Foreword

This book is the first in a series focussing on the regulation of biotechnology. The event of modern biotechnology has given rise to a plethora of regulatory challenges. Whereas modern biotechnology is a relatively new phenomenon, many of these are familiar to regulatory theorists and regulators. Precautionary risk regulation, for instance, was pioneered in European environmental regulation, years before it came to form the backbone of the regulation of GMOs within the EU. Issues of privacy and autonomy that arise in the sphere of human genetics are nothing new to the medical lawyer either.

In all these instances, those faced with responsibilities to regulate biotechnology would do well to investigate if lessons can be learned from previous experience. To be sure, even the search for useful existing models for the regulation of a new technology is a challenging and time-consuming intellectual exercise, as it requires awareness of legal domains that may have little prima facie significance for the problem at hand. For example, researchers struggling with the implications of the emergence of bio-banks for the continued viability of requiring prior bilateral informed consent could possibly find some answers to their questions if they appreciated that prior informed consent, a regulatory communicative instrument, was first developed in medical law as a bilateral tool, but later evolved into a multilateral instrument in environmental law.

But the intellectual investment needed to identify and then usefully apply existing regulatory instruments to the new regulatory context of modern biotechnology is worth the effort if it means that the open-ended process of designing an effective regulatory framework from scratch can be avoided. This volume contains various chapters that represent attempts to engage in this process of learning from past experience. In doing so, however, we should continuously query what previous practice is sufficiently relevant for biotechnology to warrant such an exercise of transposition to new technologies, and who we should entrust with that judgement. This, in good part is a normative question and therefore invites public dialogue. In this respect, scientists tend to be much more inclined to adopt a ‘business as usual’ approach than wider society. Geneticists often respond with bewilderment to public anxieties about technologies that, in their perception, as a matter of principle are no different from traditional and
routinely used practices. Why should we approach the issue of genetic testing fundamentally differently from, say, HIV testing? Should food safety law targeting genetically modified foods be based on an entirely different paradigm, for example, as encapsulated by precaution, rather than that underpinning traditional food law? Are there compelling reasons to maintain that the classical requirements for the patentability of inventions should be re-assessed in the context of the patenting of biotechnological inventions, or that ethical considerations should be reviewed by patent offices? How come that the contested concept of human dignity appears to act as a hurdle for potentially life-saving techniques, whilst at the same time abortion and euthanasia have become widely used medical interventions? These are important and difficult questions, which often mask thorny political and ethical issues.

The fact that different societies answer identical questions in different ways, for example, the US and EU as regards the regulation of genetically modified organisms, also proves that socio-political context matters a great deal in this regard. It is clear that such divides between jurisdictions, but also different paradigms within a single jurisdiction, complicate the regulation of biotechnology. It is precisely because so little consensus exists about regulatory goals, that Gunningham (Chapter 1) argues that regulatory pluralism, which has proved useful in the context environmental regulation, cannot play a similarly useful role for the regulation of biotechnology. Gunningham thus identifies a first important characteristic of biotechnology as a regulatory field: a relative lack of agreed standards or goals that should be pursued. Paradoxically perhaps, this is true. This conclusion can guide regulators in the design of their regulatory approach. More specifically, regulators should in those instances assign a different task to law: law, Gunningham asserts, could become ‘procedure oriented rather than directly focused on a prescribed goal, and . . . design self-regulating systems by establishing norms of organization and procedure’.

As pointed out by Gunningham, forms of meta-regulation or reflexive regulation are at first sight attractive for the regulation of biotechnology, as they seem to be able to respond to both the complexity of the problem, as well as to the knowledge asymmetry between government and the biotechnology industry. Indeed, manifestations of meta-regulation can be seen to operate relatively well in those areas of biotechnology policy where public trust is more robust. It is common knowledge that public anxieties, for now at least, focus on agricultural biotechnology more than on human genetics. It is perhaps for this reason that the UK Human Fertilisation and Embryology Authority (HFEA) is effectively carrying out tasks that are embedded in what, in essence, is a system of meta-regulation. However, Gunningham stresses, there remain very serious hurdles to be negotiated.
before meta-regulation and civil regulation can be of similar value as in environmental policy, in particular because of the lack of public trust that such alternative forms of regulation are likely to be met. Also, biotechnology regulation to an important degree revolves around the regulation of risk and ethical issues, in which the state must play a key role either directly, or indirectly in the meta-regulatory model. Such considerations limit the scope for some of the other models discussed by Gunningham, in particular, civil regulation.

