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WHITE PAPER

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Second Medical Use Patents in Europe: Are the UK and Germany Swapping Approaches?

The UK Supreme Court's ruling in *Warner Lambert v Actavis* resulted from deliberations over the proper approach to matters relating to infringement of second medical use patent claims. The standard proposed by the UK Supreme Court diverges from the approach of German courts and will likely lead to important consequences for pharmaceutical patent litigation in Europe.

This *White Paper* defines "second medical use" claims and explains the "roles of intent" and "plausibility" in these infringement cases.

TABLE OF CONTENTS

The UK Supreme Court's recent ruling in *Warner Lambert v Actavis*[1] is the latest European appellate decision to consider the proper approach to infringement of second medical use patent claims. Whilst the differing approaches in the individual judgements do not make the law[2] clear, the ruling has moved the UK to an infringement test for second medical use claims that is focused on how a generic pharmaceutical product is prepared, presented, and marketed. In contrast, the German courts, which until recently applied an equivalent test, now appear to be slowly moving away from such an approach and instead are increasingly placing some reliance on the surrounding circumstances and looking at what would have been objectively foreseeable to the generic manufacturer. This latest UK decision also highlights the differing approaches of the UK and German courts to the "plausibility" needed for second medical use claims.

SECOND MEDICAL USE CLAIMS

Second medical use claims protect inventions for the use of a known pharmaceutical composition for a new medical use. As a way of enabling patent protection, the European Patent Office ("EPO") initially adopted the practice of granting "Swiss form" purpose-limited process claims in the form of "the use of substance X for the preparation of a medicament for treating indication Y." The EPO no longer grants Swiss form claims, as the European Patent Convention ("EPC") now allows for second medical use claims to be granted in the form "compound X for treatment of disease Y"—known as "EPC 2000 claims."

Whilst the claims in issue in the *Warner Lambert* decision were Swiss form claims, it seems likely that the underlying logic of the court would also be largely applicable to EPC 2000 claims.

INFRINGEMENT: A QUESTION OF INTENT

The central issue on infringement in *Warner Lambert* was whether the subjective intent of a generic manufacturer should be taken into account in the overall assessment (as was advocated by the trial judge) or whether the court should favour a more objective test by looking at what was reasonably foreseeable to the manufacturer. (This is the approach preferred by the UK Court of Appeal, although the Court of Appeal actually adopted a qualified foreseeability test excusing a generic from liability if it had taken all reasonable steps to avoid the product being used for the second medical use.)

This was at the heart of the infringement debate, given Actavis had put on the market a generic drug (pregabalin) with a "skinny label" (i.e., a label that did not reference the novel patented indication) after patent protection for the compound itself had expired. Warner Lambert argued that despite this, Actavis knew—or should have been aware from the surrounding circumstances—that its generic product would have been prescribed and dispensed for the patented use.[3]

The Supreme Court justices all disapproved of the qualified foreseeability test advocated by the UK Court of Appeal, suggesting that it places too much importance on the interests of the patentee. However, three of the five judges were also against a test that relies on the subjective intention of the manufacturer. This was due primarily to the uncertainty that a subjective test inevitably causes as to whether a product is infringing, especially to downstream handlers of the product, such as distributors.

Instead, this majority (though for varying reasons) preferred a test that focuses on the objective physical characteristics of the product as it emerges from the relevant process of manufacture and its presentation, including the product's formulation and dosage, packaging, and labelling (the so-called "outward presentation" test). Whilst all three judges acknowledged that such a test is imperfect—one of the judges expressly stated that in some cases, other surrounding circumstances or general knowledge may need to be taken into account or require that the patented indication be positively excluded—they would nevertheless prefer it over a test based on subjective intent or reasonable foreseeability alone.

This latest "outward presentation" test from the UK Supreme Court bears many similarities with the "sinnfällige Herrichtung" formulation developed by German courts for assessing infringement of second medical use claims. This approach was criticised by the UK Court of Appeal (which dubbed it as the "only packaging will do" approach), but it now appears to be the one preferred by the UK Supreme Court. It is interesting to note, however, that German courts just recently have been moving away from a rigid application of such a test and have been willing to find infringement even without such outward presentations where the surrounding circumstances suggest

that the generic manufacturer knew or was wilfully ignorant of its product being put to use for the patented purpose.

