STATUTORY INSTRUMENTS

S.I. No. 50 of 2006

European Communities (Limitation of Effect of Patent) Regulations 2006

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S.I. No. 50 of 2006

European Communities (Limitation of Effect of Patent) Regulations 2006

I, Micheál Martin, Minister for Enterprise, Trade and Employment, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purposes of giving effect to Article 10.6 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001[1] (as last amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004[2]) and Article 13.6 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001[3] (as last amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004[4]), hereby make the following regulations:

1. These Regulations may be cited as the European Communities (Limitation of Effect of Patent) Regulations 2006.

2. Section 42 of the Patents Act 1992 (No.1 of 1992) is amended –

(a) in paragraph (f), by substituting "," for ".", and

(b) by inserting the following paragraph after paragraph (f):

[1] OJ No. L311, 28.11.2001, p.67
[2] OJ No. L136, 30.4.2004, p.34
[3] OJ No. L311, 28.11.2001, p.1
[4] OJ No. L136, 30.4.2004, p.58

"(g) acts done in relation to the subject matter of the relevant patented invention which consist of:

(i) acts done in conducting the necessary studies, tests and trials which are conducted with a view to satisfying the application requirements of paragraphs 1, 2, 3 and 4 of Article 10 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001[5] (as last amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004[6]) for a marketing authorisation in respect of a medicinal product for human use, or

(ii) acts done in conducting the necessary studies, tests and trials which are conducted with a view to satisfying the application requirements of paragraphs 1 to 5 of Article 13 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001[7] (as last amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004[8]) for a marketing authorisation in respect of a veterinary medicinal product, or

[5] OJ No. L311, 28.11.2001, p.67
[6] OJ No. L136, 30.4.2004, p.34
[7] OJ No. L311, 28.11.2001, p.1
[8] OJ No. L136, 30.4.2004, p.58

(iii) any other act which is required as a consequence of the acts referred to in subparagraph (i) or (ii) for the purposes specified in those subparagraphs, as appropriate.".

Given under my Official Seal,

__30 January_ 2006.

L.S.

_____Micheál Martin___
Minister for Enterprise,
Trade and Employment

Explanatory Note

This note is not part of the Instrument and does not purport to be a legal interpretation

These Regulations, made pursuant to the European Communities Act, 1972, amend Section 42 of the Patents Act, 1992 to limit the rights conferred by a patent where certain acts are undertaken to fulfil the application requirements of Article 10 of Directive 2001/83/EC (as last amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004) for a marketing authorisation for a generic or similar biological medicinal product for human use and Article 13 of Directive 2001/82/EC (as last amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004) for a marketing authorisation for a generic or similar biological medicinal product for veterinary use.