

## **BOOK REVIEW**

### **THE REGULATORY CHALLENGE OF BIOTECHNOLOGY: HUMAN GENETICS, FOOD AND PATENTS**

By Han Somsen (Editor),

Edward Elgar Publishing Limited, 2007, 265pp., £75.00, ISBN 978-1-84542-489-3.

If the success of a skilful editor is measured by his or her bringing together some of the key thinkers in a field and facilitating the elucidation of their ideas then Somsen succeeds magnificently in this edited collection which examines the regulation of biotechnology. To a researcher working in this field the book comes as a welcome treat. There is an impressive line-up of contributors which is noteworthy for its academic pedigree and includes inter alia; Roger Brownsword, Colin Scott, Neil Gunningham and Graeme Laurie. Overall Somsen's book offers a sophisticated introduction to the regulatory challenges in the sphere of biotechnology. This book both fills a more than a small gap in the current literature and will additionally succeed in stimulating debate which will doubtless lead to research spin-offs.

The book opens with two very insightful chapters which set out some general perspectives and themes on the regulation of biotechnology. These chapters are provided by Neil Gunningham and Colin Scott, who in line with a number of academics in this field have worked extensively in the area of environmental law and policy. Indeed it is to environmental law that Gunningham turns to examine whether the regulators of biotechnology can learn from past experiences of environmental regulation. Learning from past experience is a central theme running through a number of the chapters and is extended to include the area of nuclear technology by Scott. Gunningham presents a variety of regulatory options for biotechnology which include: smart regulation, reflexive and meta regulation. He then proceeds to assess the potential of each in its application to biotechnology. This provides the reader with a useful framework for the subsequent chapters.

The second 'setting the scene' chapter comes from Colin Scott who contests that biotechnology has not yet adequately matured to be classified as a discrete area of public policy. Scott's chapter is a real tour de force, he argues very convincingly that the state has been over-active in establishing 'standard setting processes' to the extent that it has inhibited the capacities of businesses and civil society to participate in or determine the standards. This, he argues, has meant that the opportunity to promote 'ownership' of regulatory norms is being missed.

Following the opening chapters, the book is divided into three distinct parts: human genetics, GMOs and agricultural biotechnology and the regulation of biotechnology through the patent system. In terms of the structure, the book is disappointingly biased against human genetics. In fact, a dissection of the book shows that for the five papers relating to GMOs and agricultural biotechnology, there are only two on human genetics. Somsen mentions that this is the first book in a series so maybe this imbalance is intentional and will be rectified in the next volume. My second comment on structure also pertains to substance: on a personal note I would like

edited collections to aim for greater cohesiveness of purpose. While there is the implicit assumption that all the authors are working from the same hymn sheet, it is more often the case that they are post hoc adapting conference papers to fall under an umbrella of shared subject matter. To this end, a greater coherence would have been achieved if the authors could have referred to the ideas set out in the opening two chapters. While as stand-alone papers the chapters work wonderfully and meet their author's own aims, there should be a little more emphasis paid to the fact that they form part of a whole. To this end, personally I would have extended Somsen's foreword into a short chapter which outlined the aims and purpose of the book as a whole and set out the regulatory challenges in very clear terms. It would be more reader-friendly to make explicit the common goals of the book and a more tightly drawn out set of aims would push the authors on to express in greater clarity the potential solutions they are offering to the challenges faced by biotechnology.

Biotechnology is riddled with ethical issues that have the potential to inculcate public concern, be the concerns based upon perceived or actual risks. The predominant challenges range from issues such as the different reactions to the technology across legal jurisdictions which make harmonisation or the establishment of regulatory norms difficult. The central issues, both ethical and risk-based, lead regulators and academics to question whether the adaptation of existing regulation is appropriate or whether it is necessary to develop novel regulatory frameworks to deal with them. There is generally a lack of consensus within and across states as to the regulatory goals in this area. There are currently many different ways that the regulation can develop and direct, shape and govern the technologies. Although it is critical to bear in mind, as Duffield comments that other forms of control exist outside of regulation and equally that regulation is not an absolute force of control.

In relation to the questions and challenges raised by the regulation of biotechnology, Brownsword draws up a four dimensional framework comprising of regulatory phasing, pitch, mode and range. He utilises this successfully to scope out the regulatory options available. Additionally, Brownsword provides a novel angle to the study of regulation of human genetics in that he suggests we look at human genetics less as a regulatory target and more as a regulatory tool. This chapter is one of the most stimulating in the collection terms of the issues that surround the regulation of genomics and leaves the reader wanting to extend the discussion of techno-regulation (technology that assists regulation) further. The second chapter on human genetics comes from Burley who adopts a very abstract approach in her discussion of the moral and ethical considerations in human genetics. She presents the reader with a hypothetical, fantasy world in which genetic technologies have advanced significantly and where she can play with regulatory and policy directions. Burley's motivations for such a method are the failure of regulators to adopt abstract reasoning and this proves to be a useful device in the unpacking of the moral dilemmas posed and the remedies available to regulators.

