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Patents: dosage and formulation patents

Summary

The High Court has held that a drug formulation patent was invalid but a patent relating to dosage of the drug was valid and infringed.

Background

A patent may only be granted for an invention which is new *(section 1, Patents Act 1977)* (1977 Act). An invention is new if it does not form part of the state of the art. Prior art in the form of an earlier patent application that was unpublished at the priority date of an invention can only be used to establish lack of novelty, not lack of inventive step *(section 2(3)*, 1977 Act).

An invention is entitled to priority from a priority document filed before the patent application, if it is supported by matter disclosed in the priority document *(section 5(2), 1977 Act)*.

Facts

Patent protection for a drug used to treat male erectile dysfunction (ED) was due to expire in 2017. L was the exclusive licensee of two further patents related to the dosage of the drug (the dosage patent) and its formulation (the formulation patent).

Four pharmaceutical companies, including A, sought to clear the way to market generic versions of the drug by applying to revoke the patents for invalidity. A alleged that both patents were not entitled to the claimed priority and were invalid for lack of novelty and inventive step, as well as for added matter and insufficiency.

A argued its pre-emptive revocation action was not a threat to infringe which could give rise to a counterclaim for an injunction. A also argued that, to infringe a use claim, the focus had to be on information provided to the prescribing doctor in the summary of product characteristics. L's summary of product characteristics for a 5 mg tablet showed that they were also approved for on demand prescription for a maximum dose of 10 or 20 mg per day. The marketing authorisations for A's products followed L's summary of product characteristics. L relied on A's patient information leaflets where the highest dose mentioned was 5 mg per day.

Decision

The court held that at least one claim of the dosage patent was valid and infringed, but that none of the claims of the formulation patent were valid.

The invention of the dosage patent was the discovery that the drug administered at low doses was still clinically effective but also had low adverse side effects. Daily doses of 2.5mg and 5 mg day were said to be effective and the patent set the upper limit of the daily dose at 5mg. A skilled reader would not think the patent excluded higher doses of the drug as not safe and effective treatments for ED, but higher doses would

not take advantage of the invention. The word “maximum” meant that the claim did not cover administration of higher daily doses. So if the regulators only approved 20 mg daily then (assuming no off-label use) the claim would never be infringed. But if the regulator approved both 20 mg daily and also 5 mg daily, the latter would infringe.

Prior art referred to administering one or more 1mg to 20mg dosage forms as needed, up to a total daily dose of 20mg. This raised two priority issues relating to ranges in connection with the dosage patent: whether a range of 1mg to 5 mg for an individual dosage was supported; and whether a maximum total dose of 5mg per day was supported. There was no special law for priority concerning sub-ranges. The skilled reader would see that any dose from 1mg to 20mg was expressly contemplated. This included the idea of using dosages between 1mg and 5mg each, so the sub-range was disclosed in the priority document. However, there was no express disclosure in the priority document of a dosage form containing 2.5mg of the drug so the claims to that dosage lacked priority.

Novelty-only prior art was relied on against the claims which maintained priority. This was only prior art against these claims if it was itself entitled to its own claimed priority. Legal priority must always be established. The burden of proof lay on A, but if sufficient evidence was available to support an inference that legal priority existed, the burden shifted to the patentee to rebut that inference.

Here, there was a difference between the named inventors on the US priority document referred to in the cited prior art. This was because in the US, unlike Europe, patent applications must be made in the name of the individual inventor before being assigned to the employer.

As the prior art patent application was by a major international company, the court was entitled to assume that it had professional advice to ensure correct compliance with formalities. Without evidence to the contrary, there was sufficient evidence to support the inference that legal priority existed. It was for L to rebut that inference. As L did not, the prior art was entitled to priority from its priority document.

In relation to obviousness, the prior art cited against the dosage patent did not specifically disclose a 5mg daily dose of the drug within the wide range disclosed, nor that that dose was an effective treatment for ED. Dosing regimes were capable of being patentable, although most were obvious. Pharmaceutical development work involved a series of costly clinical tests of uncertain outcome, where the skilled team must judge at each stage how to proceed based on results obtained. The fact the results were not predictable from the outset did not necessarily make these decisions inventive. An obvious goal was not turned into an invention by an unexpected bonus effect, but finding surprising or unexpected properties could amount to an inventive step. The programme had to be considered as a whole. If the case turned on whether a particular test was "obvious to try", the skilled team's views about the likely prospects of success would be critical. A fair prospect of success would be required for that step to be obvious.

Here, although for blockbuster drugs the skilled team would have an enhanced expectation of efficacy with a second in class drug, and would be motivated by the prior art to test lower drug dosages, tests on a 5mg dose would not be undertaken with a reasonable expectation of success. There was also a surprising result: the existence of a useful effect with reduced side effects, so the invention was not obvious.

A could not bring a revocation action, with a contingent intention to launch a generic product if the action succeeded, without threatening to infringe the patent. The UK market for the drug was large and valuable, and A had applied for marketing authorisations, an expensive and time-consuming process. A said it only intended to sell the drug if the patents were revoked, but did not undertake to abandon the marketing authorisations if it lost the revocation action. The court also inferred from A's international business that it would have substantial supplies of the product once the original patent expired. Overall, an injunction would probably be required to prevent A from infringing, which justified bringing the infringement counterclaim. This inference was not because A had sought to clear the way by applying to revoke patents, but due to the marketing authorisation process.

In relation to the formulation patent, the prior art had clear teaching to administer the formulation in order to treat ED, but no associated data. L argued that the only basis on which these claims could lack novelty was inevitable result and that this had not been proved on the balance of probabilities. The evidence showed that the product which would inevitably be produced by a skilled person following the prior art would, on the balance of probabilities, fall within certain patent claims, making those claims lack novelty. The formulation patent was also invalid for obviousness.

Comment

Applying to revoke a patent with the intention to clear the way is not in itself proof of an intention to sell, and so not as such a threat to infringe the patent. However, here, an international business likely to have substantial supplies of the product applying for and obtaining marketing authorisation for generic products, did support an inference of an intention to sell in the context of revocation proceedings. Generic pharmaceutical companies might be able to avoid counterclaims for threatened infringement by formally undertaking not to sell the product, or, as suggested in this decision, by undertaking to abandon the marketing authorisation, if they lost the revocation action.

The decision also shows that challenges should not be made to the legal priority of prior art unless the deficiency is clear from the documents or evidence supporting a positive case that the inference of legal priority is incorrect. An inference of legal priority could reasonably be drawn when the prior art was of a third party.

Case: Actavis Group PTC EHF and others v Icos Corp and Eli Lilly & Co (Third Party) [2016] EWHC 1955 (Pat).

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