The new approach by the German courts is directed at mitigating the potential for cross-label use: If the actual cross-label use in the market is of significant scope and the generic manufacturer nonetheless supplies its wholesalers, it is deemed justified to hold him liable for patent infringement.[4]

PLAUSIBILITY: A POSITIVE TEST

The *Warner Lambert* appeal also considered the test for plausibility for second medical use claims. Again, the UK Supreme Court judges differed in their opinions. The leading judgment for the majority was critical of the UK Court of Appeal's comment that the test could be met by "the slimmest of evidence" and firmly rejected the suggestion that evidence of plausibility is required only where the skilled person would be sceptical regarding the disclosure in the patent—an approach often adopted at the EPO.

It also went on to say that, given the possibility that speculative patenting is particularly acute for second medical use claims, a mere assertion or an abstract possibility that something would work is not enough. Whilst there is no requirement of definitive proof or experimental data, the majority stated that there is nevertheless a requirement for the patentee to show that there was a reasonable prospect that the claimed assertion would prove to be true in order to be plausible. They were also clear that support for plausibility must be derived from the teaching of the patent and cannot be based on common general knowledge alone.

The standard proposed by the UK Supreme Court lies in contrast with the approach of the German courts. While the German Federal Supreme Court and German Federal Patent Court in principle acknowledge the necessity for an effect to be plausible from the original disclosure, the actual bar resulting from this requirement appears to be lower than in UK courts.[5] In particular, the German Courts are more likely to accept post-filed evidence for a medical effect into the proceedings[6]. Furthermore, there has been, at least to date, less emphasis on whether data is representitive for the full scope claimed[7].

KEY TAKEAWAYS

The diverging approach of the UK and German courts with respect to second medical use patents clearly has important consequences for pharmaceutical patent litigation in Europe. In particular:

1. Generic companies may become increasingly bold in relying on "skinny labelling" in the UK to get around second medical use patents. However, this could be tempered by an awareness that the German courts are starting to look beyond the outward presentation of the product.

2. Defending second medical use patents from plausibility challenges may prove a higher hurdle in the UK than some commentators have previously thought. In contrast, plausibility is, for the time being at least, likely to remain less of a concern for patentees in Germany.

Given the lack of consensus amongst the judges in *Warner Lambert*, especially on the test for infringement, and the majority's acknowledgement that the 'outward presentation' test is imperfect, lower courts may be unwilling to apply the test too rigidly. In particular, we expect lower courts will be sympathetic to a patentee where a generic company is effectively using skinny labelling as a "charade" or where there is a clear demonstrable risk of cross label use. Finally, it is worth noting that Lord Sumption, who gave the lead judgement, is due to retire next year, and Lord Kitchin—who before his recent appointment to the UK Supreme Court gave an endorsing judgement in the Court of Appeal *Warner Lambert* decision—may not agree with the current state of the law. As the first specialist patents judge in the Supreme Court, Lord Kitchin is likely to be highly influential on patent matters in the years to come, and it would not be surprising if second medical uses did not return to the UK Supreme Court before too long.

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ENDNOTES

1 2018] UKSC 56.

2 Whilst the UK Supreme Court's analysis of infringement is strictly *obiter,* we would nevertheless expect lower UK courts to apply the approach and reasoning in subsequent decisions.

3 In the UK, unless there is a good reason to do otherwise, doctors will usually prescribe generically by reference to the international non-proprietary name of the drug rather than the brand or proprietary name. Doctors will not usually include on the prescription any description or the indication being treated, which means that a dispensing pharmacist will often just dispense the generic product given the price difference.

4 cf. District Court Düsseldorf, judgment of July 5, 2018, 4c O 47/17; Düsseldorf Court of Appeals, GRUR 2017, 1107 – Östrogenblocker.

5 cf. German Federal Supreme Court, BGH GRUR 69, 265(II2b) - Disiloxan.

6 cf. German Federal Supreme Court BGH GRUR 1972, 541 – Imidazoline; German Federal Patent Court, 3 Ni 20/15 Chinazolinderivate.

7 cf. German Federal Supreme Court, BGH GRUR 2013, 1210 – Dipeptidyl-Peptidase-Inhibitoren.