Is Europe's patent system discouraging innovation among pharmaceuticals?

The European pharmaceutical industry is in danger of foundering unless the right conditions for innovation, such as a harmonised patent system and increased funding, are created. This was the resounding message from participants at a seminar organised by the European Life Science Circle and the European Patent Office (EPO) on 19 December.

The pharmaceutical sector plays a key role in Europe, both as a knowledge-based industry and as a source of wealth improvement. But over the last 25 years, Europe has gradually gone from being the world’s pharmaceutical research powerhouse to a ghost of its former self. Whereas 25 years ago, the European pharmaceutical sector produced the majority of drugs in the market, now 8 out of 10 drugs are developed in the US.

The reason behind this decline is simple, according to Nicole Fontaine, MEP and former president of the European Parliament. The pharmaceutical industry faces more stringent regulations and higher costs than any other industrial sector. Developing new drugs is also a very risky business. On average, only one out of 5,000 to 10,000 promising substances will survive extensive testing in the research and development (R&D) phase to be approved as a quality, safe and efficient…
Due to the high risks associated with drugs, the industry must also undergo rigorous review and traceability processes, pay high insurance premiums, and adhere to strict licensing laws. 'These constraints and the extra costs incurred greatly impact the research budget and slow down the R&D process,' she pointed out.

Another stumbling block for the industry is the current European patent system, which Ms Fontaine described as 'dissuasive', especially in terms of the cost of patent protection, which is said to be two to four times higher than in the US. This is due in part to litigation costs and the fact that the patent must be translated into the official languages of each country in which the patentee wants protection.

All medicines have a 20 year patent. But soaring costs - combined with downward pressure on prices - are making it harder and harder for many pharmaceutical companies to recoup their R&D expenditure before patents expire. Pharmaceuticals companies would need an extension on the 20 year life of their patents to cover the time it takes to gain regulatory approval, said Ms Fontaine. 'The current patent system which gives the same length of patent for a new video console as to a medicine appears to me is inappropriate,' she added.

These views were echoed by Johan Vanhemelrijck, Secretary General of the biotech industry association EuropaBio. He noted that the current high patent protection costs, which average €40,000 in the EU, compared to under €3,000 in the US, are a huge disincentive to innovate, particularly for small and medium sized enterprises (SMEs). Helping SMEs to innovate should not be neglected, given that they account for 99% of European businesses and 80% of all EPO applicants.

In the long term, Mr Vanhemelrijck believes that a Community Patent is the only way to reduce costs, 'but in the short term, we have to keep in mind some other alternatives.' One alternative is the ratification of the London Protocol, an agreement which would allow signatory countries to submit patents in just three languages - English, French and German - hence reducing the number of translations needed. Ten countries have signed up to the protocol, and only ratification by France is still necessary for the agreement to enter into force.

Another initiative which is likely to help cut costs is the European Commission's revised state aid rules for R&D. The new scheme allows aid to cover some of the patent costs incurred by SMEs, as well as aid for young innovative enterprises and innovation clusters 'If only half of Member States find the money to support SMEs in this way, it would go some way to help,' believes Mr Vanhemelrijck.

But is it not just the burden of patent costs which is stalling innovation in Europe. Not enough investment is going into early stage investment by pharmaceuticals,
Francis Carpenter, Chief Executive of the European Investment Bank (EIB). To tackle this, the EIF has started a Technology Transfer Accelerator (TTA), an initiative which provides risk capital for the financing gap between research and early stage financing. Already, several European organisations have benefited from EIF support, and Mr Carpenter believes the outcomes are showing that it is money well spent. A total of €50 million per annum has been earmarked to continue the initiative beyond its initial pilot phase.

In his closing remarks, Alain Pompidou, President of the EPO, said that he was confident that an agreement on the London Protocol would be reached soon by the French. 'If we are lucky we could have the agreement by the French presidential elections, or by no later than 2008.' Professor Pompidou said there was growing momentum among Francophone countries for its ratification, pointing out that 16 French speaking African nations recently signed up to the agreement.

The debate on the Community Patent is expected to be relaunched in 2007 under the German EU Presidency.

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