

Intention, ‘off-label prescriptions’ and new use patents after *Warner-Lambert v Generics*

Warner-Lambert v Generics [2018] UKSC 56 provides a good case study for discussing the role of *mens rea* in IP.

At the heart of the dispute was an issue of policy: how to provide sufficient protection to the proprietor of a second medical use patent whilst avoiding interference with the freedom to use the product for non-patented indications?

One proposed solution was to introduce a requirement of mens rea into the otherwise strict liability tort of patent infringement. But what form should the mens rea requirement take? Should the mens rea requirement bite on liability only or should it also impact on the remedies available? Whose mens rea was relevant? How would the requisite mens rea be proved?

The opinion of the majority in the Supreme Court, expressed obiter dicta, was that there ought to be no requirement of mens rea at all. Had the patent been valid, it was the opinion of Lords Sumption, Reed and Mance that the correct test for infringement would have been an objective one based on the ‘outward appearance’ of the alleged infringing article. The minority opinion, expressed by Lords Hodge and Briggs, was that mens rea ought to play a role and that the correct mental element would have been one of subjective intention.

The difference of opinion turned principally on two points: which test best reflected the meaning of the purpose-limitation in the second-medical use claim and which best balanced the competing interests of patentee, generic manufacturer, downstream suppliers and pharmacists, and patients?

Significant questions remain, not least because of the notable reluctance of Lord Mance to fully endorse the outward appearance test in his opinion. How is the ‘outward appearance’ test to be satisfied? In what circumstances can the Court look beyond the outward appearance of the product to the particular conditions of the marketplace or the manner in which the product is marketed? Should the manufacturer ever be required to positively exclude use for the patent-protected purpose and, if so, what steps should the manufacturer take to do so? Will the ‘outward appearance’ test also apply to EPC 2000 claims and, if so, how?

Background

The Patent

The patent in *Warner-Lambert* was a second medical use patent. The patent taught that pregabalin could be used for the treatment of pain, in particular neuropathic pain. Neuropathic pain was the medical term used to cover a variety of different pathological pain conditions, all of which were distressing and debilitating for patients and resistant to treatment with known painkillers.

At the priority date, pregabalin was already known as a pharmaceutical for the treatment of epilepsy and generalised anxiety disorder (“GAD”). As such, a claim to pregabalin alone would have lacked novelty¹. Similarly, a claim to the use of pregabalin for the treatment of pain would have fallen foul of the prohibition on patenting methods of medical treatment². Warner-Lambert therefore adopted the “Swiss-form” style of claim, named after the Patent Office that originally devised it, as a mechanism for obtaining a valid claim to a second medical use of pregabalin. The relevant claims for the purposes of the infringement case were claims 1 and 3:

1. Use of pregabalin for the preparation of a pharmaceutical composition for treating pain

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

The commercial products

Warner-Lambert’s commercial pregabalin product was called Lyrica® and was authorised for neuropathic pain, epilepsy and GAD. In February 2015 Actavis launched its pregabalin product, Lecaent®. Actavis launched under a ‘skinny-label’ meaning that its product was authorised for the treatment of epilepsy and GAD only. The ‘indications for use’ on the patient information leaflet (“PIL”) included in boxes of Lecaent® covered only epilepsy and GAD. In accordance with good practice, the PIL included warnings as to adverse events when pregabalin was taken for the treatment of neuropathic pain and the following ‘blue box’ wording:

“Lecaent may be prescribed to treat other conditions not listed in this leaflet. If you have any questions, ask your doctor or pharmacist”

¹ s. 1(1)(a) Patents Act 1977 (“PA”)

² s. 4A(1)(a) PA

Procedural history

Warner-Lambert started proceedings against Actavis by seeking an interim injunction against Actavis on the basis that Lecaent® was an infringing product. There followed a series of interim hearings in the Patents Court and Court of Appeal expressed different views as to the correct test for infringement. Arnold J's view was that it was one of subjective intention. The Court of Appeal disagreed, stating that it was an objective test of reasonable foreseeability. The upshot of the various interim applications was that the interim injunction was refused but NHS guidance was put in place in an attempt to prevent Lecaent® being used for the treatment of pain.