Whereas Gunningham feels that for these reasons the role of the state in biotechnology regulation is likely to remain central, Scott (Chapter 2), on the contrary, infers from the fact that biotechnology policy places so much confidence in the state to exert control over social and economic actors that biotechnology policy has not yet matured into a field of regulation at all. Thus, Scott argues, ‘extensive standard-setting by state agencies, risks crowding out the capacities of businesses and civil society organization to participate in or determine the standard-setting processes, and risks missing opportunities to promote “ownership” of regulatory norms’.

Apart from the state, markets, social control and technology itself are modalities of control that, with or without state intervention, do regulate biotechnology. Scott therefore explores effective examples of hybrid forms of control that, in a way, have not altogether different from what regulatory pluralists advocate.

Evidently, outcomes of this exercise will differ depending on the problem and associated social field involved. Just as ‘the environment’ is much too diverse a policy field to justify meaningful generalizations pertaining to its regulation, the same applies to ‘biotechnology’. Like Scott, Brownsword (Chapter 3) seeks to correct over-simplistic notions of regulation. For this purpose, regulation is conceived as having four key dimensions: phasing, pitch, mode and range. Where regulation is first phase its purpose is to control ex ante any given genetic practice. Second phase ex post regulation comes into play when such ambitions have been abandoned and, for example, the issue of compensation arises. The need for third phase regulation arises if second phase regulation is not feasible, etc. Regulatory pitch concerns the way in which regulation seeks to engage with its targets, and which can be moral, practical and behavioural. The different options that can be considered to channel behaviour, which were earlier considered by Scott and which includes a ‘technical fix’, are what Brownsword terms regulatory modes. Regulation can range from a blanket prohibition to uninhibited permission, or tilt towards either of the two extremes.

In combining these four dimensions, an almost endless spectrum of regulatory options emerges. Two additional corrections are introduced that compensate for crude conceptions of the regulation of human genetics: the
focus on ‘rogue providers’ of genetic services, and the preoccupation with human genetics as a regulatory target. As for the focus on rogue geneticists, Brownsword shows that possibly more serious but certainly more realistic threats stem from perfectly respectable actors, including purchasers of such services, the pharmaceutical industry and insurance companies. Whereas Scott considers techno-regulation a promising regulatory mode in the context of GMO regulation, in the context of human genetics, Brownsword explores ‘the nightmare that is techno-regulation’.

In their discussion of appropriate regulatory frameworks to channel developments in human genetics Brownsword and Burley (Chapter 4) both employ a mind experiment as a tool. This approach is widely used when policies must be developed now that will still be appropriate to cope with uncertain future scenarios. This is particularly useful in the context of new technologies, including human genetics (see Punic et al. 2006).*

Burley’s is a hypothetical world in which present genetic technologies have advanced significantly, although still within the bounds of what is reasonably possible. In this world, Burley posits that government should be informed by contemporary liberal thought, characterized by its dual emphasis on freedom and equality. The position taken is a prescriptive and normative one, but at the same time one of direct practical application: regulation that falls foul of these two basic values is ‘wrong’. This perspective allows Burley to arrive at the conclusion that state-run insurance schemes that mitigate brute luck with respect to individuals’ genetic constitutions are to be preferred over private schemes. Using similar reasoning, she argues that it would be illegitimate for regulators to deny citizens access to therapeutic cloning.

The book then turns to the regulation of genetically modified organisms (GMOs) and agricultural biotechnology. Much of the complexity and controversy surrounding the regulation of GMOs concerns the regulation of risk. In the tradition of Beck, central to Chapter 5 by Street is the argument that risk is a social phenomenon. Different constructions and perceptions of risk associated with any given technology thereby exist that may be equally valid. This, in turn, calls into question the legitimacy of current institutional practice, and has triggered institutional strife. Street catalogues the importance of institutional competition in the context of the discussions about the relationship between the Sanitary and Phytosanitary (SPS) Measures Agreement and the Cartagena Protocol on Biosafety. This analysis culminates in a call for more inclusive forms of decision-making about the marketing of GMOs and the risks they pose.

Within the EU, a logical starting point for the operationalization of such ambitions is the precautionary principle. Much, perhaps too much, has been written about this principle that informs the regulation of scientific
uncertainty within the EU. However, Van den Daele (Chapter 6) offers a truly challenging and insightful analysis of principle. His starting point is that what really is at issue is not so much the regulation of risk, but the democratic control over the forces of social change associated with biotechnology. Escalating risk perceptions and the precautionary principle have come to serve as a strategy for states to gain political control over technology within a liberal regime of innovation. Closer analysis of the precautionary principle suggests that the expectations of critics who believe that it will foster increased democratic control and imply a ban on GMO products may be misplaced.