Of the five chapters on red biotechnology, one is an account of the regulation of GM foods by Van der Meulen who presents a concise overview of the approval, handling and labelling of GM foods under European law. Van der Meulen makes a strong case that the regulation is creating too great a burden upon the food industry and that a more effective regime should be designed. This balancing of technological developments against the protection of the environment from risk is the subject of Paul Street's chapter. Street has produced a convincing argument for the necessity of a more inclusive approach in regulatory decision-making as a means to examine the

various and often conflicting perceptions of risk in the area of biotechnology. The centrality of the public in the regulation of biotechnology is examined further by van den Daele in his chapter on the precautionary principle and risk perception in the regulation of new technologies. Van den Daele examines the gap between the political and regulatory handling of biotechnology in which the political battles relate to the process of modernisation and the democratic control over forces of social change whereas the issue at the heart of the regulation is the containment of risk. Van den Daele argues that 'the procedures designed to resolve conflicts over new technology hence fail to address the major themes that drive these conflicts' (van den Daele; 118).

The remaining two chapters in this section come from Sara Poli who writes about coexistence of EU and domestic law in the case of GMOs and Mary Footer who offers a chapter on plant genetic resources and trade reform. Poli's chapter picks up one of the central problems with multi-national regulation of biotechnology, the lack of agreement across the states. The case of the cultivation of GMOs brings to the fore very clearly the different wishes of European publics.

The third section of the book centres on the role of patenting within the regulatory system in the promotion of inventive activity which benefits the public. There is very clearly a greater unity across the chapters under this umbrella and they work exceptionally well together. These chapters are provided by Graham Dutfield, Graeme Laurie and Geertrui Van Overwalle. Dutfield focuses upon terminator technologies and examines the scope the patent system, most specifically the applicability of the *ordre public*, in the prevention of legal protection for applications on moral grounds. The pros and cons of terminator technology are fleshed out concisely. A pertinent point raised by Dutfield is that the very denial of the patent may actually lead to a greater adoption of the technology. This highlights very forcefully the limitations of patent law and as Laurie reiterates the need for it to be seen as a part of the wider social systems in which it exists.

Laurie has produced a beautifully eloquent analysis of informed consent in patent law, or more specifically the consent to patent an individual's biological material. A central theme of the chapters on patent law is the extent of the reach of patent law into the regulation of biotechnology as a whole. Laurie draws out the important point that to view the patent system as being in isolation 'driven only by its own internal dynamics and unencumbered by broader social agenda' is an attitude that is changing and the nature of the relationship of the patent system with other social systems is being explored. In his analysis he clearly illustrates the limitations of the patent system in terms of its role in the regulation of science and scientific conduct. The contribution of the patent system argues Laurie is 'not in the realm of direct regulation, but in incentivization or perhaps more accurately, disincentivization' (Laurie; 226).

The final chapter of the book is left to Van Overwalle who sets out the primary objections of the public to the patenting of biological material. These objections raise the dominant issue of the role of patenting as a control or influence in the shaping of the moral and ethical dimensions arising from the application of genetic technologies. Van Overwalle comments on how the debate over the ethical reach of patenting has moved from an inner circle of lawyers, experts and courts to a wider circle encompassing interest groups, consumer associations and the public (Van

Overwalle:242). Pivotal to the current politics of regulation of biotechnology is the inclusion of civil society in this debate.

In terms of readership, I would recommend Somsen's book to researchers in the field of biotechnology and additionally in keeping with Somsen's comment that 'while the technology may be novel, many of the regulatory issues posed have been seen before', the book will be an interesting and stimulating read for those interested in areas of regulation beyond biotechnology. The book is divided into sector specific parts because as argued by the authors, biotechnology is deemed too diverse to be analysed in general terms. However, a creative approach may reap greater rewards and I would thus suggest sub-division of the field on the grounds of regulatory themes or public attitudes rather than as has been done here in relation to the application of the technology to either human or agricultural genetics. Indeed the chapters on patent law are the most cohesive and hold together most successfully. These comments are essentially a minor diversion though as in terms of substance, Somsen's collection maintains a high level of critical thinking which is derived from robust research.

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