NHS Guidance

The NHS guidance was conceived as a pragmatic solution to the problem of generic prescribing. Clinicians in the UK generally write prescriptions by reference to their international non-proprietary names ("INN"). The choice as to which brand is left to the pharmacist. In the majority of cases the pharmacist will not know the purpose of the prescription. As a consequence, where a prescription is written by reference to the INN, a skinny label product is likely to be used to treat the patented indication. In contrast, if a prescription is written by reference to a brand name, the pharmacist will dispense the branded product.

The hope was that if the NHS issued guidance to clinicians requiring them to prescribe by reference to brand name when prescribing pregabalin for the treatment of neuropathic pain, the amount of generic product being dispensed to treat the patented indication would be minimised.

The evidence at trial indicated that the NHS guidance was proving effective. The overall figures indicated that in the 3-month period following launch of generic product, the amount of generic product sold was consistent with it only being used for the non-patented indications³.

Judgments of High Court and Court of Appeal

The legal issue as to what the test for infringement should be had been discussed at the interim stage of proceedings. As it transpired, claims 1 and 3 of the patent were invalid⁴ and so there could be no infringement. However, in the substantive judgment following trial, Arnold J dealt with the

³ Approximately 70% of the pregabalin market was for pain. In the 3-month period following launch of generic pregabalin product, just 17.4% of sales of pregabalin were made by the generics. Warner-Lambert therefore retained over 80% of the pregabalin market [§§415, 560-564 Arnold J judgment]. Whilst the possibility that generic product was being used for pain could not be excluded, overall the figures indicated that the generics were not encroaching on the market for patented indications.

⁴ On the ground of insufficiency: Warner-Lambert's appeals against the finding of invalidity failed at both the Court of Appeal and Supreme Court.

infringement case fully and expressed reservations about the test set out by the Court of Appeal at the interim stage.

Arnold J found that Actavis had not intended Lecaent® to be dispensed for the treatment of pain: therefore, had the test been one of subjective intention, it was not met. Furthermore, Arnold J applied the Court of Appeal's test of reasonable foreseeability and found that that test was not met either: it was not foreseeable to Actavis that Lecaent® would have been intentionally administered for the treatment of pain (save perhaps for *de minimis* use) at any relevant date.

Two points are worth noting. Firstly, Arnold J's view was that there would only be 'intentional' administration of Lecaent® for pain where the pharmacist dispensed Lecaent® in the knowledge that pregabalin had been prescribed for pain. Secondly, it was relevant to the question of reasonable foreseeability that various measures had been implemented to minimise the possibility that a pharmacist would dispense Lecaent® in the knowledge that pregabalin had been prescribed for pain. Such measures included the NHS guidance.

Warner-Lambert's appeal against the finding that the patent was invalid failed. However, given the difference of opinion expressed between the Patents Court and the Court of Appeal on the appropriate test for infringement at the interim stage, Floyd LJ revisited the issue of infringement. He concluded, *obiter dicta*, that a test of reasonable foreseeability was appropriate subject to the gloss that where the manufacturer had taken all reasonable steps within its power to prevent its product being used for the patented indication there would be no infringement. Floyd LJ went on to express his disagreement with Arnold J's formulation of the reasonable foreseeability test. In Floyd LJ's view the correct question was not "was it reasonably foreseeable that the product would be *intentionally used* to treat pain" in the sense that '*intentional use*' meant that the pharmacist knew that the product would be used to treat pain, but was simply "was it reasonably foreseeable that the product would *in fact* be used to treat pain". Floyd LJ clarified that his earlier reference to such use being 'intentional' was simply meant to distinguish deliberate from accidental use i.e. the situation where a patient is prescribed pregabalin for GAD but also suffers from pain so that, incidentally, their pain is also treated.

