

STATUTORY INSTRUMENTS

S.I. No. 50 of 2006

European Communities (Limitation of Effect of Patent) Regulations 2006

PUBLISHED BY THE STATIONERY OFFICE DUBLIN

To be purchased directly from the

GOVERNMENT PUBLICATIONS OFFICE,

SUN ALLIANCE HOUSE, MOLESWORTH STREET,

DUBLIN 2

Or by mail order from

GOVERNMENT PUBLICATIONS POSTAL TRADE SECTION,

51 ST. STEPHEN'S GREEN, DUBLIN 2

(Tel: 01 6476834/35/36/37; Fax: 016476843)

Or through any bookseller

(PRN. A6/0101)

€1.27

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 2001¹ (as last amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004²) and Article 13.6 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001³ (as last amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004⁴), 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 2001⁵ (as last amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004⁶) 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 2001⁷ (as last amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004⁸) 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

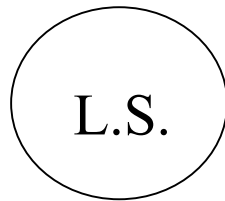
⁷ OJ No. L311, 28.11.2001, p.1

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.



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.