Central to Van den Daele’s chapter, however, is the thesis that its application in the sphere of GMOs shows that the precautionary principle is no longer a legal principle. Instead, evidenced by a number of notorious cases, the precautionary principle has become politicized in a way to suppress innovation that is deemed undesirable for reasons that have nothing to do with risk. Political planning is thereby taking place under the guise of risk precaution. The Commission and the European Court of Justice (ECJ) appear to have understood that this position is untenable, however, and have responded in a way to restore the distinction between politics, the exclusive preserve of parliaments, and risk regulation carried out by regulatory agencies. In any event, Van den Daele argues, the moratorium has been insignificant as a measure of precaution, and any impression that it symbolizes the sovereignty of politics over science is false. Neither should we assume that the moratorium has been in the public interest. At the very least, it represents considerable wasted political capital that could have been usefully applied to address more pressing and proven agricultural problems.

The current EU regulatory regime for GMOs for human consumption discussed by Van den Daele is assessed in more detail by Van der Meulen (Chapter 7). Judged by criteria such as legal certainty for applicants and the public, transparency of the authorization process, and the proportionality of, in particular, provisions on traceability, labelling, coexistence and segregation, his conclusion that this regime leaves much to be desired is a persuasive one.

Sara Poli (Chapter 8) focusses her discussion on national coexistence policies and the numerous issues of EC law to which they give rise. Measures intended to create GMO-free zones such as those adopted by a number of regions in Austria, and which are the product of strong and almost universal local opposition to GMOs, must pass the test of Article 95(5) EC. In the light of earlier cases involving the adoption of more stringent national rules after EC harmonization, the sorry fate of the Austrian rules was perhaps predictable. The Austrian case appears to indicate that
the Commission is no more sympathetic towards protective national rules concerning GMOs than other national initiatives that depart from the internal market paradigm.

Nonetheless, in the context of coexistence the Community only claims competences over aspects that concern issues related to the environment and health. This has given rise to (failed) national initiatives based on Article 23 of Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms (Deliberate Release Directive OJ L106/1 2001), which allows Member States to take appropriate measures to avoid the unintended presence of GMOs in other products. Economic aspects explicitly fall within Member States’ reserved powers, but in practice this may prove neither a clear nor sufficient basis for Member States to adopt appropriate coexistence measures. All in all, there is every reason to expect future political conflict over national coexistence policies.

Mary Footer (Chapter 9) addresses a phenomenon associated with biotechnology that is of global concern: the commodification or ‘enclosure’ of the common heritage of mankind that is represented by, on one hand, crop germplasm and, on the other hand, by what may be termed socio-agricultural pluralism. Her historical and legal analysis lays bare two distinct processes of enclosure that operate in respect of these different commons. Driving forces are, respectively, claims of permanent sovereignty and ownership over natural resources and mechanization of agriculture, and multilateral trade instruments including Trade-related Aspects of Intellectual Property Rights (TRIPS). Both types of commons are in danger of disappearing permanently if these processes are to follow their natural course. This leads us to the role of patent law in agricultural biotechnology. Brownsword and Scott, in different contexts have each offered different perspectives on techno-regulation. Dutfield (Chapter 10) explores a specific and (economically) significant example of techno-regulation, so-called ‘terminator technology’, a technological fix that protects and enforces intellectual property rights (IPR) over patented crops. Three questions arise in connection with this technology: how will it affect the future of agriculture, should we encourage it and, if not, are there sufficient grounds to conclude that no patents should be granted to protect it?

As for its potential impact, Dutfield concludes that ‘terminator technology has the genuine potential to seriously disrupt poor world agricultural systems that support the livelihoods of hundreds of millions of people’. As for the question whether this kind of technology should be patentable, however, attention is drawn to the paradox that a negative answer might actually encourage research in this area, since it is especially in jurisdictions where IPR protection is weak that the technology would be useful. In any
event, there are other, perhaps more appropriate ways to regulate terminator technology, most notably through laws forbidding it. Once again, this chapter concludes with a warning about the socio-economic implications of terminator technology, especially for developing country farmers. Similarly, patents have radically altered the landscape of medical research involving genetics. A common fear is that patents granted, for example, to Myriad for its BRCA1 and BRCA2 genes have stifled much-needed medical research into breast and ovarian cancer. In Chapter 11, Laurie concentrates on the question whether research subjects must consent to the patenting of research in which they have participated as a precondition for the granting of such a patent.