Issue before the Supreme Court

The Supreme Court initially gave permission to appeal on issues concerning the validity of the patent. The Supreme Court later granted a joint request by the parties to also consider what the correct test for infringement was and, if the patent was valid, to determine based on the findings of fact below whether or not there was infringement.

As framed, the issue of infringement before the Supreme Court was whether the correct test for infringement of medical use patent claims was one of “intention” or “reasonable foreseeability”.

The Legal context

Before turning to consider the judgments of the Supreme Court, it’s important to put the issue of infringement in its proper legal context.

The acts that constitute patent infringement are set out in section 60 PA:

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”.

A Swiss-form claim is a process claim, the process being the manufacture of the pharmaceutical for the particular indication. The relevant section is therefore s.60(1)(c)⁵.

The statutory language of s.60(1)(c) imposes a tort of strict liability: it is an infringement to dispose of, use or import or keep for those purposes any product that is obtained directly by a patented process. So why were the parties arguing about mental elements at all?

⁵ Warner-Lambert also framed their case as one of indirect infringement under s.60(2). However that aspect of the case was dismissed in short order by the Supreme Court.

The answer lies in the wording of the patent claim itself. To determine whether or not a patent is infringed it is necessary to first construe the patent claim. It is only once that is done that it is possible to address the question of whether, pursuant to s.60(1)(c), a particular product has been obtained by use of the patented process. The basic principles of construction are found in s.125 PA and the Protocol on the Interpretation of Article 69 EPC. Neither a strict, literal approach to the claim language nor an approach that treats the claim as merely a guideline is permissible: instead, the claim should be interpreted so as to combine “*a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties*”.

A Swiss-form claim is in the following form: “use of X in the preparation of a pharmaceutical composition for treating Y”. When it comes to infringement, the question of construction turns on the correct meaning to be given to the word “for”.

What does the word ‘for’ mean?

The general rule in patent law is that the word “for” in a patent claim means “suitable for”. However, that construction does not work in Swiss-form claims. That is because the active ingredient has always been ‘suitable for’ the new purpose, it was just not known to be so until the disclosure of the second medical use patent. If ‘for’ simply meant ‘suitable for’ then the claim would lack novelty.

So ‘for’ must mean something else, but what? Before the Supreme Court, the two competing candidates were:

- (1) “intended for” i.e. a test of subjective intention; or
- (2) “where it is known or reasonably foreseeable that some of the medicine will be used for” i.e. a test of reasonable foreseeability.

During the course of argument, the Supreme Court referred to a third possibility, that “for” means “that from its outward appearance can objectively be said to be for” and invited further submissions on the point. Actavis supported this as a viable alternative to a test of subjective intention. Ultimately this was the test that the majority of the Supreme Court preferred – the “outward appearance” test.

The Supreme Court’s decision

The Supreme Court was split on the correct test for infringement although they were unanimous in finding that had the patent been valid Actavis would not have infringed.

There was a 3:2 majority in favour of the “outward appearance” test as against the “subjective intention” test. Lords Sumption, Reed and Mance opted for the “outward appearance” test on the ground that it best reflected the meaning and purpose of a second medical use claim and provided the most appropriate balance between the competing interests at play. Lords Hodge and Briggs disagreed, preferring the “subjective intention” test.

However, whilst agreeing with Lords Sumption and Reed, Lord Mance expressed reservations about whether the outward appearance test should apply in all circumstances or whether, in an “*extreme case*”⁶ or “*remote situation*”⁷, factors other than the outward appearance of the product ought also be relevant.

As a consequence, the door remains open to patentees to argue that theirs is an “*extreme case*” or “*remote situation*” in which factors in addition to the packaging and labelling of the generic product ought to be taken into account. That, in turn raises the questions of what additional factors and when will they be relevant?

