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### **“Enabling Disclosure” Considered in a “Crystalline Form” Case in the UK**

The issue of “enabling disclosure” in relation to prior art was recently considered in a “crystalline form” pharmaceutical case by the House of Lords, in effect the UK’s “Supreme Court”, in **Synthon BV v. Smithkline Beecham plc**.

The case concerned a specific crystalline material, paroxetine methanesulfonate (PMS), which was claimed in Smithkline’s patent. Synthon sought revocation of the patent on the ground that the material was not new over Synthon’s prior unpublished patent application. Under the rule of “whole contents novelty” well-known in first-to-file countries as the test for relative validity of co-pending patent applications in a jurisdiction, with intermeshing priority, filing and publication dates, the Synthon prior document was available as potential prior art, but only for the assessment of novelty.

Certain facts were not in Synthon’s favour:

- The example of its prior application stated that the material it had prepared had different spectral peaks to those claimed by Smithkline.
- Its pre-trial attempt to reproduce the example succeeded in preparing a crystalline material only after substantial additional (untaught) steps had been taken by a highly skilled chemist; this could, however, be explained by special problems caused by the taught use of ethanol as solvent (and possibly water as an impurity).
- It failed to prepare any material conforming to the melting point and spectra indicated in its example; this was, however, due to errors in the data given in the example.

Synthon brought evidence to show that crystallisation of organic chemicals is more of an art than a science, and that the skilled worker would expect to have to try a number of solvents. Crucially, Synthon also showed that PMS is monomorphic, i.e. always crystallises in the same way, whichever crystallisation method and solvent is used. Furthermore, the general parts of the Synthon application taught in general terms to crystallise PMS and Smithkline had acknowledged in their own patent that their material could be prepared by “conventional” crystallisation in a number of ways and using a number of solvents.

On the totality of the evidence, it was held that the Synthon application was an enabling disclosure of the Smithkline material, despite the problems with Synthon’s specific example. Therefore, Smithkline’s patent lacked novelty and was invalid.

The Opinion of Lord Hoffmann goes further, and analyses in detail the nature of the test for “enabling disclosure” in relation to a prior art document. Important points made in his Opinion are:

- Prior disclosure and enablement are to be considered separately (*Opinion, paragraph 28*). The short composite expression “enabling disclosure” must be used with care.
- This is particularly important when considering whether any experimentation is permitted when reproducing the prior art. The need for some experimentation will not necessarily prevent the prior art from being enabling, if that experimentation would be within normal trial and error for getting something in that art to work. (*Opinion, paragraph 30*).
- However, if there is need for further experimentation in order to determine the invention from the prior art teaching (i.e. if the prior art does not contain the necessary clear and unmistakable directions) then that need for further experimentation will mean that the prior art does not disclose the invention. (*Opinion, paragraphs 31 to 32*).
- The questions of enablement and disclosure in relation to the prior art must be kept separate from questions of enablement and disclosure (“sufficiency”) of the claimed invention (*Opinion, paragraph 33*). The dates on which the two sets of issues must be judged will always be different.

→ <http://www.parliament.the-stationery-office.co.uk/pa/ld200506/ldjudgmt/jd051020/synth.pdf>

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### **Lipitor™ UK Master Patent Construed Broadly in Challenge by Ranbaxy, but Later Salt Patent Held Invalid – Observations on the Patentability of Selection Inventions in the UK**

The UK High Court has held, in **Ranbaxy UK Limited et al v. Warner-Lambert Company**, that Warner-Lambert’s master patent covering Lipitor™ (atorvastatin hemicalcium salt) would be infringed if Ranbaxy were to launch their imitation product before patent expiry. However, a later patent directed specifically to the hemicalcium salt was held to lack novelty and inventive step in view of the master patent (published application text) and a PCT application of Warner-Lambert (which is “novelty-only” prior art in the way explained in the Synthon report above).

Pharmaceutical patentees commonly file patent applications directed to specific selected embodiments within the claim scope of a master patent, with a view to extending the patent life on the pharmaceutical.

If the later patent application is not filed until after publication of the master patent application, then, in order to be patentable, the later invention must be both novel and inventive over the complete disclosure of the master patent.

Ranbaxy had requested a Declaration of Non-Infringement of the master patent, asserting that the claims of the master patent covered only a racemic mixture of atorvastatin and its enantiomer, and not the resolved atorvastatin that Ranbaxy proposed to sell.

The court applied the normal approach of "purposive construction", as explained by the House of Lords in Kirin-Amgen (see the October 2004 issue of this Newsletter). In particular, the court avoided an over-meticulous analysis, and read the claims in the light of the description of the invention and common general knowledge in the art. The court concluded that the master patent covered both a racemate and the relevant individual (resolved) optical isomers, so that Ranbaxy's product, if marketed before expiry, would infringe the master patent. (*Judgement, paragraph 41*).

As far as the salt patent was concerned, the issue was whether the claimed hemicalcium salt of atorvastatin was novel in view of the "novelty-only" PCT application, and whether it was patentable as a "selection invention" from within the teaching of the master patent. The court held that the specific reference to atorvastatin in the PCT application, coupled with the (separate but generally applicable) statement there that salts could be formed with an ion selected from a list of seven, one of which was calcium, disclosed the hemicalcium salt of atorvastatin, so that the salt patent lacked novelty over the "novelty-only" prior art. The master patent application contained the same list of ions but was less clear as to whether the atorvastatin should be used in resolved form. Nevertheless, the court held that, at the priority date of the salt patent, resolution of racemates was common knowledge and that it was also common practice to identify useful salts. The result was that the salt patent was obvious from the master patent application. Warner-Lambert attempted to support the salt patent with evidence of after-discovered advantages, as it had done successfully before the EPO Board of Appeal, but the court held that in the UK an after-discovered advantage is unlikely to overcome evidence that a person of ordinary skill in the art would obviously have gone straight to the invention, and the reformulation of the "objective problem" which the EPO Board of Appeal undertook will only be persuasive to the UK court if the reformulated problem is "implied in or closely related to" the problem discussed in the patent (*Judgement, paragraph 72*).

The court also stated that, where an invention can be viewed as a selection from a previous generic disclosure, the first issue is whether the selection is **novel** (i.e. undisclosed to the skilled reader of the previous disclosure). Once novelty is established, inventiveness is then to be tested by normal principles. (*Judgement, paragraph 65*).

It has been reported that an appeal will be lodged. We will keep you informed of developments.

→ <http://www.bailii.org/ew/cases/EWHC/Patents/2005/2142.html>

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