

Knowing your right hand from your left

It is well known that enantiomers of chemical compounds may possess different physiological properties. A recent Court of Appeal decision from the United Kingdom, *H. Lundbeck A/S v. Generics*,¹ discusses the patentability of a purified enantiomer when the racemate is already known.

The Circumstances

In 1979 Lundbeck obtained a patent in the UK for the antidepressant drug citalopram. The patent specification disclosed a racemic mixture which had antidepressant effects. Following the expiry of this patent in 1999, several generic pharmaceutical manufacturers began producing competing versions of the citalopram racemate.

In 1987 Lundbeck had derived a novel method for preparing the separate (+) and (-) enantiomers of citalopram. Lundbeck discovered that the antidepressant effects of citalopram were mediated by the (+) enantiomer, and in 1989 patented a method to produce the (+) enantiomer (escitalopram). The novelty and inventiveness of Lundbeck's claim directed to the new method of producing the (+) enantiomer has never been challenged. However, in addition to the method claim, the 1989 patent also included claims directed to the (+) enantiomer itself and pharmaceutical compositions containing the (+) enantiomer, and it is these claims that have been contested.

The Issue

Several generic drug manufacturers applied to the UK High Court to have the 1989 patent revoked on the grounds that Lundbeck was simply repatenting citalopram (or at least the active ingredient of citalopram) in an attempt to extend its patent protection beyond the term of the original 1979 patent. The UK High Court agreed and held that the claims to the (+) enantiomer and pharmaceutical composition were invalid. The court found that by 1988 medicinal chemists with knowledge of racemic mixture of a compound would routinely attempt to investigate its enantiomers. The (+) enantiomer was therefore known and all Lundbeck had invented was a new method of producing it. Lundbeck had effectively, by claiming the (+) enantiomer by itself, obtained a patent which granted it a monopoly covering the (+) enantiomer – regardless of the method used to produce it. In other words, the Court

found that Lundbeck had obtained more than it had invented and it limited the patent accordingly.

The High Court considered that in order to claim the (+) enantiomer, it would be necessary for Lundbeck to have disclosed information in the 1989 patent relating to every possible method of producing the (+) enantiomer. This rather narrow interpretation suggests that any claims to a novel compound may be invalid, if an alternative method of manufacturing the compound - which has not been disclosed in the patent specification - is discovered at a later date.

The Appeal Decision

Lundbeck appealed and the Court of Appeal overturned the High Court ruling. The Court of Appeal stated that the claims to the purified (+) enantiomer of citalopram were valid because the patent specification adequately taught the skilled person how to make the (+) enantiomer. In other words, the purified (+) enantiomer was itself a significant contribution to the art and because Lundbeck was the first to produce the (+) enantiomer, it was entitled to claim the associated rights.

What does this decision mean?

This decision provides an incentive for developing a method of manufacturing previously unavailable products. If a new method of synthesising a product, *i.e.* separation of previously inseparable enantiomers, is devised which provides an improved product, *i.e.* a single enantiomer which was previously unattainable, it may be possible to obtain broad patent rights to that product which extend beyond the methods disclosed in the original patent specification.

A reminder: if you have any queries regarding patents or patent ownership, or indeed any form of intellectual property, please direct them to:

Patent Proze
Baldwins Intellectual Property
PO Box 852, Wellington
Email: email@baldwins.com

1. *H. Lundbeck A/S v. Generics (UK) Ltd. & Ors*, [2008] EWCA Civ 311.



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