Before attempting to answer those questions, it is worth considering the reasoning of the Supreme Court justices as that gives an insight into their thinking, in particular the competing policy considerations that come into play.

The competing policy considerations

The starting point is the policy of encouraging research and development into the “re-purposing” of known pharmaceutical compositions. Development of a single, pharmaceutical composition to the point that is proven to be safe for human use can and typically does take many years and very substantial expenditure. The ability to re-purpose a known pharmaceutical composition has real potential value: new and effective treatments may well emerge without the need to go back to basic research, formulation work and safety trials. There is therefore a public interest in encouraging the investigation of new uses of known pharmaceutical compositions⁸. Patent law gives effect to that public interest by permitting second and subsequent medical use patents: in exchange for the disclosure that a known pharmaceutical has a new therapeutic use, the inventor obtains a monopoly that enables it to recoup the expenditure it incurred in establishing that new therapeutic use.

⁶ §217 Supreme Court Judgment

⁷ §218 Supreme Court Judgment

⁸ See e.g. the recent article in the Economist, 2nd March 2019, “*Re-purposing off-patent drugs offers big hopes of new treatments*”

Just as there is a public interest in ensuring that new treatments are developed, there is an equally strong public interest in ensuring that pre-existing treatments are available for use at a reasonable price. The period of patent protection is designed to incentivise research and development work by providing a period of monopoly during which the patentee can recoup its research costs and take the benefit of its invention. Once that monopoly has expired the patent bargain requires that the teaching of the patent be freely available for all to use. It is therefore crucial to maintaining the legitimacy of the patent system that patentees are not able to obtain a *de facto* monopoly over non-patented use of known products.

Commercial uncertainty has a chilling effect on competition. In the generic market, profit margins are likely to be small: not only does the generic have to compete against the originator but also against other generics and price competition is fierce. Any uncertainty as to whether or not supply of a particular generic to the market is lawful or not is likely to dissuade the generic manufacturer from entering the market at all. And it is not only the manufacturer who is subject to that uncertainty. By section 60(1)(c), all those that deal in and use the product obtained by way of the infringing process are also liable, including pharmacists.

Finally, there is the policy of ensuring that clinicians are free to exercise their clinical judgment unhindered by issues of patent law. This is the policy underlying the prohibition on patents for methods of treatment or diagnosis.

Assessment of the candidates in light of the relevant possibility

Having identified the competing policy considerations, the question is how to craft, within the limitations of the statutory framework, an infringement test that most effectively and fairly balances those competing considerations.

Reasonable foreseeability

This was the test put forward by Warner-Lambert, preferred by the Court of Appeal, but unanimously rejected by the Supreme Court. The problem with it is that it tips the balance too far in the patentee's favour. It creates huge commercial uncertainty and generates a chilling effect on the supply of generic medicines to the ultimate detriment of patients.

It was common ground before the Supreme Court that given prescribing practice in the UK, it is inevitable that some proportion of generic medication will be used for the patented indication. That means that if the test were one of reasonable foreseeability, the test for infringement would always be met.

The wording of s.60(1)(c) is such that when a manufacturer produces a batch of product in circumstances where it is reasonably foreseeable that some of that product will be used for the patented indication, the entire batch is infringing. In other words, the infringing product is not limited to the proportion that in fact ends up being used for the patented indication, but covers all product produced by the process. In turn that means that each person downstream of the manufacturer who handles the infringing product is also liable for direct infringement. As Lord Sumption noted, this means that if the test were one of reasonable foreseeability then:

“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”⁹

That would clearly not be a result that would permit the Court to distinguish between legitimate and illegitimate use.

