

UK COURT CLARIFIES LAW ON SELECTION PATENTS UNDER THE PATENTS ACT 1977

By Matthew Royle

Dr Reddy's Laboratories v Eli Lilly [2008] EWHC 2345 (Pat)

Floyd J handed down judgment in *Dr Reddy's -v- Eli Lilly* on 13 October 2008. Dr Reddy's challenged the validity of EP 0 454 436 (Eli Lilly's patent covering olanzapine, the successful anti-psychotic agent). The challenge failed and the Patent was held to be valid.

The challenge raised interesting questions relating to 'selection inventions' as an earlier patent, also owned by Eli Lilly, had covered olanzapine within a general 'Markush' formula. Although this general formula covered a great number of different compounds, olanzapine was not specifically disclosed nor exemplified. The question of selection inventions had not been addressed by the UK Courts under the Patents Act 1977, although the cases of *Farbenindustrie* (1930) 47 RPC 289 (Maugham J in the High Court) and *Du Pont* [1982] FSR 303 (House of Lords) had considered the law under the Patents Act 1949. This decision was therefore, eagerly anticipated.

EPO Approach to selection inventions

Floyd J reviewed the case law relating to selection inventions as it has developed in the EPO and referred to the recent UK decision on enantiomers in *Generics v Lundbeck* [2008] EWCA Civ 311. He decided that the approach taken by the EPO was correct.

A general 'Markush' formula does not necessarily destroy the novelty of all the compounds contained within it. Given the large number of compounds disclosed by such a formula, "attention would focus on the compounds actually described". Moreover, such a disclosure cannot be said to contain "a clear description of, or clear instructions to do or make, something which would infringe the patentee's claim."

Floyd J decided that this approach was not inconsistent with the decision of the House of Lords in *Du Pont*.

UK approach to selection inventions under the Patents Act 1949

The criteria for a classical 'selection invention' were set out in *Farbenindustrie*, and approved in *Du Pont*. Following these criteria, in order to be a valid selection invention:

- a patent must be based on some substantial advantage (or avoidance of a substantial disadvantage) attributable to the selected members;
- the whole of the selected class must have that advantage; and
- the selection must be in respect of a character that can fairly be said to be peculiar to the selected group.

Ultimately Floyd J was doubtful whether satisfying these criteria would prevent a finding of anticipation if there had been a specific prior disclosure. Further, he held that they were relevant only to the overall assessment of obviousness and were not determinative of the issue.

In Appendix 2 Floyd J set out his conclusions were the *Farbenindustrie* criteria to apply. Eli Lilly had claimed at trial that olanzapine had the advantage over the class that it avoided certain side effects. Whether or not this was true (and Floyd J decided as a fact that it was), the patent was invalid under these criteria because the patent specification does not assert such an advantage.

On the facts, Floyd J decided that none of the prior art cited against Eli Lilly's patent, including a 'Markush' formula that covered olanzapine, destroyed the novelty of the patent because olanzapine was not specifically named or exemplified. Neither was olanzapine obvious in light of the prior art cited.

The decision clarifies the law on selection inventions and confirms that the law in the UK is consistent with the case law of the EPO. Given that this is the first case to consider this under the 1977 Act it seems likely to go to appeal. The Court of Appeal's views will be awaited with interest.