The question first gives rise to a critical evaluation of the importance of informed consent in general, and in a research context in particular. In this respect it is noted that the fundamental issue at stake is not the obtaining of consent, but the furnishing of respect. In as far as there are alternative ways of showing respect, consent may not always be required. It is also important to realize that rules on consent have been developed in the context of medical care and treatment, and that in a research context different standards of disclosure should apply. These observations imply that a requirement of prior informed consent for patents emanating from medical research involving humans is not self-evident. The ECJ (European Court of Justice), in Case 377/98, Netherlands v. Parliament and Council [2001] ECR I-7079 has ruled so as to shield the patent system enshrined in Directive 98/44/EC on the Legal Protection of Biotechnological Inventions (Biotechnology Directive) against the introduction of an additional condition in the shape of prior informed consent. The purpose served by such an additional condition is already sufficiently protected by regulation.

However, the Court’s ruling does not settle the issue. In part this is because a narrowly drafted consent requirement in patent law, that is, one that strictly concerns the filing of a patent, would avoid usurpation of the regulatory system the ECJ was so eager to avoid. Also, as the infamous Moore case illustrates, although civil remedies may compensate aggrieved research subjects, this leaves the validity of the patent unaffected. Laurie argues that, since patents are about incentives, there is a case for introducing a threat that patents may be invalidated on the grounds that they were obtained without prior informed consent. Moreover, based on the premise that there should be congruence between the patent system and regulation, there is much to be said for incorporating the vehicle of consent in patent law as an expression of respect for human dignity and integrity that governs both systems.

All these considerations ultimately lead Laurie to argue for a limited role of prior informed consent in patent law. The fact that, in practice, those
who wish to participate in research often will have no choice but to accept commercialization of the outcomes of the research, does not affect the importance of that conclusion.

Concluding the book is Chapter 12 by Van Overwalle, who offers a panoramic view of objections against the patenting of biological material. Such objections focus on the subject matter, which is not the result of a creative process and could be ethically objectionable, and non-compliance with the substantive patentability requirements of novelty, inventive step and industrial applicability. Reservations against the patentability of biological material also relate to the impossibility to comply with the requirement of disclosure: often it proves impossible to describe the process of making the end product, or to repeat the original process of making. Concerns about patents for biotechnological inventions also concern their impacts, in particular on the freedom of research but also on agricultural practice and the dissemination of technology more generally.

Having surveyed public anxiety about biotechnology patents, Van Overwalle does not take the position so often adopted by specialists in patent law that these concerns can be best addressed through the regulatory process. Instead, she explores tools that patent law offers that may alleviate these concerns. These include use of the possibility offered by Article 27.3 of TRIPS that allows for the exclusion of plants and animals from patentability, the exclusion of genetic methods of testing, the granting of patents on end products only, reconsideration of morality clauses such as Article 6 of the Biotechnology Directive, and the more radical idea of developing a compensatory liability regime.

Alternatively or simultaneously, patent offices could apply more stringent patent standards. Patent offices could also reduce the scope of patent claims that are excessively broad. The idea of introducing additional patent requirements such as informed consent was discussed by Laurie. The Biotechnology Directive offers a legal basis for this approach, which could also justify introduction of an origin requirement.

Detrimental effects of biotechnological patents on research and health care may be prevented or mitigated through research exemptions, which in Europe are part of patent law, but are applied differently from country to country. Similarly, the denial of patents for methods for diagnostic treatment alleviates negative effects of health care patenting. Compulsory licensing to address health concerns is an option that is gaining interest and finds its legal basis in Article 31 of TRIPS.

All these options are located within the system of patent law itself. However, from the perspective of public participation and transparency, it is attractive to consider possible mechanisms outside the patent system. Indeed, voluntary codes of conduct or other private standards are
increasingly widely used, and offer prospects of both reinforcing and supplementing the current patent regime.

Such public participation in genetic governance is increasingly regarded as a discrete value in democratic society. It is also acknowledged that the quality and effectiveness of regulation is served by deliberative models of governance. Without exception, these chapters acknowledge and, in different modalities, advocate public participation in the resolution of the countless political, social and ethical issues to which modern biotechnology gives rise. This volume may be seen as a contribution to that endeavour.

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Series Editor

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