Warner-Lambert suggested that the answer to that problem might lie in a flexible regime for remedies. s. 61 PA provides that the remedies for patent infringement include an injunction; order for delivery up; damages or an account of profits. Warner-Lambert’s proposal was that there could be a two-tier regime for relief in respect of infringement of a second medical use patent with the usual suite of remedies only available against infringers who had acted deliberately or recklessly. Those who infringed simply because the test of reasonable foreseeability was met would only be liable to account for profits made on sales of product that were actually used for the patented indication. The proportion of sales for the patented indication would be worked out at the account stage.

Whilst this suggestion may have a superficial attraction, its flaws readily become apparent on further analysis. Lord Sumption identified three fundamental problems with the proposal at §80. Firstly, it assumes that all suppliers of generic pregabalin for non-patented use are infringers. That is an impermissible assumption for the Court to make given that the monopoly conferred by a second medical use patent does not render such acts illegitimate. Secondly, the introduction of a flexible regime for remedies would require considerable judicial law-making. For example, the patentee has a statutory right to elect between damages or an account of profits and there is currently no legal basis upon which the court can interfere with the right to choose damages. Thirdly, if the patentee did elect damages based on its lost sales, the amounts claimed would likely far outstrip the profits made by the generic manufacturer. Why would a generic manufacturer wish to enter a market where there was an uncontrollable risk of a finding of infringement and a prospect that any profit it could ever expect to make would be wiped out? And that is even before factoring in legal costs. Inquiries and accounts are notoriously time-consuming and expensive. The forensic exercise required to attribute the correct

⁹ §79 Supreme Court Judgment

proportion of patented to non-patented uses of a particular generic product, especially in a case where multiple generics were on the market, would be a hugely complicated exercise that any rational person would wish to avoid.

Warner-Lambert's fall-back was to adopt the Court of Appeal's approach, namely that a finding that there was a reasonable foreseeability of use for patented indications could be negated if the generic manufacturer had taken all reasonable steps to prevent such use from happening. This approach was also rejected by the Supreme Court. Firstly, there was a principled objection. It was common ground that whilst the extent to which a product was used for patented indications could be minimised, such use could not be excluded all together. Therefore, even if all conceivable reasonable steps were taken, it would not be possible to fully negate the intention. Secondly, properly analysed the 'all reasonable steps' approach operated as a defence not a requirement for liability. But the statutory regime did not include such a defence and it was not possible for the courts to craft one. Thirdly, this solution would not give adequate commercial certainty. How would a supplier downstream of the original manufacturer know what steps had been taken and whether or not those steps were reasonable?

Subjective intention

This was the original test contended for by Actavis which was favoured by Arnold J. It was preferred by Lords Hodge and Briggs but rejected by Lords Mance, Sumption and Reed.

A test of subjective intention would have required the Court look to whether the manufacturer had made the product with the intention of targeting the patent-protected market.

Lord Briggs and Lord Hodge considered that the test of subjective intention would best meet the policy objectives of providing reasonable protection to the patentee; protecting the public against loss of patent-free use of the drug; and providing reasonable legal certainty for those engaged in the supply of the drug. In addition, it had the advantage that it most closely mirrored the wording and gave best effect to the meaning of the Swiss-form claim:

“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.

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.

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"¹⁰

The reasons given by Lord Sumption (with whom Lord Reed agreed) for rejecting a test of subjective intention were four-fold.

Firstly, Lord Sumption was uncomfortable with the notion that the scope of the patent monopoly was dependent on the intention of the manufacturer. The sentiment underlying Lord Sumption's objection is clear: it is obviously desirable that a person dealing in a product ought to be able to look at a product, look at the patent and assess whether or not the product is an infringing product without having to enquire into the mental state of the manufacturer.

Secondly, Lord Sumption considered that it would be highly unusual to impose tortious liability in circumstances where the wrongfulness of an action depended not on the acting party's state of mind (e.g. the downstream supplier or pharmacist) but on the state of mind of a third party (i.e. the manufacturer). It may be unusual, but Swiss-form claims themselves are an oddity (described by Arnold J as a "judicial fudge"), and so the unusual nature of the solution is not necessarily a good reason for dismissing the test.

