



## INTELLECTUAL PROPERTY UPDATE | 18 DEC 2009

### Selection patents no longer “part of living law”

#### Dr Reddy’s Laboratories v Eli Lilly and Company Court of Appeal Judgment dated 18 December

The law on selection patents required some clarification since the English Court in the case of *IG Farbenindustrie’s Patent* (1930) formulated what became known as the three IG Farben rules: to avoid a finding of invalidity (1) the selection patent must be based on some substantial advantage of the selected members (or avoidance of a substantial disadvantage), (2) the whole of the selected members must possess the advantage and (3) the advantage must be peculiar to the selected group.

In its Judgment of today concerning the patent on olanzapine (ZYPREXA) the Court of Appeal has decided that “*the best thing to do is to regard them [the IG rules] as part of legal history, not as part of the living law*”. In reaching this decision both Lord Justice Jacob and the Master of the Rolls noted that there was nothing in the 1977 Patents Act which recognised or implied a special approach to selection patents which required a different approach when determining validity. Further, the EPO’s approach in cases such as these was consistent and clear. The Master of the Rolls observed that insofar as there was a difference between the approach of the EPO since the 1977 Act came into force and the approach of the English Courts under the pre-1977 law, the former is to be preferred unless it can be shown to be “*one-off, impractical, illogical, inconsistent with principle, not open as a matter of domestic law, or (perhaps) not applied in domestic courts of other signatory states of the EPC*”. He ruled that in this case there were no good reasons for not following the EPO’s approach.

Having considered the correct approach to “so-called” selection inventions, the Court of Appeal went on to find the olanzapine patent valid.

#### THE FACTS

The patent in dispute claims olanzapine. It describes the advantages of olanzapine by reference to what the Court of Appeal found to be “*real evaluations both in animals and in early clinical tests*”. The patent refers to an earlier Lilly patent (the ‘235 patent’), the provisional specification of which was relied on by Dr Reddy’s for their obviousness and novelty attacks. The ‘235 specification describes a novel class of thienobenzodiazepines by reference to a Markush formula containing at least 10<sup>19</sup> compounds and a narrower class of preferred class comprising around 86,000 compounds. The ‘235 specification describes the utility of the compounds as being “*potent centrally acting compounds with neuroleptic, sedative or relaxant effects*”. Olanzapine is one of the 10<sup>19</sup> and the preferred class but is not mentioned specifically in the patent.

---

## THE JUDGEMENT

### Anticipation

The Court firmly rejected Dr Reddy's contention that olanzapine was not novel and gave two reasons. Firstly as a matter of *a priori* reasoning a generalised prior description could not be said to disclose a specific matter falling within it, Lord Justice Jacob stating: *"It is at least faintly ridiculous to say that a particular leaf has been made available to you by telling you that it is in Sherwood Forest. Once identified, you can of course see it. But if not identified you know only the generality: that Sherwood Forest has millions of leaves"*. The Court also made clear that it regarded the listing out of a great number of compounds as opposed to the use of a Markush formula in the same way. Secondly the EPO jurisprudence requires an individualised description of the later compound or class for anticipation and UK law, as most recently stated by the House of Lords in *Synthon*, required the prior art to *"necessarily result in an infringement of the patent"*. The Court noted that in this case '235 could be performed in 10<sup>19</sup> ways but only one of them would result in infringement.

### Obviousness

The Court preferred the EPO approach of considering whether or not there had been a mere arbitrary selection for a class thereby rendering the patent obvious in preference to the IG rules. In rejecting the IG rules, the Court noted that *"if one thinks about them, it is difficult to see how, realistically, they could be complied with unless the patentee carried out an enormous range of experiments"*. The Court observed that the IG rules were too strict with the consequence that the technical advance of the sort made by Lilly would be unpatentable and unpatentability would have meant that olanzapine would not have been available.

The Court considered that the answer to what was meant by an "arbitrary selection" could be found in the guiding principle – is there a real technical advance? It found that the identification and disclosure of olanzapine's properties could not be said to be an arbitrary selection. Firstly the patent discloses the superior properties of olanzapine compared with its closest analogue and the lead compound of the wider class. The Court notes *"None of that [the disclosure in the patent] indicates a mere arbitrary selection telling the reader in effect no more than he would get from reading 235."* Secondly the Court notes that no reasons are given in the '235 specification for why this class is preferred and the statement of utility is a mere assertion unsupported by any experimental evidence which leaves the skilled reader unable to decide if it is true, soundly based or plausible. Therefore the disclosure of '235 *"would have been read in 1990 with at least a pinch (perhaps a sackful) of salt"*.

The obviousness attack over another price of prior art (Chakrabarti 1980) was also rejected.

### Foreign Decisions

Given the drive to have consistency between national Courts on parallel patent cases, it is worth noting that both Lord Justice Jacob and the Master of the Rolls, whilst recognising that they were not bound by a decision of another national court, welcomed the fact that they reached the same conclusion as the Oberlandsgericht and the Bundesgerichtshof in Germany.

Howrey (London) represented Eli Lilly in this action.

**FOR FURTHER INFORMATION:**

If you require more detailed information about this particular case or any other Intellectual Property issue please call **Marjan Noor** in our London Office (Direct: +44 (0)207 936 5389), any attorney at Howrey LLP with whom you have an existing relationship, or contact one of our offices below:

**Amsterdam:** +31 (0)20 592 4411

**Brussels:** + 32 (0)2 741 1011

**Chicago:** +1 312 595 1239

**East Palo Alto:** +1 650 798 3500

**Houston:** +1 713 787 1400

**Irvine:** +1 949 721 6900

**London:** +44 (0)207 936 5300

**Los Angeles:** +1 213 892 1800

**Madrid:** +34 91 426 44 70

**Munich:** +49 (0)89 20 308 1200

**New York:** +1 212 896 6500

**Northern Virginia:** +1 703 663 3600

**Paris:** + 33 (0)1 42 22 4611

**Salt Lake City:** +1 801 533 8383

**San Francisco:** +1 415 848 4900

**Taipei:** +886 2 8175 6600

**Washington, DC:** +1 202 783 0800

© 2009 Howrey LLP. This document is intended as a report on legal developments. It is not intended as legal advice. Readers should not act upon the contained information without professional advice. No portion of this paper may be reproduced without express permission.

Howrey LLP is the Data Controller for any personal data that it holds about you. To correct your personal details, or if you do not wish us to provide you with information that we believe may be of interest to you, please contact Camilla Todd on +44 (0)20 7936 5332 or at [toddc@howrey.com](mailto:toddc@howrey.com)