The Regulatory Challenge of Biotechnology

Hans Somsen

Edward Elgar Publishing, Cheltenham, UK; ISBN: 978 1 84542 489 3; 2007; 265pp; hardback; £75.00/$130.00

Journal of Commercial Biotechnology (2008) **14,** 361–364. doi:10.1057/jcb.2008.26

If biotechnology has spawned any universally acknowledged truth, it is that regulating the developing field – from its nanoscale personalised medicines to patented genetically modified foods – is not for the faint of heart. That has not stopped pundits and fear-mongers from decrying the dangers of biotechnology and demanding government action. And if we were to listen and give in, writing rules without forethought or asking 20th century regulations to take on 21st century complexities, we would only postpone our inevitable need to control biotechnology and its innovations in a balanced manner.

This is the overarching argument Hans Somsen and his contributing authors make in *The Regulatory Challenge of Biotechnology*. The results mirror today's discourse and range from the academic to the practical. Each author attempts to present possible approaches to biotechnology regulation, from cloning to medicines to foodstuffs. Tying the arguments together, however, is a more difficult task, and one that Somsen has chosen to put forth early on in the book, providing solid context for the more specific arguments that follow later on.

Neil Gunningham and Colin Scott are the authors of the overarching context for necessary biotechnology regulation and its complexity. Gunningham presents the three key models that have so far been proposed in society's discourse on regulating biotechnology – regulatory pluralism, meta-regulation and civil licensing – with unbiased analyses, noting that each of these, by themselves, will not have the desired impact. It is, however, his recognition of the common theme of previous regulatory frameworks, 'the power of civil society to change the behaviour of large reputation-sensitive companies' (p. 16), that ultimately underscores the logic behind why the earlier regulatory approaches only provide a starting point: most biotechnology innovations are undertaken by entrepreneurial startups and small-scale businesses whose very nature precludes the same degree of reputation sensitivity endemic in large, multinational corporations with consumer shareholders.

Scott then carries the argument further, proposing hybrid controls and drawing upon examples outside the biotechnology arena such as forestry and oil pollution. His ultimate argument lends itself to a situation wherein nongovernmental organisations (NGOs) set the stage by establishing standards which government regulations force companies to achieve. Whether this is broadly applicable outside of each narrow biotechnology specialisation is debatable, and is put to some

degree of testing by the remainder of the contributing authors.

Roger Brownsword and Justine Burley attack these holistic regulatory frameworks in light of human genetics. Brownsword walks the reader through one of the typical worst-case scenarios, the rogue genetic scientist, to see how a regulatory framework might be able to handle this scenario. Given the often small-scale teams of biotechnologists labouring in obscurity to bring forth an innovation or idea, the rogue genetic scientist is a good test case. Unfortunately, Brownsword's conclusion is not a solution or even suggestive of a solution, but rather a reiteration that a greater danger for society and biotechnology innovation lies in regulations without forethought.

In contrast, Burley takes for granted that the biotechnology landscape is a difficult one to regulate and focuses on the construction of a regulatory framework, as well as its philosophical underpinnings. Burley's use of concrete case studies to explore the more philosophical implications of various biotechnology control strategies is fascinating reading. Sadly, the realistic examination of these case studies and their implications seemingly vanishes when Burley states his conclusions. His set of regulatory recommendations are based upon a fundamentally flawed assumption: that human beings, once they see a rational explanation for why their personally favoured approach does not work, will eagerly drop their personal agenda in favour of the better approach.

Having dealt with the very difficult topic of genetics, Somsen then devotes a third of the book to discussion of the regulation of agricultural biotechnology and genetically modified organisms (GMOs). For the European reader, this section is an excellent summary of the issues and concerns facing European society today. For the North American and Asian reader, these chapters provide insight into why Europeans have raised such red flags when it comes to GMOs.

The first chapter in this section, authored by Paul Street, is an academic review of European legislative action combined with risk methodology philosophies. Its end is simply an appeal to delay regulation and controls until we know more information: '…the only acceptable option is to engage in increased public dialogue further enfranchising environmental decision-making while reinventing politics and law to further these ends as we go' (p. 114). For those who call for government action today rather than in some far off future, Street's conclusion will not sit well.