Thirdly, his view was that subjective intention implies choice but that, in the particular circumstances in issue, the ultimate choice as to whether or not the product would be utilised for the patented indication would be made by a person downstream of the manufacturer. This objection overlooks the fact that the choice to target the patented market would have been made at the time of manufacture: the question of whether the target market was actually hit would be irrelevant to liability.

¹⁰ §§165-167 Supreme Court Judgment

Lord Sumption's fourth reason for rejecting a test of subjective intention were the real practical problems such a test would cause. Lord Sumption's objection was directed both to the evidential difficulties of proving intention and the uncertainty that the downstream supplier or pharmacist would be under if their own liability were ultimately to depend on the subjective intention of the manufacturer, of which they may know very little if anything.

Lord Mance's concerns about a test of subjective intention were similar to those raised by Lord Sumption. In addition, he queried what a finding that there was subjective intention would actually mean: if, for example, a manufacturer deliberately made more pregabalin than could ever be required to satisfy the non-patented use, would all batches produced by that manufacturer infringe or only some?

Ultimately, the majority of the Supreme Court rejected the subjective intention test on the basis that whilst it might strike a reasonable balance between the competing interests of the patentee in protecting its patent monopoly and the manufacturer in being able to make product for non-patented indications, it did not give sufficient weight to the interests of third parties in having commercial certainty as to whether a particular product was infringing or not nor did it give sufficient weight to the policy of protecting the autonomy of clinical judgments.

“Outward appearance”

This was the test preferred by Lords Sumption, Reed and Mance. The test was preferred as an imperfect solution to a difficult problem, but one that, in the view of the majority, best took into account all the relevant competing interests.

In his judgment, Lord Sumption pointed to the following advantages of the outward appearance test:

- (1) it was objective, based on outward statements made by the manufacturer as to the purpose for which the product was made. Downstream suppliers and users of the product could look to the product itself to ascertain whether or not it infringed;
- (2) it accorded more closely with the notion of an 'invention' than did a test based on subjective intention. Where an invention is purpose-limited, the designated purpose is an inherent characteristic of the invention. It followed that the purpose should be ascertainable from the product itself, not from extrinsic elements such as the mind of the manufacturer or the particular characteristics of the market onto which the product was released;
- (3) It reflected the critical feature of Swiss-form claims, namely that they were directed at the process of manufacture and not at subsequent use of the product. A test that could be applied, once and for all, at the factory gates was therefore appropriate;
- (4) It provided legal certainty for third parties;
- (5) It struck a fair balance between the interests of the patentee and the interests of third parties;

(6) It derived some support from case law at the EPO Technical Board of Appeal¹¹.

The Supreme Court recognised that the outward appearance test was imperfect. In particular, it would not properly address a case where a manufacturer packaged its generic product as a skinny label product but fully intended, promoted and encouraged its use for the patented market – the “charade” case¹². That had been one of the concerns of Floyd LJ when considering whether an “only packaging will do” test would be appropriate in the context of a subjective intention test¹³. However, Lord Sumption adopted a robust line:

“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... 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”¹⁴

Lord Mance’s reservations

In his judgment, Lord Mance expressed his unwillingness to pronounce on the issue of infringement at all. But he did so with a view to “*diminish, though I fear not exclude, the prospect of further litigation*”¹⁵. It is unlikely that his opinion will have this effect.

Lord Mance’s starting point was that, properly construed, a Swiss-form claim protected the process of manufacturing a composition or product which, as prepared, presented and put on the market, could be said objectively to be ‘for’ the patent-protected use¹⁶. However, he went on to say that:

“a process leading to a composition or product, which does not make clear that its permitted use is limited will infringe...I prefer however to leave open whether there might be some

¹¹ Lord Sumption referenced T 1673/11 *GENZYME / Treatment of Pompe’s disease* [2016] EPOR 33

¹² Such a situation arose in a Dutch case – *Novartis v Sun*, District Court of the Hague, 5 April 2017. The generic manufacturer marketed its product under a skinny label. Whilst it informed wholesalers of the skinny label, it undermined the purpose for doing so by stating that “this notice is a formality”. It went on to secure a supply tender in circumstances in which no distinction was made between patented and non-patented use and the size of the market for the patented indication dwarfed that for the non-patented indication (97% : 3%).

