

The Lundbeck case

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Background facts

- Lundbeck had discovered and patented the SSRI anti-depressant citalopram
- By the priority date (1988) citalopram was in advanced development and its beneficial properties were well known
- It was known that citalopram was a racemate – a 50:50 mixture of two enantiomers

Motive to resolve

- Awareness of potential differences in activity / toxicity of enantiomers provided “a clear motive to isolate and test the enantiomers”.
- “Investigation of the enantiomers of citalopram was an obvious goal for the ordinary skilled medicinal chemist in 1988.”

Lundbeck's patent

- Lundbeck identified two routes to making the enantiomers, both involving resolution of the diol precursor into its enantiomers followed by stereoselective conversion to the enantiomers of citalopram
- It discovered that the activity lay almost entirely in the (+) enantiomer

Claims

- Claim 1: (+) citalopram
- Claim 3: a pharmaceutical composition comprising (+) citalopram as an active ingredient
- Claim 6: a method for making (+) citalopram which comprises converting the (-) diol in a stereoselective way to (+) citalopram

Novelty and inventive step

At first instance and on appeal:

- Claims 1 and 3 were novel because they were to be interpreted as excluding the prior art racemate
- All claims involved an inventive step; it was not obvious that the necessary reaction of the resolved diol intermediate could be performed without loss of stereochemistry; it was not obvious to resolve citalopram by chiral HPLC

Biogen v. Medeva (1)

- S.14(3) = Art 83; s.14(5)(c) = Art 84;
s.71(1)(c) = Art 100(b) / Art 138(1)(b)
- “The substantive effect of s.14(5)(c), namely that the description should...constitute an enabling disclosure, is given effect by s.72(1)(c).”

Biogen v. Medeva (2)

“S.72(1)(c) is...intended to give the court a jurisdiction in revocation proceedings...to hold a patent invalid on the substantive ground that...the extent of the monopoly claimed exceeds the technical contribution to the art made by the invention as described in the specification. ...The disappearance of “lack of fair basis” as an express ground for revocation does not in my view mean that general principle which it expressed has been abandoned. The jurisprudence of the EPO shows that it is still in full vigour and embodied in Arts 83 and 84...”