Far more satisfactory is the superb work written by Wofgang van den Daele. Van den Daele advocates a practical framework reliant upon risk management, rather than the idealistic yet ephemeral risk elimination strategy seemingly favoured by Street. Working through the legal reasoning (for instance, 'precluding anticipated adverse effects' rather than 'precaution against risks' (p. 122)) underpinning a number of cases in German courts, a strong argument is made for a practical framework of regulation that can apply broadly to every subfield of biotechnology. His conclusion that today's political landscape is focused on 'risk prevention' rather than risk management is disheartening. A list of risk-free innovations throughout human history makes for short reading indeed.

The next few chapters in this section on GMOs and their regulation are less fascinating. Bernd van der Meulen's is a review of various GMO regulatory attempts in Europe. His concluding insight, 'It is evident that more thought needs to be put into designing a regime that fairly distributes the burdens associated with it' (p. 153), is only a reminding echo of earlier conclusions and earlier authors. Sara Poli's chapter is a summary collection and an analysis of why the original GMO restrictions were too restrictive and in her assessment, no longer realistic going forward. For the reader who has followed the implementation of GMO rules early on in the

EU, and then their country-by-country repeal, there is not much new ground in Ms. Poli's chapter.

More interesting is Mary Footer's take on the 'law of the commons'. Her argument that trade agreements, public health expectations and intellectual property protection are the new boundaries of today's public commons is a fascinating one. While ultimately, she does not offer specific prescriptions to be included in any regulatory framework, the envisioning of a new law of the commons is something that regulators should take very seriously. Unfortunately, because the boundaries draw so heavily on those aspects of public domain outside the typical regulators influence – multilateral trade, for one – her argument is likely to remain a theoretical one that can only find small measures of impact in the final regulatory framework. Readers familiar with the lesser human natures of private fiefdoms and narrow viewpoints will only be discouraged when comparing today's self-cantered *realpolitik* and the new commons possibilities drawn by Footer.

The last section of Somsen's book turns to intellectual property and patent regulation to control biotechnology. Graham Dutfield leads off this section with a well-crafted argument not to use the patent system as a means of control, 'If patenting is about promoting inventive activity for the benefit of the public' (p. 205); we should shy away from patents that control inventions. To Dutfield, patents that control innovation are ultimately not in the interest of the public, but the interest of the patent holder.

Graeme Laurie's chapter on patient disclosure and patents presents a discussion of biotechnology innovation in light of the need to rely upon patients to further test and refine any innovation into something commercially patentable. Unfortunately, the big issue – patient consent – is tackled in a roundabout, almost trivial manner by selecting a focus on process as the solution ('the issue is largely one of procedural regularity'). A better argument would have explored the larger implications of reliance on the public's cooperation to achieve private patents to the benefit of the patent holder while potentially putting the cooperating public at significant risk.

The last chapter tackles this argument better by focusing on the concerns of society itself, not just those of the patent seeker or the regulator. Geertrui Van Overwalle, the author of the chapter, advances a regulatory framework based not only on the need to control tangible risks, but also the need for ethical monitoring. Can biotechnology that relies upon the genetic makeup of human beings be appropriated and controlled by a select few humans? Van Overwalle's argument that laws – including patent laws – cannot operate and accept innovation in a vacuum mirrors those of some of the greatest philosophers of the Enlightenment, that laws are an outgrowth of the opinions of the society. Van Overwalle suggests specific tools to be placed into the regulator's toolkit, leaving the reader to ponder even more such practical solutions: what other tools should be used that might be specific to GMOs? Are there other such tools?

At the end, this is the strength and the weakness of *The Regulatory Challenge of Biotechnology*. Parts of the book are merely academic regurgitations of previous regulatory efforts with little real analysis other than a desire for more information. Much of the book, however, uses case studies and applications outside of biotechnology to pose critical questions and provide at least some of the answers.

Taken alone, each author's argument falls short, but within the context of the whole, Somsen and his team have crafted a series of suggestions and analyses that will help unlock biotechnology innovations in a manner consistent with societal expectations and long-term, realistic controls. For bioethicists, legal scholars and regulators struggling with what controls to place on biotechnology, this is required reading. For

the biotechnologist looking for insight into what he or she may face in the future, many of the chapters in Somsen's work can provide the answers. For the rest of us, *The Regulatory Challenge of Biotechnology* provides unequivocal proof that in even with our 21st Century biotechnology, we labour under the ancient Chinese curse: May you live in interesting times.

John Avellanet
Cerulean Associates LLC, Williamsburg, VA, USA
E-mail: feedback@ceruleanllc.com