Warner-Lambert Company, LLC v (1) Actavis Group PTC EHF (2) Actavis UK Limited (3) Caduceus Pharma Limited, 28 May 2015 (England and Wales Court of Appeal)

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Case summary

In this decision on interim relief for alleged patent infringement, the Court of Appeal (hereinafter "the Court") construed the scope of a pharmaceutical patent claim in "Swiss" format, which is typically phrased as a process claim for the use of a compound in the production of a medicine for use in a particular therapeutic indication (new medical use claim).

The facts

The claimant Warner-Lambert originally held a patent on the drug pregabalin (marketed under the brand name "Lyrica") for the treatment of epilepsy and general anxiety disorder (GAD). This patent expired in October 2013. In addition, the claimant still holds a new medical use patent on the "use of pregabalin for the preparation of a pharmaceutical composition for treating pain". The respondent Actavis has applied for marketing approval of pregabalin limited to off-patent uses, i.e. for the treatment of epilepsy and GAD (marketed under the brand name of "Lecaent"). The respondent only referred to these off-patent indications in the summary of the product characteristics and the patient information leaflet. Another generic producer (Consilient) also interested in the off-patent use went a step further by establishing a scheme under which it expressly encourages physicians to limit prescriptions of its generic product to the off-patent indications only. The respondent has expressed the view that such scheme is unrealistic and will only generate limited sales. The claimant applied for injunctive relief against the dispensing of pregabalin by Actavis, based on the concern that physicians and pharmacists would prescribe Lecaent also for the patented indication. By contrast, the claimant did not take any action against Consilient. The Patents Court on 21 January 2015 refused to grant an injunction, considering the respondent's action to fall outside the claimant's new medical use claim. The claimant appealed that decision. The Court of Appeal upheld the Patents Court in its decision of 28 May 2015, which is summarized here. In the main proceedings, the respondent subsequently succeeded in challenging the claimant's new medical use patent before the Patents Court. That decision was equally upheld by the Court of Appeal.[1]

The legal issues

The legal issue before the Court concerned the scope of "Swiss-type" new medical use claims. [2] The claimant alleged direct infringement of its patent through the

[1] *Warner-Lambert Company LLC v (1) Generics (UK) Ltd (trading as Mylan), (2) Actavis Group PTC EHF, (3) Actavis UK Limited, (3) Caduceus Pharma Limited*, England and Wales Court of Appeal, 2016.

[2] Although claiming only a process, these claims refer to the manufacture of a medical product to avoid rejection of the claim by the patent office. Under the European Patent Convention (EPC) and its Member States, standard process claims to the use of a medical product for the treatment of a particular

manufacture of the respondent's Lecaent for the treatment of pain (i.e. the patented indication). In this context, it is essential how to understand the term "for" the treatment of pain. The claimant argued that in order to fall within the scope of the claim, it is sufficient for a non-authorized person to know that pharmacists were likely to prescribe the generic drug also for the patented indication, unless positive steps were taken to prevent this. The respondent contended that such knowledge alone was insufficient and that, in order to be caught by the patent claim, it was necessary for the respondent to have the subjective intention that its generic product should be used for the treatment of the patented indication.

Regarding indirect infringement, the claimant argued that by making Lacaent available, the respondent enabled ultimate users to infringe its patent by using Lacaent for treating pain, i.e. the patented indication reserved to Lyrica. On direct infringement, the Court considered that

> "it is the intention for which the compound is administered which is at the heart of the invention. Against that background the skilled person would understand the word "for" in the claim to be providing a link between the act of manufacture using pregabalin and the ultimate intentional use of the drug by the end user to treat pain. The critical issue for me to decide is what is sufficient to constitute that link."[3]

The Court subsequently expressed the view that this link is established where the alleged infringer has the knowledge/can foresee that others will intentionally use the drug for the patented indication. By contrast, the Court rejected the respondent's view that patent infringement would only occur where the alleged infringer had the intention that others should use the generic drug for the patented indication. In this context, the Court observed that it would be too much of a task to place the burden of proving such intention on the patent holder, as this would "rob Swiss claims of much of their enforceability."[4] On the other hand, the Court stressed that where a generic producer "has taken all the steps open to him to avoid his medicine being prescribed for the new use", his production of the generic would not infringe the scope of the new medical use claim. Finally, the Court expressed the view that indirect infringement does not depend on the generic producer alone but can also occur in combination of activities of the generic manufacturer and the users. The generic producer would then contribute to putting the invention into effect by himself and the users together.[5]

Points of significance

- For any examination of patent infringement, the accused activity has to be compared to the claims in the patent. A finding of infringement requires the

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indication have to be rejected, based on Article 53(c) of the EPC 2000, which mirrors the TRIPS Article 27.3(a) exemption from patentability of methods of medical treatment. "Swiss" type claims to the manufacture of a product for a specific use have been considered as not falling under this exemption.

[3] Paras 121, 122 of the judgment.

[4] Para 126 of the judgment.

[5] Paras 138, 139 of the judgment.

accused activity to include all essential elements of the claims. The meaning of the latter is construed by the court.

- In a "Swiss" type of claims format for the protection of a new medical use, a finding of patent infringement requires a third party to manufacture the patented drug for the claimed purpose. The reference to the production of a drug "for" the treatment of a protected indication protects the patent holder from any unauthorized production undertaken in knowledge of the end users' intention to treat the patented indication, in addition to the off-patent indications. This knowledge is an essential element of the scope of the "Swiss" claim.
- To avoid such finding of direct patent infringement, the generic producer should make best efforts to limit the marketing of its product to the off-patent indications, for example by expressly encouraging physicians and pharmacists to restrict prescriptions of the generic to such indications. In that case, the generic producer cannot be presumed to know that the generic will be used to treat the patented indication, even if under the national health system physicians and pharmacists are free to ignore the generic producer's request.
- As opposed to direct infringement, a finding of indirect infringement according to the Court of Appeals for the Federal Circuit in the United States requires specific intent to induce infringement by others. That court in a case similar to the present one rejected indirect infringement, due to the claimant's failure to show such intent on the part of the defendant.[6]
- The English Court of Appeal in this case did not discuss the subjective requirements for indirect infringement. On the objective side, it considered indirect patent infringement possible through a combination of activities by generic producer and user, rather than by any one of these alone.[7]

Key words: Swiss claims; new medical use claim; process patent; direct infringement; indirect infringement; inducement.

Available at http://www.bailii.org/ew/cases/EWCA/Civ/2015/556.html

[6] *Warner-Lambert Co. v. Apotex Corp*, 316 F.3d 1348, 65 USPQ2d 1481 (Federal Circuit, 2003).
[7] See para 138 of the judgment.