¹³ §191 CA Judgment

¹⁴ §86 Supreme Court Judgment

¹⁵ §199 Supreme Court Judgment

¹⁶ §213 Supreme Court Judgment

circumstances in which a generic manufacturer could or should be expected to go further, by a notice positively excluding the patent-protected use”¹⁷

That statement raises the question of what the generic manufacturer is required to do to “*make clear that its permitted use is limited*”. Is it sufficient to put the product on the market under a skinny label? Or is something more required? As noted by Lord Mance himself, there may be regulatory issues with requiring a statement to be placed on packaging that the product is not to be used for the patented use. Is there an intermediate position between a skinny label and an express exclusion that the manufacturer ought to adopt?

Lord Mance went on at §217 to say that:

“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”

As is clear from the rest of the paragraph, Lord Mance had in mind here the “charade” case. Unlike Lord Sumption, who was content to adopt a robust pragmatic line, Lord Mance was uncomfortable with the risk that a patentee could be left under-protected if the outward appearance test was adopted.

The problem is that if the outward appearance test is adopted in some circumstances then, on the majority’s own reasoning, it must apply in all cases. The meaning to be placed on the word ‘for’ cannot change depending on the particular market situation pertaining to any particular product or indication at any particular point in time. There is no rational basis for assessing the outward appearance of some products at the factory gates but others in the pharmacy.

Unfortunately, Lord Mance’s judgment has left the door open for patentees to argue that theirs is an exceptional case, in which either the outward appearance test ought not to apply at all or it applies in some modified form. The very fact that such argument can be made in the first place undermines the commercial certainty that the outward appearance test was designed to achieve.

Other issues

In addition to the issues that were raised very squarely by Lord Mance’s judgment, an additional question is the extent to which, if at all, the outward appearance test will apply to EPC 2000 claims.

¹⁷ §213 Supreme Court Judgment

Warner-Lambert was concerned with a Swiss-form claim: “use of X for preparation of a medicament for treatment of Y”. However, in November 2000, the EPC was amended to permit claims in the form “X for use in treating Y” (the so-called “EPC 2000 claim”). EPC 2000 claims were introduced as a replacement for Swiss-form claims. They differ from Swiss-form claims in that they are product claims, not process claims, and accordingly direct infringement will be dealt with by s.60(1)(a), not s.60(1)(c).

The Supreme Court was very careful in its judgment to emphasise that its decision was concerned with Swiss-form claims only and that it was not considering EPC 2000 claims. Nevertheless, some of the reasoning in favour of the “outward appearance” test is directly applicable. EPC 2000 claims are purpose limited as are Swiss-form claims and there is no obvious basis on which to attribute a different meaning to the word “for” in an EPC 2000 claim to that in a Swiss-form claim.

However, one difference of potential significance is that that EPC 2000 claims are product claims, not process claims. As such, they are not focussed on the process of manufacture in the same way as Swiss-form claims. This may have an impact. In particular, there is no need to limit assessment of the outward appearance of the product to the point in time that it leaves the factory gates. Given the regulatory framework surrounding the supply of medicines, it is difficult to conceive of a situation in which the outward appearance of a product, and therefore its inherent characteristics, would change between the factory and the pharmacy. But, depending on the way that the Court applies the outward appearance test and the factors that it takes into account in making the objective assessment of what the product is for, the possibility that differences may evolve between the test for infringement of Swiss-form and EPC 2000 claims cannot be ruled out.

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