Editorial

Patents and the Drugs Companies

When the UK Government acceded to the demands of the pharmaceutical industry and allowed patents for medicines granted under the 1949 Patents Act to escape the licensing of right provisions which would otherwise apply after year 16, it was only after considerable argument. Now the EC Commission proposes to restore the term of protection for medicines to something like the full twenty years provided for on the face of the European Patent Convention.

Pharmaceuticals have always been said to be a special case. They take so long to come to market because of the drawn-out approval process through which they must go that the actual term of protection is dramatically reduced.

In debates on the Copyright, Designs and Patents Bill the government acknowledged that the process took an average of 11 years. If the patent only lasted for 16 years (as is the case under the 1949 Act, with licences of right for a further four years to bring the term up to the European Patent Convention's 20 years) that doesn't leave a lot of time to recoup your investment.

The delay caused by the approval process has been getting longer. In the early sixties it was only three or four years, leaving an effective patent term of 12 years. The extension of the 16 year term when the 1977 Act came in, albeit subject to licences of right, was a concession to help redress this balance.

The Commission now proposes, by Regulation (not Directive), to restore the patent term by adding an extra period to the life of pharmaceutical patents. This will be calculated by taking the delay from the date of the patent application to the date of the first authorisation to place the product on the market in the Community, and subtracting four years. If you get to market within four years from the application date, you get nothing extra – though you probably don't need it.

This may sound like special pleading, and certainly the pharmaceutical lobby is immensely powerful. There are sound public interest arguments; if research costs cannot be recouped in Europe, the work will be relocated to those countries (the USA and Japan) where longer protection is given. Funnily enough, much the same argument was deployed in Parliament, but there the foreign jurisdiction with the generous protection was said to be Germany.

But what does this matter in a global pharmaceutical market and with worldwide patent protection? Surely the pharmaceutical companies can already budget to recover their costs on the basis of existing terms of protection in different countries. An increase here or there in the term of the monopoly merely gives them a greater opportunity to reap super-normal profits.

Harmonisation of the effective term of protection within the Community is a much more compelling argument, but using a Regulation rather than a Directive as the instrument to effect the change reduces its water-holding capacity.

The argument for an extended term has also been deployed in favour of pesticides. Initially the UK government gave it a cool reception, but then caved in and added such patents to the exception by statutory instrument. We can only wait to see how long Brussels can hold out.