HERBERT SMITH FREEHILLS

PATENT AND PHARMA UPDATE, APRIL 2019

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Legal Briefings

Key recent developments in the United Kingdom and Europe relating to patents and the pharmaceutical sector

This issue reports on the recent UK Supreme Court decision in the *tadalafil* case, which foreshadows how English courts will probably respond to issues of obviousness arising from patents directed to dosage regimes going forward. We discuss the Court of Appeal's decision in the *Conversant v Huawei* saga on *forum non conveniens* and recent English court decisions that have applied the *Actavis v Lilly* equivalents test for infringement. From a European perspective, we bring you key legal updates on SPCs, including developments around the SPC waiver, the CJEU's decisions in relation to skinny-labelling, orphan designations, CRISPR-modified organisms and finally, the General Court's decision in *Servier*. We also have a short update on marketing authorisations in the UK in case of a no-deal Brexit.

A summary of the key themes are below.

1. UK SUPREME COURT AGREES WITH COURT OF APPEAL THAT TADALAFIL DOSING PATENT IS OBVIOUS

The Supreme Court in *Actavis v ICOS and Eli Lilly* has upheld the earlier decision of the Court of Appeal holding ICOS' dosage regime patent invalid for obviousness. This decision emphasises a flexible, fact-specific approach to the statutory question of obviousness that the Supreme Court states will take into account the relevance and the weight of various factors, depending on the dispute. The Supreme Court has affirmed that there is no general prejudice against dosage regime patents or inventions based on empirical research.

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2. DEVELOPMENTS TO EQUIVALENTS: JUDGE HACON'S APPROACH TO THE INVENTIVE CORE, NUMERICAL CLAIMS, FORMSTEIN DEFENCE AND MORE

A series of decisions from the English High Court have applied the law of doctrine of equivalents in the UK following the UK Supreme Court's decision in *Actavis v Eli Lilly*and the Court of Appeal's decision in *Icescape v Ice-World*. The decisions in *Regen Lab v Estar*, *Technetix v Teleste* and *Marflow Engineering v Cassellie* (all by the same judge) emphasise the court's approach to assessing claim scope under equivalents separately from assessing claim scope purposively and also the importance of ascertaining the inventive core/concept of the patented invention. Whilst each decision has developed the law of doctrine of equivalents in respect of specific scenarios (such as where there are multiple differences between a variant and the claims or where there are numerical claims), it is striking that all three cases have found infringing equivalents, although such a finding is technically *obiter* in two decisions.

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3. REACH OF UK COURTS CONTINUES TO EXPAND IN THE FRAND SPHERE

In its recent decision in *Huawei Technologies v Conversant*, the English Court of Appeal has yet again signalled its willingness to accept jurisdiction over global FRAND licensing disputes, even where certain factors might point to a different jurisdiction (in this case, China). It was important to the Court's decision that UK patent rights were in issue and some level of infringement (albeit low) had taken place in the UK, and the Court saw the content of Conversant's FRAND undertaking (and therefore a global FRAND licence) as an inseparable part of this dispute. In any case, Huawei and ZTE were unable to provide satisfactory evidence to show that Chinese courts would be willing to settle the terms of a global FRAND licence.

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4. SPC UPDATES

In *Eli Lilly v Genentech*, the English Patents Court has made a reference to the CJEU as to whether the SPC Regulation permits a patent holder to rely upon an unrelated third-party marketing authorisation to obtain an SPC. In France, the courts have applied the CJEU's guidance in *Teva v Gilead* on Article 3(a) of the SPC Regulation in two recent cases concerning combination medicinal products. In the *Abraxis* case, the CJEU has proceeded with a narrow, literal interpretation of Article 3(d) of the SPC Regulation and has held that new formulations of previously approved products could not obtain new SPCs. Finally, considerable progress has been made in relation to the European Commission's proposal to introduce a new SPC waiver in the SPC Regulation, and the draft text is scheduled to be debated and voted upon by the European Parliament on 17 April 2019.

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5. PATENT SETTLEMENT AGREEMENTS: WHAT TO WATCH OUT FOR FOLLOWING THE SERVIER DECISION

In December 2018, the General Court annulled a part of the European Commission's decision in the *Servier* (perindopril) case, reducing Servier's fine and annulling the fine imposed on one of the generics. It held that the European Commission was mistaken in finding that Servier held a dominant position by limiting the relevant market solely to the perindopril molecule. The General Court in fact considered the relevant market to extend to a wider class of ACE inhibitors and the Court's analysis shows that it is prepared to carefully scrutinise the European Commission's adoption of market definitions in pharmaceutical cases.

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6. CJEU DECIDES ON SKINNY-LABELLING AND ORPHAN DRUG DESIGNATION

In *Staat der Nederlanden v Warner-Lambert*, the CJEU has decided upon a reference from the Dutch Court of Appeal that the non-inclusion of certain indications in a generic company's Summary of Product Characteristics constitutes a request to limit the scope of its marketing authorisation. In a separate decision in *Bristol-Myers Squibb v European Commission and European Medicines Agency*, the CJEU refused to annul the European Commission's decision to withdraw the "orphan drug" designation for Bristol-Myers Squibb's drug elotuzumab, but, interestingly, ordered the Commission to pay the pharmaceutical company's costs due the Commission's conduct.

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7. CJEU IMPOSES REGULATORY HURDLES ON COMMERCIALISATION OF CRISPR MODIFIED ORGANISMS

A recent decision from the CJEU has applied the "precautionary principle" to the classification of gene-edited plants as genetically modified organisms, thereby subjecting them to the strict regulation imposed on GMOs.

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8. MARKETING AUTHORISATIONS IN A NO-DEAL BREXIT – GUIDANCE FROM THE UK AND THE EU

In March 2019, the UK Medicines and Healthcare products Regulatory Agency published several guidance notes which relate to the regulation of medicines and medical devices in the event of a no-deal Brexit. Amongst other issues discussed, the guidance notes shed light on pending marketing authorisations at the time of Brexit and certain new routes of assessment of UK marketing authorisation applications.

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9. TABLE OF PATENTS DECISIONS

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10. TABLE OF OTHER DECISIONS RELEVANT TO THE PHARMACEUTICAL SECTOR

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KEY CONTACTS

If you have any questions, or would like to know how this might affect your business, phone, or email these key contacts.

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