a further decade. This raises the question as to whether the approach adopted in this decision would be equally applicable to EPC 2000 second medical use claims.

The authors believe that a good argument can be made that the same policy considerations – protecting against speculative patenting – apply equally to EPC 2000 second medical use claims. The requirement of plausibility has been held to apply to the test for insufficiency in relation to EPC 2000 claims,[17] and the authors can see no reason why the same test for assessing plausibility ought not to be applied to the claims in such patents. In the very recent decision in the Patents Court in *Eli Lilly v Genentech*,[18] which was heard after the Supreme Court's decision in *Warner-Lambert*, it was common ground between the parties, and accepted by Arnold J, that the same test for plausibility applied to EPC 2000 second medical use claims (and also to first medical use claims). Pending consideration at a higher level, therefore, it seems that the test is the same irrespective of the form in which the patent claims are drafted.

In terms of infringement, EPC 2000 second medical use claims are product claims, not process claims, and section 60(1)(c) would have no applicability. The relevant section of the Patents Act 1977 for a direct infringement claim would be section 60(1)(a), which states that a patent is infringed by a defendant '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'. As with section 60(1)(c), direct infringement of a product claim is a tort of strict liability, and any mental element in the test for infringement is a result of the form of the patent claim itself. In the authors' opinion, it would make sense for the word 'for' in an EPC 2000 second medical use claim to be interpreted in the same manner as in a Swiss form claim. If that were accepted by the courts, it would mean that the legal test for direct infringement of EPC 2000 second medical use patents would be the same as for Swiss form patents (albeit that there is currently no certainty as to the nature of that test).

In respect of indirect infringement of such claims, however, the legal position may very well be different. The section 60(2) indirect infringement claim in this dispute was rejected on the grounds that the invention in the patent is the manufacture of pregabalin for the designated use, an activity that only the manufacturer, and no party further down the chain, is carrying out. Given, though, that EPC 2000 second medical use claims are product claims, a wholesaler or pharmacist supplying a product could potentially be caught by section 60(2), where foreseeability of use of the product for the patented indication is made out. That could be so even if direct infringement under section 60(1)(a) is held to involve an objective test. Certainly, in the subsequent decision in *Eli Lilly v Genentech*, Arnold J held that foreseeability that some ultimate users will intend to put the invention of EPC 2000 claims into effect using the essential means suffices to establish infringement on the part of the manufacturer. Determination of whether the same principle applies to parties further down the chain will have to wait for a suitable test case.

Conclusion

This is very unlikely to be the final word on this subject. It is clear, from the financial data mentioned in the 'Background' section, that substantial amounts of money can be at stake in this and other similar disputes, so the authors expect that this sector will give rise to considerable new case law in the next few years, particularly in respect of EPC 2000 second medical use claims.

16) Lord Sumption at paragraph 81. See also Lord Briggs at paragraph 160.

17) See, for example, *Regeneron Pharmaceuticals Inc v Genentech Inc* [2013] EWCA Civ 93 and *Idenix Pharmaceuticals Inc v Gilead Sciences Inc* [2016] EWCA Civ 1089.

18) [2019] EWHC 387 (Pat).