Book review

GATT and Patent Reform. The Global Strengthening of Patent Protection and the Implications for the Pharmaceutical Industry by Tom Raggett, FT Pharmaceuticals and Healthcare Publishing, 1996. £320 (vii + 320 pages)
ISBN 1 85334 431 1

This is a high-quality overview of how recent changes in patent legislation are affecting the industry. The introduction explores the patent from first concept, contrasts the first-to-file and first-to-invent systems and outlines the importance of patenting in the context of R&D, information flows and the pharmaceutical industry. Subsequent chapters explore in greater depth the implications of patenting and the associated patent legislation treaties for the pharmaceutical industry and the product life cycle.

One of the key influences, with major implications for world trading, has been the GATT agreement (The General Agreement on Tariffs and Trade), specifically the key section of the agreement relating to implementation of key patent legislation, which is known as TRIPS (Trade Related Aspects of Intellectual Property Rights). TRIPS relates to all aspects of intellectual property, including patents, copyright and design. Controversies and consequences relating to the implementation of TRIPS are described. One such revision is the change in patent protection duration from 17 years from issue to 20 years from filing, which meant that the USA was obliged fall into line with other countries and switch from the first-to-invent to the first-to-file system. This caused a furore among the US biotech companies for whom this would represent a shortening of effective patent life. Nevertheless, given that companies with existing patents would be granted the later of the two possible expiry dates, this represents a considerable windfall for the US industry. Benefits of extended patent lives are illustrated using net present value (NPV) models, and the implications of TRIPS, in terms of market growth around the world, are examined.

The report looks at changes in a range of patent protection legislation and its global implications, for example there is a separate chapter on the EU and patent reform. A range of controversies, test cases and their implications are explored, such as *Biogen v. Medeva*, *Diamond v. Chakrabarty* and *Amgen v. Chugai*.

The author of this report has written numerous treatises on a broad range of issues affecting the industry. Perhaps this is why the report is so readable, and can be easily understood by the non-expert in patenting, drug research and finance alike.

The report highlights just how dependent the industry is on the level and scope of patent protection around the world. It is therefore recommended, and although it is not cheap, the price is not out of line with the cost of similar industrially focused products.

David Hughes

In short...

Zeneca (Macclesfield, UK) has entered a three-year collaboration agreement with **Pharmacopeia** (Princeton, NJ, USA). Pharmacopeia will design and synthesize new small-molecule combinatorial libraries for screening in Zeneca's internal assays. The libraries will be licensed to Zeneca, and Zeneca will have the commercial rights to any compound discovered using the libraries. In return Pharmacopeia will receive license fees and will be given milestone payments and royalties for drugs derived from the libraries. The exact monetary terms of the agreement were not disclosed.

SmithKline Beecham Biologicals (Rixensart, Belgium) has completed its Phase III trial for a vaccine against Lyme disease in the USA and is planning to file a Marketing Application with the FDA later this year. Lyme disease is caused by different strains of the *Borrelia* bacteria, and is transmitted by the bite of infected ticks. The vaccine developed for the US market is monovalent, containing antigen from *Borrelia burgdorferi*. SmithKline Beecham is working on a vaccine for Europe, which will also contain antigens from *Borrelia afzelli* and *Borrelia garinii*.

Roche Laboratories (Nutley, NJ, USA) has received FDA clearance to market FEMSTAT One (active ingredient: butoconazole nitrate), an antifungal preparation for the local treatment of vulvovaginal infections caused by *Candida albicans*. The product utilizes KV Pharmaceutical Company's (St Louis, MO, USA) proprietary delivery technology, SITE RELEASE®, and will be manufactured in part by KV.