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Vt. Ágúst Geir Ágústsson

Málefni: Frumvarp til laga um breytingu á lögum nr. 17/1991, um einkaleyfi, með síðari breytingum. Þskj. 269 — 251. mál.

Eli Lilly hefur fyrr á þessu ári fengið þetta frumvarp til umsagnar frá Iðnaðar- og viðskiptaráðuneytinu og sent umsögn.

Ekki verður séð að Iðnaðar- og viðskiptaráðuneytið hafi tekið tillit til umsagnar fyrirtækisins. Efnislega höfum við enn sömu athugasemdir og sendum þær því hér með í formi afrits af bréfi Eli Lilly til Iðnaðar- og viðskiptaráðuneytisins dags. 7. september 2004.

F.h. Eli Lilly

Aðalsteinn Jens Loftsson

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Ministry of Industry and Commerce
Arnarhvoll 150
Reykjavik
Iceland

Att.: Jón Ögmundur Thormódsson

7 September 2004

Dear Jón Ögmundur Thormódsson

Ref: Your letter of 16 July 2004 – Parliamentary bill to amend Act No. 17/1991 on patents

Directive 2004/27/EC, which amends Directive 2001/83/EC on the Community code relating to medicinal products for human use, entered into force on 30 April 2004. The EU and EEA Member States are required to transpose the provisions of Directive 2004/27/EC into their national laws no later than 30 October 2005.

The proposal from Iceland is to transpose into the Icelandic Patent Act that part of Directive 2004/27/EC that relates to the so-called "Bolar" provisions for generic medicinal products, whilst delaying transposition into the Act on Medicines the remaining aspects of the Directive, including the change to data package exclusivity to the so-called 8+2+1 term.

Lilly is not in favour of this split approach to the transposition of the provisions of Directive 2004/27/EC. In particular, the directive was drafted following extensive consultation with numerous interested parties in Europe. The result is a directive that seeks to balance the interests of all of those parties. It is therefore undesirable to transpose into Icelandic law some of the provisions, whilst delaying the transposition of others. To do so would result in an imbalance of the interests of the parties that was not intended by the EU/EEA legislators (even if such an imbalance is only temporary).

Lilly recognises that it might, in practice, be difficult to coordinate the amendment of two separate pieces of legislation. Nevertheless, we suggest that it might be possible to amend Article 4 of the draft Parliamentary Bill amending the Patent Act to read: *"This act enters into force on the same date as entry into force of amendment to the Act on Medicines implementing Directive 2004/27/EC, and in any event shall enter into force no later than 30 October 2005."*

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With reference to the wording of the "Comments" that accompany the draft Parliamentary Bill amending the Patent Act, Lilly proposes that the comment on Article 1 of the draft Parliamentary Bill should make it clear that manufacture, import and possession of the generic medicinal product is not exempted (at present, the comment only refers to manufacture). Thus, the penultimate sentence of the first paragraph of the comment on Article 1 should read:

> *"It shall be stated that this does not involve permission to manufacture, import or possess generic medicinal products during the protection period of the patent for the purpose of putting the product on the market."*

We also observe that the amendment does not arise from paragraph 6 of Article 10 of Directive 2004/27/EC, but rather it is Article 1, point 8 of Directive 2004/27/EC that amends Article 10 of the previous Directive 2001/83/EC. Therefore, we suggest that the first sentence of the general comment on the bill should be rewritten along the lines of:

> *"This parliamentary bill entails amendments to the Patent Act, No. 17/1991, with subsequent amendments, because of legalization of paragraph 6 of Article 10 of Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended by Article 1, point 8 of Directive 2004/27/EC of the European Parliament and Council, dated 31 March 2004."*

Similarly, the second paragraph of the comment on Article 1 should be rewritten along the lines of:

> *"This amendment incorporates paragraph 6 of Article 10 of Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended by Article 1, point 8 of Directive 2004/27/EC of the European Parliament and Council, dated 31 March 2004."*

Yours faithfully

Ole Nygaard Pedersen