Anfang November erreichte unsere Kanzlei folgende Mitteilung:

Dear Mr. Sträter

In the December/January issue of Global Counsel we are running an article entitled "The Global Counsel Top 10: Life Sciences lawyers", based on our research for the Global Counsel Life Sciences Industry Report 2001, which was published recently. The article will profile the 10 regulatory life sciences lawyers most highly regarded by their peers and clients, You are on of the 10.

For the purposes of the article, I should be grateful if you could therefore answer briefly the four following questions.

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1. In your view, what was the most interesting case of the last 12 months in the life sciences industry worldwide, and why?

The Lipobay case was a special experience for shareholders above all else. Nevertheless, life sciences companies are and will remain an interesting target group for medium- to long-term investments. The Lipobay case also showed, however, that a modification to the risk/benefit assessment and thus ultimately to the legal analysis as a result of only slight changes in risk can have a dramatic effect. For our firm it is a real challenge to advise Bayer in pharmacovigilance proceedings and its licensees in questions of product liability following the withdrawal of the product. The case is of special interest because the picture presented by the media to the public is not congruent with the real risk/benefit assessment.

According to existing data, if the product is used correctly the risk/benefit ratio of Lipobay by comparison with all other products of the same product group, the so-called statins, is clearly to be assessed positively.Correct use means in particular that the contraindication of combining the product with the active substance Gemfibrozil should be observed. The prime reason for the recall of the product was the question of how significant the incorrect use by doctors is for the assessment of safety. By comparison with other statins, Lipobay has one main disadvantage, namely a negative interaction with Gemfibrozil, a substance also used to reduce cholesterol levels from the family of fibrates. Whilst there is a warning about this interaction for the other statins, the risk in the case of Cerevastatin is distinctly higher. From a legal point of view is it therefore necessary to take the product from the market for reasons of highly precautionary consumer protection if doctors and patients ignore the contraindications? In this respect Bayer made a very responsible decision which gives no reason to assume liability, especially since advantages can be discussed for Cerevstatin compared to the other statins. The public discussion did not reward this action; it was moreover irrational and ignored the facts. The root of the trouble here must be sought in communication.

2. In your view, what was the most interesting deal of the last 12 months in the life sciences industry worldwide, and why?

The purchase of Knoll AG by Abbott was not in itself exciting. It does, however, show a systematic continuation of the orientation of the life sciences companies. BASF has taken its leave of the pharmaceuticals business, whilst Aventis' sale of crop sciences means that it is focussing on this very business. The same applies to Schering. Bayer continues to pursue the '4-pillar model' which is viewed differently by the shareholders. The comparison groups are now clearly lined up. The winner in the competition of concepts will be decided by how share prices fare in the medium- and long-term.

3. In your view, which area of life sciences regulation is most in need of reform, and why?

The European Union's regulation of Data Protection and Intellectual Property Rights is urgently in need of improvement. The rulings of the European Court of Justice on the term 'Essential Similarity' as defined by Art. 4 (8 a iii) of the EU Directive 65/65 have led to 'line extensions' to medicinal products not being entitled to supplementary protection. According to the decision of the Court of Justice, this principle also applies if a further development e.g. in new fields of application or with new galenic technology is innovative and brings new additional benefit to the patient. The generics companies are at liberty to serve themselves during the authorisation procedure and to make use of the data collated by research companies at great financial expense. This legal situation is not only unfair towards the research industry but it will automatically lead to a drastic reduction in research activities on known substances. This will result in substantial disadvantages for the patient. A re-orientation is urgently called for in order to create incentive systems for innovative research, initially and primarily in the interests of the patient. However, it is also of importance to the global transatlantic competition which demands the same framework conditions for fair competition.

Paediatric research is also of special significance in this context. The misunderstood and wrongly guided protection of children has led to the development of dramatic therapeutic gaps in the treatment of children. It is estimated that in Europe approximately 50% of the necessary medication for children is provided by off-label use. The figure is 100% in paediatric oncology. This necessarily means that treatment is provided on the principle of "trial and error" and with children of all things! An irresponsible state of affairs which is urgently in need of correction, not least through incentive systems that are known to provide the fastest remedy.

4. Which individual at any of the regulatory authorities do you consider to have made the most valuable contribution to life sciences regula-tion in recent years, and why?

As head of the Pharmaceuticals Unit of the European Commission's Directorate General III and later of the European Medicines Evaluation Agency (EMEA), Ferdinand Sauer's approach was pioneering and successful. In the European Commission he was greatly involved in the concept of the European authorisation system which he later implemented as head of the EMEA. The history of the EMEA is doubtless a success story. However, it should be remembered that the number of cases so far dealt with is small by comparison with the work load of the national authorisation bodies. Since its establishment in 1995 the EMEA and the European Commission have authorised approximately 200 medicinal products in centralised authorisation proceedings. More than 1,000 decisions were made over the same period decentrally. The national authorities granted a great many more purely national authorisations. This means that after a good start in 1995 the system still has to prove itself.

5. Which other life sciences lawyer (not at your firm) do you hold in the highest regard in the international arena, and why?

Ian Dodds-Smith joined Arnold & Porter's London office in October after many successful years at Cameron McKenna. He is a specialist not only in life sciences law in the United Kingdom but also a recognised expert on the European authorisation system and the regulations protecting intellectual property. He advises the major pharmaceutical companies. His expertise and sincerity make him a pleasure to work with.