PATENT AND PHARMA UPDATE, DECEMBER 2018

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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 several ground-breaking decisions from the UK courts on second medical use patents and skinny labels, infringement by equivalents and the possibility of global FRAND licences for standard essential patents (SEPs). We also look at some significant decisions from the CJEU on SPCs and reimbursements in relation to medicinal products and a few developments at the European Patent Office. Finally, we provide our usual round-up of the latest UPC developments (this time from Italy) and Brexit-related developments relevant to the pharma sector.

A summary of the key themes are below.

UK SUPREME COURT RAISES SUFFICIENCY STANDARD FOR SWISS-FORM CLAIMS AND LIMITS THE ABILITY TO ASSERT THEM AGAINST "SKINNY LABEL" PRODUCTS

The Supreme Court in *Warner-Lambert v Actavis and Mylan* appears to have adopted a higher standard of assessment for plausibility in the context of sufficiency, thereby potentially increasing the amount of information required to be disclosed in a patent's description for Swiss-form claims. This may influence when innovator companies file their patent applications during their clinical trials, since more specific information may now be required to ensure that a patent remains valid. Although obiter, the Supreme Court has proposed an objective test to direct infringement based on "outward presentation", under which "skinny labels" carving out the patented indication will often be effective in avoiding infringement.

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ICESCAPE SKATES HEAD-ON INTO INFRINGEMENT BY EQUIVALENTS

The Court of Appeal applied the *Actavis* test of infringement by equivalents to hold that Icescape's system falls within the scope of Iceworld's patent claims. Although the infringement decision is technically *obiter* (the patent having been found invalid), it is significant as this is the first time infringement by equivalents has been found in the UK applying the *Actavis* test.

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FRIEND OR FRAND: THE (UNWIRED) TALE OF A PLANET-WIDE APPROACH

The Court of Appeal upheld the first instance decision that, in principle, a global FRAND licence is possible. However, there is no single set of FRAND terms for any given set of circumstances. This signals that the UK courts are willing to decide complex questions relating to SEPs and FRAND licensing, including global patent portfolio licences.

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PROCEED WITH CAUTION: A SPOTLIGHT ON TWO IMPORTANT UK PRIVILEGE DECISIONS

The importance of legal privilege in the context of internal communications is highlighted by two recent UK court decisions, which have adopted a narrow approach to privilege.

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ENGLISH PATENTS COURT CONSIDERS EXHAUSTION OF RIGHTS AND WHAT AMOUNTS TO REPAIR OF A PATENTED PRODUCT

The Patents Court considered the issues of exhaustion of rights and what amounts to repair (rather than manufacture) of a patented product. It held that contractual restrictions on an initial purchaser did not thwart the doctrine of exhaustion of rights upon resale to future purchasers. Further, the replacement of numerous components of a patented system may amount to mere repair, rather than manufacture, thereby exhausting the rights of the patentee following any resale.

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DISCLOSURE – SOME POINTERS FROM RECENT DECISIONS

Recent English Patents Court and Commercial Court decisions have looked at the types of documents that may become disclosable in FRAND/RAND proceedings (*TQ Delta v Zyxel*) and the restrictions placed on the collateral use of not just disclosed documents, but also the information contained therein (*ECU Group v HSBC Group*).

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SPC UPDATES

The CJEU held in *Boston Scientific* that a CE conformity certificate obtained for a medical device cannot be used to obtain SPCs for the drug part of the medical device. On a separate note, a French Court has upheld the validity of an SPC protecting the ezetimibe/simvastatin combination under Article 3(a) of the SPC Regulation, following the CJEU guidance in the *Gilead* (tenofovir/emtricitabine) decision.

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THE CJEU AND SKINNY LABELLING

The CJEU held that Italian national laws, which encouraged off-label use and the reimbursement of medicinal products for such use under the national healthcare insurance system (NHS), are consistent with EU law (*Novartis Pharma v Italian Medicines Agency and Roche*). In another case, Advocate General Kokott has opined, in the context of Dutch law, that when a generic wishes to carve-out patented indications/dosage regimes from its SmPC and package leaflets, it should be considered to be limiting its MA to the remaining indications/dosage forms (*The Netherlands v Warner-Lambert*).

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EPO INJECTS A DOSE OF NEGATIVITY INTO OBVIOUSNESS

In a decision relating to a second medical use patent held by Novartis, the EPO TBA has decided that patient information sheets in clinical trials testing several dosage regimes could result in any of the disclosed regimes being found obvious, especially when none of the regimes are indicated as being preferred.

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EPO "GETS REAL" ON ARTIFICIAL INTELLIGENCE

Over the past year, the EPO has taken various steps to ensure that European patent law remains suitable and robust to tackle AI-generated inventions. We take a brief look at these developments.

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UPC DEVELOPMENTS

Whilst we await the ratification of the Unified Patent Court Agreement by Germany, we report on various steps taken in Italy to prepare the Italian IP Code for the UPC.

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PATENTS, PHARMA AND BREXIT

Although the UK's position following Brexit and the fate of any transition arrangements remain uncertain at present, we take a look at some provisions relating to MAs and SPCs in the draft Withdrawal Agreement endorsed by the EU Council in November 2018.

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PERSONALISED HEALTH AND THE FUTURE OF PHARMA

We are actively considering the transformative changes in the pharmaceutical sector in our new Personalised Healthcare and Future of Pharma Hub and invite you to subscribe to our content here.

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TABLE OF OTHER UK DECISIONS RELEVANT TO THE PHARMACEUTICAL SECTOR

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