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Editorial Preface

"Some industries are different but some are more different than others. The pharmaceutical industry fits the latter category" (Scherer 1996:336). There is really no other industry where the nature of the products, the economics of research and development as well as the market structure and the societal implications of the industry's strategic decisions are as unique as in the pharmaceutical industry. Furthermore, there is no other industry that tests the boundaries and effects of intellectual property (IP) rights on a national and international level as the pharmaceutical industry.

The current issue of the Stockholm IP Law Review provides an eloquent presentation of pharma-related IP challenges exploring these from different angles and perspectives.

Genetic engineering is one of the major challenges in modern pharmaceutical research. It opens up for revolutionary therapeutic applications and represents considerable commercial value. CRISPR technology is a central technological development in this respect, being also the subject-matter of intensive patenting activity and patent-related disputes. Thomas Hedner and Jean Lycke explore the extensive technological potential of CRISPR innovations as well as the patent landscape in the field and discuss future trends in what may be expected to be a central area of future medicinal research.

Defining the concept of invention is without a doubt a challenge in the pharmaceutical sector. A new revolutionary invention might today consist of a new dosage regime or a second medical indication. Ester-Maria Elze discusses in her article how the novelty and inventive step requirement apply to dosage patents as well as the difficulties connected to their interpretation and enforcement on a national level. Claim drafting as well as enforcement of second medical indication patents are a complicated matter. Enforcement of second medical indication patents in Germany provides an interesting illustration of the difficulties of patent claim interpretation. As Clara Berrisch notes in her article, shaping the protection of second medical indication patents is still a work in progress.

John Hornby analyses UK case-law concerning the application of the Actavis equivalence test. He concludes that the balance has clearly been shifted in the UK in the direction of legal uncertainty. Parties and their advisors are being left to distil some generalized (though perhaps not amorphous) idea of what the extent of a patent's protection might be.

A major challenge of exercising exclusive rights in the pharmaceutical sector concerns how pharmaceuticals are sold. Applying for a patent is not the only nor the last thing a product owner has to do before placing the product on the market; pharmaceutical products need to successfully go through the stringent and time-consuming marketing authorization procedure. As a compensation for the time spent between the patent application and the actual commercialization date, the Supplementary Protection Certificate (SPC) Regulation provides an up to five-year exclusive right. The scope of this right and in particular the interpretation of article 3(a) of the SPC Regulation, and the definition of the term "product", are according to Lisa Åkerblom's article one of the most complicated aspects of the Regulation and the result of a "cultural shock" and a less successful transplantation from their American counterparts. The interface between patent rights and marketing authorization, in particular with respect to skinny labelling is also in focus in the recent CJEU case of Warner Lambert Company, analyzed in the case note by Sofia Bergenstråhle and Valter Gran.

The interplay between regulatory law and exclusive rights from an economic perspective is further explored by Ove Granstrand, who writes about the strategy of evergreening employed by pharmaceutical companies, with specific focus on the Losec case. Evergreening is generally the extension of the duration of an existing temporary monopolistic or market dominant position by various means or strategies.

The societal effects of patent protection of pharmaceutical products in particular on the international level are non-negligible. Katarina Foss-Solbrekk

discusses how developing countries' access to medicines is impeded by the patent system as well as how flexibilities in the international and national legal framework contribute to this end. The article shows that while exceptions to patent rights might not be as effective, they have however triggered a very interesting development of voluntary licensing, a company-centered initiative providing access to free or low-priced pharmaceuticals. Thus, instead of addressing public health concerns by means of compulsory licensing and generic alternatives, the pharma industry itself takes the responsibility to provide pharma with affordable modern medicines.

Commercializing pharmaceutical products is of course not only about exclusive rights for the technology. Choosing an appropriate name for a new product is a daunting task. In other industries, this is usually left to the creativity of the marketing department but in the pharmaceutical industry there is a considerable regulatory framework to take into account. The practical implications of this framework and its limitations on creativity in pharma branding is analyzed in Kristina Björnerstedt and Gunnel Nilsson's article.

Chemical molecules, gene sequences, patient security, expensive and lengthy research, international markets, innovative business models and prioritized public health concerns constitute necessary ingredients influencing the way the IP system is applied and interpreted in the pharma sector. And it is this unique interaction that makes pharma so special.

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