

Recycled Use – Utility Must be Claimed and Supported

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Utility

Where there is a new compound, utility can be described in the specification. For a new use for an old compound, utility must be set out in the claims.

In *AstraZeneca Canada Inc. v. Apotex Inc.*, 2010 FC 714 the invention at issue was a new method of separating the enantiomers of the drug Oesomeprazole. The claim at issue was for a salt form of the (-) enantiomer at an optical purity of at least 99.8%.

J. Hughes held that the claim was directed to a previously known compound (the enantiomers had been separated previously), but at a high level of purity. As the compound was previously known, its utility must be claimed.

[90] Even if claim 8 does not expressly claim utility, the claimed invention must possess utility. **For example, one cannot simply prepare a compound, then claim it at various levels of purity, say 90%, 92%, 94%, 96%, etc., without stating why such purity level is useful.** The invention is not simply a molecule or a molecule of a certain purity, it must, as the Federal Court of Appeal said in *Merck & Co. v. Apotex Inc.* (1995), 60 C.P.R. (31) 356 at page 373 “inherently” possess utility: (emphasis added)

Insufficiency

Insufficiency was addressed concurrently with utility. Ultimately the general statement in the specification that an isolated enantiomer would provide “*an improved therapeutic profile*” was held to be the promise of the patent.

The lack of support for this promise (not even sufficient for a sound prediction), both in the specification and in the inventor’s possession, resulted in a successful challenge on this ground.

Anticipation

Prior art revealed method to separate optically distinct enantiomers, but did not describe specific purity. Testing indicated that previous method could have been used to achieve same level of purity, but that it was not an inevitable result. Consequently, J. Hughes held that there was no anticipation.

Obviousness

While the prior art didn't necessarily result in higher purity levels, it showed one how to achieve them if desired, and there was expert evidence that higher purity is generally desired for pharmaceutical preparations. Consequently, the claim of obviousness was held to be justified.