

Law and Science

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Law and Science

Volume II

Regulation of Property, Practices, and Products

Edited by

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ASHGATE

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Series Preface

The International Library of Essays in Law and Society is designed to provide a broad overview of this important field of interdisciplinary inquiry. Titles in the series will provide access to the best existing scholarship on a wide variety of subjects integral to the understanding of how legal institutions work in and through social arrangements. They collect and synthesize research published in the leading journals of the law and society field. Taken together, these volumes show the richness and complexity of inquiry into law's social life.

Each volume is edited by a recognized expert who has selected a range of scholarship designed to illustrate the most important questions, theoretical approaches, and methods in her/his area of expertise. Each has written an introductory essay which both outlines those questions, approaches, and methods and provides a distinctive analysis of the scholarship presented in the book. Each was asked to identify approximately 20 pieces of work for inclusion in their volume. This has necessitated hard choices since law and society inquiry is vibrant and flourishing.

The International Library of Essays in Law and Society brings together scholars representing different disciplinary traditions and working in different cultural contexts. Since law and society is itself an international field of inquiry it is appropriate that the editors of the volumes in this series come from many different nations and academic contexts. The work of the editors both charts a tradition and opens up new questions. It is my hope that this work will provide a valuable resource for longtime practitioners of law and society scholarship and newcomers to the field.

AUSTIN SARAT

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Introduction

This second volume of exemplary scholarship on law and science focuses on the practices of scientists and the consequences of scientific production. If Volume I attended to science as it entered legal domains, primarily as evidence, Volume II collects accounts of law acting within the domains of science, primarily as resources and regulations.

When most people think of scientists, they conjure up images of white lab coats and incomprehensible formulae, medical miracles and electronic marvels, smelly substances and elaborate glass tubing, risks of environmental degradation and nuclear disaster. Laboratories appear as frightening as they are generative, elegant as they are messy. Most scientific laboratories are built from a limited set of templates, uniformly organizing space and equipment as standardized places with interchangeable cookie-cutter parts – architectural testaments to the universality of science and scientific knowledge (Gieryn; 1998, Silbey and Ewick, this volume, Chapter 11). Built with aspirations to disinterested, universal, collectively shared knowledge, science is also a terrain of raw competition and destructive jealousies driven by strong personalities. Although many scientific achievements have led to longer, richer, healthier and freer lives for many, scientific innovations have also produced increasingly effective surveillance and an abundance of instruments for raining pain and death on a scale heretofore unknown. Extending and enriching the lives of some, science also stokes the chasm between the haves and the have-nots. To talk about scientific miracles while attending to scientific dystopias requires looking under the surface of science, where history and sociology show it to be a contradictory human practice, born of both collective hope and individual ambition, both fuelling and feeding upon processes of capitalist accumulation.

Part I of this volume comprises a collection of essays addressing the ways in which modern science has been institutionalized in the United States with particular focus on the capitalization of science: the organizational and financial support from government, business, private philanthropy and public-interest organizations.¹ This institutional infrastructure is especially fragile because the exchanges and trade-offs among the various parties that constitute material support for science may be more cultural than economic, symbolic as well as instrumental (cf. Mukerji, 1989). For example, it is true that public funding supports most scientific research: in government laboratories, through contracts and grants to non-government scientists or through indirect support of higher education and industrial R&D. Nonetheless, ‘good science is not exchanged for funds; [and] neither do scientists merely follow the political winds to scrape together the monies they need for research’ (Mukerji, 1989). Rather, in exchange for the wherewithal to do science and develop scientific expertise, government secures a reserve labour force that can be mobilized, when needed, for advice, technical support and emergency response. Government trades material resources for the most effective form of modern legitimacy – knowledge. Because ‘the power of science lies less in what scientists

¹ A weakness of this volume that should be acknowledged upfront is the paucity of materials on science in other nations. This should be remedied in a subsequent volume.

tell the government than in the cultural authority of science as an institution' (ibid., p. xi), the discoveries and inventions produced through government funding simultaneously legitimate both science and the state: 'For the money it allocates to support research, the state gets the right and ability to use that authority to legitimate its actions and for continuation of the soft-money funding systems, scientists give up control of their cultural power' (ibid., p. xi).

The institutionalization of modern science has been achieved not only through government and philanthropic largesse, but also through legal techniques that transform the search for knowledge into a profit-making activity. Part II of this volume addresses exactly that conjunction among legal, economic and scientific phenomena in the creation of intellectual property that makes markets *of* scientific knowledge *in* scientific practice. The final three Parts address law in one of its more commonplace functions as a means of confining action through rules and rule-based decision-making. There we look at the ways in which statutes and regulations, primarily, have been used to establish criteria for legitimate, ethical and safe science. The final chapter looks at some efforts to deal with the often uncertain human, material, and environmental consequences of scientific innovations.

State Institutionalization of Science

Part I begins, then, with Larry Owens's account of a legal engagement that, despite its failure, became a template for the rapid expansion of scientific research during and after the Second World War. Owens's essay, 'MIT and the Federal "Angel": Academic R & D and the Federal-Private Cooperation before World War II', is an appropriate opening for this volume as the text itself begins with quotes from legal scholars, Henry Maine and Lawrence Friedman, extolling the role of contract as the foundation of modern social and economic relations. Owens describes how, in 1933, the TVA and MIT attempted to set up a relationship in which MIT would invent a means for transmitting electric power over long distances – something not yet physically or technologically possible – while the federal government contributed to MIT's research and development costs. Long-distance power transmission would be established through the historic technique for long-distance transmission of human agency: contract.

The parties were not unfamiliar with contract negotiations; like their Pilgrim ancestors, they too conceived of social and political arrangements in terms of the tools of the marketplace. As Owens points out, the commodification of science that was successfully consolidated during and following the Second World War was 'only a recent and vigorous example of the commercializing propensities that have marked the development of the West over the last centuries' (p. 28) The contract form lay at the heart of the process of merging private and public capital with university research from the original bequests that established the universities to the government contracts for specific technologies and projects. As Karl Llewellyn and Roscoe Pound wrote at the time, in their entry in *The Encyclopedia of the Social Sciences*, the contract embodies 'the social and legal machinery appropriate to arranging affairs in any specialized economy which relies on exchange rather than tradition (the manor) or authority (the army) for apportionment of productive energy and of product' (Llewellyn and Pound, 1931, quoted on p. 28).

Despite the contract's familiarity and suitability as a social technique, the negotiations fell apart; the bargain was not struck. At the heart of the problem, Owens suggests, was the

complexity of the contract that attempted to mix public interests in technological and economic development with historical commitments to private property, profit and small government. The contract was to be a three-party agreement between the university, the TVA and a private philanthropic organization that used the income from its members' patent licences to support science. MIT would conduct the research, the Research Corporation would hold the patents and the TVA would provide the funds, but, despite the clear division of labour, there was a lack of clarity at the heart of the bargain. In whose interest would the licences be awarded? How would public benefits be ensured? In 1933, university and philanthropic leaders were not yet ready to accept a major role for government nor was the Research Corporation willing to forego profit-making licences. The TVA was anxious to have the new technology offered by the university but was neither comfortable with the commercial self-interest implicit in the patenting agreement nor confident that either the university or the Research Corporation could forego self-interest in favour of a public good.

Although the federal angel failed to bless the Van de Graaff electric transmission system in 1933 – failed 'to establish ... [a] precedent for the privatization of federal sponsorship' (p. 27) – by 1940, only seven years later, the university and the federal government had successfully created an "arrangement" of committees and contracts that successfully mobilized for war the nation's private scientific resources' (p. 26) therein established the paradigm for post-war scientific development. The signing of the National Science Foundation Act by President Harry S. Truman on 5 May 1940 established a central core of that post-war institutionalization.

Standard histories of the seven-year struggle to establish the National Science Foundation (NSF) often depict a battle between populists and New Dealers seeking democratically accountable research and development against scientists seeking support for scientific autonomy through investigator-initiated research (Kevles, 1977; England, 1982). Daniel Kleinman, in 'Layers of Interests, Layers of Influence: Business and the Genesis of the National Science Foundation' (Chapter 2), enriches the conventional account with an analysis of the structural and sectoral bases for the various positions taken and the various forms of participation by business firms in the legislative debates over the establishment of the NSF. At the heart of the matter was the issue that could not be successfully negotiated between MIT and the TVA in 1933 – who would own the intellectual property of federally-funded scientific research: 'business generally opposed ... efforts to prohibit exclusive licenses resulting from industrial research supported with government funds' (p. 34), seeking to benefit from federally-supported university research. As such, the National Association of Manufacturers actively lobbied to oppose the populist New Deal coalition that sought non-exclusive rights and favored support for both basic and applied research, as well as a proposal by Vannevar Bush for a scientist-controlled agency to fund basic, but not applied, scientific research, and opportunities for exclusive licensing. In the end, Kleinman argues, the NSF was a compromise among the various positions that becomes apparent only if one looks at the heterogeneity within the business community and among the forms of lobbying and influence business used.

Kelly Moore, in 'Organizing Integrity: American Science and the Creation of Public Interest Organizations 1955–1975' (Chapter 3), writes about another source of support for the institutionalization of American science. She describes a productive contradiction in which scientific authority and the autonomy to determine what is and is not science are sustained not by science's processes of knowledge production but by its alliances with distinctly non-

scientific constituencies. ