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Part I
General introduction

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1

Introduction

1 Introduction

This book is an introduction to law (and, more broadly, regulation) and the technologies of the twenty-first century. At present, the particular technologies that attract our interest are information and communication technologies, biotechnologies (whether applied to humans or to plants and animals), nanotechnologies and neurotechnologies. However, science and technology is a rapidly shifting scene and it is perfectly possible that, as the decades pass, our interest will be engaged by other technologies that emerge. Similarly, although these technologies are presently on the radar in a number of legal areas – for example, biotechnologies are of interest to property lawyers, to environmental lawyers, to medical lawyers, to torts lawyers, to patent lawyers, to international trade lawyers, to human rights lawyers, to data protection lawyers, and so on¹ – the pattern is constantly changing.²

Any introduction must start somewhere, but where should we start our introduction to law, regulation and technology? To the extent that this is a novel field for legal inquiry, there is no settled point of entry. Helpfully, Bert-Jaap Koops has highlighted ten dimensions of what he calls ‘technology regulation research’, these dimensions mapping on to the three focal regions of technology, regulation and research.³ In the region of technology, we need to think about the different *types* of technology (for example, whether or not they build on the life sciences); the extent to which a technology is *innovative*; the *place* in which we find the technology (including whether it is in cyberspace); and how mature a particular technology is relative to the temporal development cycle (the dimension of *time*). In the region of regulation, we need to be sensitive to the variety of *regulatory types* as well as the *normative outlook* of the community

¹ Compare Roger Brownsword, W. R. Cornish and Margaret Llewelyn (eds.), *Law and Human Genetics: Regulating a Revolution* (Oxford: Hart, 1998).

² There are also various bespoke legal regimes, such as the UK Computer Misuse Act 1990, Directive 96/9/EC (on the legal protection of databases) and the Human Fertilisation and Embryology Act 2008, that make provision for a particular technology.

³ Bert-Jaap Koops, ‘Ten Dimensions of Technology Regulation’, in Morag Goodwin, Bert-Jaap Koops and Ronald Leenes (eds.), *Dimensions of Technology Regulation* (Nijmegen: Wolf Legal Publishers, 2010), 309.

in which regulatory action is to be taken and the *knowledge* that we have with regard to the characteristics of the technology. Finally, in the region of research, the critical dimensions relate to the particular *discipline* in which we are conducting our research, the nature of our research questions (that is, the *problem* as we specify it), and the way in which our research might be shaped by a certain *frame* of inquiry. In one way or another, these dimensions will feature in our discussion. However, before we contemplate the different kinds of technologies, or the array of strategies that are available to regulators, or the like, we can start with an innocent question: why is it that the development and application of modern technologies is a matter of interest and concern for the law?

One rather obvious reason is that some of these technologies might be thought to be dangerous in the sense that they present risks to humans and to their natural environment. For example, how confident can we be that genetically modified (GM) crops will present no risk to humans who consume GM foods; and can we be sure that these crops will not degrade their environments? Or, again, can we be confident that nanoparticles, such as those used in some sunscreens and cosmetic products, will not be harmful to humans? It follows that, where we entertain concerns of this kind, it falls to the law to regulate for the relevant risks, by putting in place such prohibitions, or licensing arrangements, or compensatory provisions as are judged to be appropriate.

Concerns about health, safety and the environment, however, are not the only reasons why emerging technologies might prompt calls for regulatory intervention. For example, there are persistent concerns about privacy, confidentiality and data protection. Some such concerns are acute – witness, for example, the flood of cautionary and critical comments provoked by social networking sites and by Google's Street View mapping service; other such concerns are chronic, the thesis being that, in the information (and surveillance) society, equipped with CCTV, RFID, GSP devices, and so on, there is a silent but steady erosion of our privacy; and, with the development of powerful brain-imaging technologies, some see an even more worrying future – for, if we can no longer keep our innermost thoughts to ourselves, what is left of our privacy? However, thus far, it is modern biotechnologies that have most conspicuously raised deeper cultural and ethical concerns, especially concerns that draw on the elusive idea of human dignity; and in the almost universal rejection of human reproductive cloning we have the outstanding expression of this sense that there are limits to acceptable technological innovation. Articulating this particular concern, Article 11 of the UNESCO Universal Declaration on the Human Genome and Human Rights (1997) provides:

Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.

It follows, as Henk ten Have has rightly remarked, that regulators need to engage with the view ‘that unbridled scientific progress is not always ethically acceptable’;⁴ and, in the next section of this chapter, we will sketch some of the debates about the ethics of patentability that modern biotechnologies have generated in this sector of intellectual property law.

There is also another, quite different, reason why the development of these technologies is relevant to the law. It is not simply that we need legal frameworks to regulate these technologies, it is that these technologies themselves might play a part in the regulatory framework. In other words, these technologies might themselves operate as regulatory tools. Sometimes their role might be supportive of traditional legal forms of regulation, in the way, for example, that DNA profiling, the use of CCTV surveillance and possibly brain imaging,⁵ might be supportive of the criminal law; but, with greater technological sophistication, it is conceivable that these technologies might function as front-line regulatory instruments.

In line with these remarks, we will consider the technologies of the twenty-first century both as regulatory targets and as regulatory tools. In Chapter 3, we will outline four key challenges that must be met if a regulatory framework is to be adequate: namely, the challenges of regulatory prudence, regulatory legitimacy, regulatory effectiveness and regulatory connection. Each of these challenges then serves as an organising focus for the subsequent parts of the book. Hence, in Part II (Chapters 5–6) we focus on regulatory prudence and precaution; in Part III (Chapters 7–10) our focus is on regulatory legitimacy; in Part IV (Chapters 11–14), we focus on regulatory effectiveness; and in Part V (Chapters 15–16) our focus is on regulatory connection. We will also consider the questions raised by the use of these technologies as regulatory tools, most urgently questions concerning legitimacy and effectiveness; and our discussion of DNA profiling in the criminal justice system, together with *S. and Marper v. United Kingdom*⁶ and its after-effects (in Chapters 4 and 17), is particularly designed to bring these latter issues into focus.

Finally, we will endeavour to do all of this in a way that we take to be consonant with the spirit of ‘contextual’ inquiry. First, we will try to place specifically *legal* (so to speak, ‘hard law’) interventions in the broader context of what we call ‘the regulatory environment’. This is a concept that we elaborate in Chapter 2; but, stated shortly, the regulatory environment is constituted

⁴ Henk ten Have, ‘UNESCO and Ethics of Science and Technology’, in UNESCO, *Ethics of Science and Technology: Explorations of the Frontiers of Science and Ethics* (Paris, 2006), 5–16, at 6.

⁵ See, e.g., Michael Freeman (ed.), *Law and Neuroscience* (Oxford: Oxford University Press, 2011); and, for some very watchable presentations given at the Second Raymond and Beverley Sackler USA–UK Scientific Forum (on neuroscience and the law) (held 2–3 March 2011, at Irvine, California), see: http://sites.nationalacademies.org/PGA/stl/PGA_062477 (last accessed 12 June 2011).

⁶ (2009) 48 EHRR 50. For the domestic UK proceedings, see [2002] EWCA Civ. 1275 (Court of Appeal), and [2004] UKHL 39 (House of Lords).

by those signals that are intended to bear on the way in which people actually behave. Sometimes the signals might be recognisably legal (as when they express and communicate a statutory requirement or the decision of a court); but, often, the legal signals are in the background and we act in the way that we do because we are responding to much stronger foreground signals emanating from our peers. To relate this to one of the standard contextual puzzles, if we want to understand why it is that there is sometimes a ‘gap’ between the law-in-the-books and the law-in-action, then we need to view the law-in-the-books as just one signal in a more complex signalling environment. Second, our approach is ‘cosmopolitan’ in the sense that it takes into account the various spheres of regulation (i.e., national, regional and international).⁷ In other words, it is not simply a matter of viewing law within a larger regulatory environment, we must also take into account the way in which multilevel regulatory regimes operate. Third, our discussion is ‘nested’ in the sense that our discussion of the regulation of (and by) particular technologies is set in the context of the generic challenges and opportunities presented by regulating technologies which, in turn, is set in the context of our larger understanding of law and regulation. Or, to turn this round, our introduction moves from a general idea of a regulatory environment to the regulation of emerging technologies to particular regulatory issues arising in connection with particular technologies.

2 Of mice and men

Twenty years ago, there were demonstrations outside the European Patent Office (EPO) in Munich. Students from the nearby Max Planck Institute, some of them dressed as white mice, carried banners protesting that there should be ‘no patents on life’. Inside the EPO, the examiners were uncertain about how to treat an application to patent the so-called Harvard Onco-mouse, a mouse that was genetically engineered to serve as a test animal for cancer research.⁸ Should the mouse be treated as patentable? There was no doubt that the process associated with the genetic engineering – the method by which the oncogene was inserted into the embryonic mouse – was innovative; there was no doubt that the product, the mouse itself, was innovative; and there was no doubt that the researchers and developers expected the mouse to have a practical utility as well as reaping a commercial dividend. In some patent law regimes – notably,

⁷ Compare the jurisprudential manifesto in William Twining, *General Jurisprudence* (Cambridge: Cambridge University Press, 2009).

⁸ Decision Onco-mouse/Harvard, 14 July 1989 (OJ EPO 11/1989, 451; [1990] 1 EPOR 4). Initially, the examiners did not see the application as raising an issue under Article 53(a). Rather, they rejected the application on the grounds: (a) that there had not been sufficient disclosure of the working of the invention (as required by Article 83 of the European Patent Convention); and (b) that Article 53(b) excluded the patenting of ‘animal varieties’. It was only when the case was referred to the Board of Appeal that the centrality of Article 53(a) was recognised: see EPO Decision T 19/90 (OJ EPO 12/1990, 476; [1990] 7 EPOR 501).

in the United States where, in *Diamond v. Chakrabarty*,⁹ the majority of the US Supreme Court laid the basis for a liberal approach to patenting – such innovation and utility would be sufficient; and, in fact, applying this liberal spirit, the US Patent Office had already cleared the mouse as patentable subject matter. However, in Europe, such features, although necessary, are not sufficient; for, in Article 53(a) of the European Patent Convention (EPC), there was (and, broadly speaking, there still is) a provision to the effect that processes and products, no matter how innovative, should not be considered to be patentable if their commercial exploitation would be contrary to *ordre public* or morality. Until the Harvard Onco-mouse application, patent examiners and intellectual property lawyers had paid little attention to Article 53(a). However, the application was a wake-up call that, with innovative work under way in plant, animal and human genetics, the patent regime would need to come to terms not only with the underlying science of modern biotechnologies but also with their ethical and cultural dimensions.

At the same time that the protests were taking place in Munich, the European Commission in Brussels was trying to develop a new legal regime for the patenting of biotechnological inventions.¹⁰ Ostensibly, the regime was a trade measure, designed to harmonise patenting rules across the European single market. However, as soon as the proposed directive reached the European Parliament, it was clear that the issues could not be confined in this way. In Europe, parliamentarians were alive to the possibility that the work under way in sequencing the human genome might lead to patent applications. Like the students from the Max Planck, an alliance of politicians protested that the Commission's quest for a common position went far beyond matters of trade. As Gerard Porter captures the mood of the time:

[T]he slogan '*no patents on life*' began to gain a degree of political currency within the Parliament during the 1990s. This umbrella term crystallized a wide range of concerns about the proliferation of intellectual property rights in the life sciences. The concerns voiced included the fear that biotech patents would stifle scientific research by inhibiting access to key technology; unease about the degree of social power granted to private organizations through monopoly rights over key life science technologies; objections to the instrumentalization and commodification of living things (particularly the human body and the human genome) on the grounds that living matter is part of the 'Heritage of Humanity and Nature in general' and should not be 'classified as private property'; animal rights and welfare; environmental safety; the interests of

⁹ US SCR 65 L Ed 2d (1980) 144.

¹⁰ For the background, see Deryck Beyleveld, Roger Brownsword and Margaret Llewelyn, 'The Morality Clauses of the Directive on the Legal Protection of Biotechnological Inventions: Conflict, Compromise, and the Patent Community', in Richard Goldberg and Julian Lonbay (eds.), *Pharmaceutical Medicine, Biotechnology and European Law* (Cambridge: Cambridge University Press, 2000), 157.

European farmers; and, finally, anxieties over the impact of ‘bio-piracy’ and ‘bio-colonialism’ on the developing world.¹¹

At core, though, politicians objected that the question of whether a particular sequence of the human genome might be treated as patentable subject matter was not so much economic as fundamentally ethical and cultural. If there should be no patents on mice, neither should there be patents on men.

Patent law thus found itself in the eye of a political storm.¹² One view (favoured by many political and industrial interests) was that Europe has too large a commercial stake in the biotechnology sector to be putting obstacles in the way of patentability. In other words, it was argued that the patent regime needed to be geared to encouraging research and development in modern biotechnologies and, crucially, investment in the European-based biotechnology sector. For their own reasons, patent practitioners, too, aligned themselves with the view that patent law should stick to the usual technical questions of originality, innovation, and the like, leaving moral debates to others. However, ranged against these views, a variety of constituencies – animal welfarists, environmentalists, dignitarians, and others – joined forces to insist that the law should not facilitate the biotechnological revolution without taking a hard look at the ethical and cultural implications of genetic engineering.¹³

Back at the EPO, at a symposium held to survey the issues raised by the Harvard Onco-mouse application, the influential British philosopher, Mary Warnock, offered a measured view of how Europeans might reason their way through their difficulties. She said:

Technology has made all kinds of things possible that were impossible, or unimaginable in an earlier age. Ought all these things to be carried into practice? This is the most general ethical question to be asked about genetic engineering, whether of plants, animals or humans. The question may itself take two forms: in the first place, we may ask whether the benefits promised by the practice are outweighed by its possible harms. This is an ethical question posed in strictly utilitarian form ... It entails looking into the future, calculating probabilities, and of course evaluating outcomes. ‘Benefits’ and ‘harm’ are not self-evidently identifiable values. Secondly we may ask whether, even if the benefits of the practice seem to outweigh the dangers, it nevertheless so outrages our sense of justice or of rights or of human decency that it should be prohibited whatever the advantages.¹⁴

¹¹ Gerard Porter, ‘The Drafting History of the European Biotechnology Directive’, in Aurora Plomer and Paul Torremans (eds.), *Embryonic Stem Cell Patents* (Oxford: Oxford University Press, 2009) 3, at 13.

¹² See Deryck Beyleveld and Roger Brownsword, *Mice, Morality and Patents* (London: Common Law Institute of Intellectual Property, 1993); and Edward Armitage and Ivor Davis, *Patents and Morality in Perspective* (London: Common Law Institute of Intellectual Property, 1994).

¹³ For the politics associated with the rival framings of European patent law (i.e., ‘economy’ versus ‘ethics’), see Ingrid Schneider, ‘Can Patent Legislation Make a Difference? Bringing Parliaments and Civil Society into Patent Governance’, in Sebastian Hauns and Kenneth C. Shadlen (eds.), *Politics of Intellectual Property* (Cheltenham: Edward Elgar, 2009), 129.

¹⁴ Baroness Mary Warnock, ‘Philosophy and Ethics’, in C. Cookson, G. Nowak and D. Thierbach (eds.), *Genetic Engineering – The New Challenge* (Munich: European Patent Office, 1993), 67 at 67.

Taking our lead from Warnock, we should start with a calculation of, on the one side, the prospective benefits and, on the other side, the possible harms (very much in line with a standard utilitarian approach). If the harms outweigh the benefits, if the technology is simply too risky, then we should not proceed. If, by contrast, the calculation indicates a net benefit, then we ought to proceed provided that there is not some overriding consideration of justice, rights or human decency, or the like.

Generally speaking, when new technologies are in their infancy, there is likely to be a good deal of uncertainty about both sides of the calculation, about both the benefits and the harms. And, again generally speaking, we will find that, while those who have a commercial, medical or political interest in the technology will talk up the anticipated benefits, those who are opposed to it will highlight the risks and advocate a precautionary approach. Some of the opposition, however, might go beyond concerns about human health and safety or even about environmental integrity; for such opponents, where their deeper concerns are engaged, the fact that the benefit-harm calculation clearly shows an overall net benefit is irrelevant – the technology should not be taken forward. For such opponents, as Warnock recognises, if the technology transgresses a ‘sense of justice or of rights or of human decency’ that sets limits to the technological applications that we judge to be permissible, then we simply should not proceed. For example, there might be some advantages in allowing a couple to use reliable technologies for human reproductive cloning but, for most societies, this kind of cloning is simply off limits. Or, to take a non-technological case, the jurisprudence associated with the prohibition against cruel and unusual punishments in the Eighth Amendment to the US Constitution suggests that, even if a particular form of punishment were to be effective in deterring crime, it should not be used where this would be contrary to human dignity or decency.¹⁵

When the examiners duly addressed the interpretation and application of Article 53(a) in the *Harvard Onco-mouse* case, they proceeded in a thoroughly utilitarian way.¹⁶ On the one hand, the mouse promised to be an important test animal for cancer research, prospectively improving our understanding of tumour development and, with that, advancing the development of effective therapies. The anticipated benefits for humans could scarcely be greater. There was also some anticipated benefit to future mice to the extent that fewer mice would be needed for testing. On the harm side, the examiners accepted that there was pain and suffering for the mice, particularly the females, which were bred and manipulated as research tools. In short, then, the calculation showed prospective life-saving benefits for a great many humans and certain pain and suffering (and eventual sacrifice) for a limited number of mice. Quite how utilitarians do their sums is never entirely clear, but the examiners were satisfied that it would not be immoral to treat the claimed processes and product as patentable.

¹⁵ For a recent example, see *Roper v. Simmons* 543 US 551 (2005).

¹⁶ OJ EPO 10/1992, 588, esp. at 593.

Even if the interests of mice could not resist the surge of modern biotechnologies, the interests of men are rather more weighty – at any rate, they tend to be so when it is men themselves who are judging the matter. At the European Parliament, the opponents of the proposed directive regarded some matters as non-negotiably off-limits. For the Commission, at the first attempt, this proved an insuperable problem; they simply could not find a form of words that both permitted and prohibited patenting parts of the human genome and the proposed directive fell. However, at a second attempt, a compromise was achieved, and a revised version of the directive was agreed.¹⁷ Significantly, it was conceded to the objectors that there are some moral outer limits to patentability. First, Article 6(1) of the Directive (in language that very closely resembles that of Article 53(a) of the EPC) provides:

Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

Second, and critically for present purposes, Article 6(2) provides:

On the basis of paragraph 1 [Article 6(1)], the following, in particular, shall be considered unpatentable:

- (a) processes for cloning human beings;
- (b) processes for modifying the germ line genetic identity of human beings;
- (c) uses of human embryos for industrial or commercial purposes;
- (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Article 6(2) draws on a number of Recitals, one of which, Recital 38, makes it clear not only that the list of four processes/uses is not intended to be exhaustive but also that inventions should simply be regarded as unpatentable where they compromise human dignity. Hence, while the examiners in the *Harvard Onco-mouse* case did not proceed beyond the first stage of Warnock's advice, we see in the Directive some indications as to where Europeans draw the lines on patentability.

In the wake of the *Harvard Onco-mouse* case, the EPO was called upon to adjudicate on the application of Article 53(a), first, to GM plants (herbicide-resistant crops)¹⁸ and, then, to copies of a human gene sequence that codes for a muscle relaxant.¹⁹ In the first of these applications, the *PLANT GENETIC SYSTEMS* case (the *PGS* case), the Technical Board of Appeal ruled that there was no clear moral objection to patentability. However, unlike the examiners

¹⁷ Directive 98/44/EC on the Legal Protection of Biotechnological Inventions. For the politics of the renegotiation, see Schneider, 'Can Patent Legislation Make a Difference?', 139–42.

¹⁸ *Plant Cells/PLANT GENETIC SYSTEMS* Case T 0356/93.

¹⁹ Howard Florey/Relaxin [1995] EPOR 541.