HASELTINE LAKE LLP
EUROPEAN PATENT AND TRADE MARK ATTORNEYS

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IP Disputes Newsletter

Latest Swiss form case – English High Court makes novel order

This is the fourth interim decision from the High Court in a patent dispute between Warner-Lambert Company, LLC (Warner Lambert) and Actavis Group PTC EHF (Actavis) and others[1], concerning the question of whether the manufacturer of an off-patent medical product which is the subject of an in-force "second medical use" claim in the Swiss form must have a subjective intention that the product be used for the patented second use, in order to infringe the claim. This decision shows the provisions a court can make to maintain the status quo and prevent the risk of any further infringement.

Swiss form claims

The grant of patents for second medical uses of known compounds must overcome two hurdles. Namely, that the compounds are not new and methods of treatment of the human or animal body by therapy are not patentable. Given that protection of second medical uses is generally in the public interest, the European patent system has attempted to overcome these hurdles. Nowadays, claims are granted in the form *"product X for treating indication Y"* (a purpose limited product claim). Prior to this, these patents had to use claims in the "Swiss" form that is *"use of substance X for the preparation /manufacture of a medicament for treating indication Y"* (a purpose limited use or process claim). An important issue in the present case arose because it is an infringement of section 60(1)(c) Patents Act 1977 to (*inter alia*) keep, dispose of or offer for disposal *"any product obtained directly by a means of that* [patented] *process"*.

The dispute

Warner Lambert marketed a prescription-only drug for three different indications under a single registered trade mark. Patent protection for the drug itself had expired, but Warner Lambert also owned a second medical use patent for one of the three indications, namely pain relief. Actavis applied for a marketing authorisation of a generic version of the drug limited to the other two indications. Warner Lambert was concerned that, notwithstanding that application, the generic drug would be dispensed for the patented second medical use – because, at least in the UK, most prescriptions are written generically and very few state the indication for which the drug has been prescribed. As such, a pharmacist will usually not know what the drug has been prescribed for. There is also an incentive on pharmacists to prescribe the generic, which is generally cheaper.

Warner Lambert sued Actavis for patent infringement and applied for an interim injunction

requiring it to take various steps to prevent its generic drug being dispensed for the patented indication. The judge refused to make the order. In that first decision, the judge held that there was no serious issue to be tried (the first limb of the test for whether an interim injunction should be ordered). He held that Swiss claims require that the manufacturer intends the medicine to be used for, in this instance, pain and Activis at the manufacturing stage demonstrably did not have such an intention. He also held that there is no infringement of a Swiss claim by mere dispensing in a pharmacy and therefore there was no infringement by either the original manufacturer or the dispensing pharmacist.

Two applications by Activis for strike out/summary judgment of the two infringement allegations were unsuccessful, although the court did strike out a claim for indirect infringement. Arnold J decided that, as this is a developing area of law, the proper course would be to establish the facts at trial before attempting definitively to determine what the law is.

NHS ordered to give guidance

Following the decision to allow the amended case on infringement of the patent to go to trial, the judge made an order intended to maintain the status quo pending trial. The government body ultimately responsible for health commissioning in England (NHS England) was joined as a respondent to the application and the court ordered it to issue guidance in a form agreed between the parties.

The guidance, to all doctors in general practice and all dispensing pharmacies, was to state that only the branded Warner Lambert products should be dispensed for neuropathic pain. Warner Lambert was ordered to give a cross-undertaking in damages to the Department of Health, NHS England and Activis, as well as to other generic manufacturers which it had also sued for infringement.

This novel order appears to be a useful tool in cases of this type, preventing inadvertent infringement of a "second use" patent by manufacturers and/or pharmacists (both conceivably "preparers" or "manufacturers" of the medicament), if – which still needs to be decided finally by the English courts - the Swiss form of claim would be infringed by one or both of them.

The Court of Appeal has given permission to appeal against the judge's decision to refuse an interim injunction, and this itself was a factor in the judge's decision to make the order against NHS England. We will report on the outcome of the appeal proceedings when that is known.

[1]*Warner-Lambert Company, LLC –v- Actavis Group Ptc EHF & Others [2015] EWHC 72 (Pat) 21 January 2015; [2015] EWHC 223 (Pat) 6 February 2015; [2015] EWHC 249 (Pat) 6 February 2015; [2015] EWHC 485 (Pat) 2 March 2015*

Latest unitary patent news - EPO proposal on renewal fees

The European Patent Office (EPO) is considering two alternative proposals for renewal fees for the new unitary patent (UP)

Both alternatives appear to lead to higher fee levels than, for example, the combined renewal fees for the often designated states of Germany, France and Great Britain.

The information suggests the following structure for setting UP renewal fees:

- years 3 to 5 - the level of the EPO's internal (pre-grant) renewal fees (IRF)
- years 6 to 9 - a level lower than the IRF level
- from about year 10 - a level equivalent to the total sum of the national renewal fees payable in the states in which European patents are most frequently validated (TOP level).

The first EPO proposal uses a TOP4 level based on the sum for the four most frequently validated countries (assumed to be Germany, Great Britain, France and the Netherlands) The second EPO proposal uses a TOP5 level based on the sum for the five most frequently validated countries (assumed to be Germany, Great Britain, France, the Netherlands and one other) and suggests a 25% reduction for SMEs, natural persons, non-profit organisations, universities and public research organisations, as well as a separate 15% reduction if the patentee offers that licences under the patent are available to third parties as of right.

In both proposals, the TOP level annual fee after year 11 is higher than the EPO's internal (pre-grant) renewal fee, over 3 times higher in the later years of the patent term. The reaction from industry bodies so far has generally been that these fees are too high. We will keep you informed as further information on this important question becomes available.

High Court restricts CTM injunction and damages inquiry to UK

In a trade mark infringement dispute between two well-known global competitors in the field of vehicle rental services (***Enterprise Holdings, Inc*** –v- ***Europcar Group UK Limited and another*** [2015] EWHC 300 (Ch)) the High Court has restricted the grant of a Community trade mark (CTM) injunction and its related damages inquiry to the UK. The court also made a publicity order.

The judge's reasons for this were that it was unclear that a European Court of Justice ruling that an injunction should generally be made across the whole EU applied in likelihood of confusion or dilution cases and, even if it did, the claimant had restricted the territorial scope of its action. If that were wrong, the judge continued, then there was nevertheless insufficient evidence that Europcar's use of its "e" logo affected (or was liable to affect) the functions of the CTM in any Member State other than the UK. In the circumstances, the geographic scope of the inquiry as to damages should stand or fall with the geographical scope of the injunction.

The court also made a publicity order requiring the defendant to place a notice on its website for three months so that a reasonable number of consumers would see it, whilst not an automatic remedy, this is increasingly common in IP infringement cases.

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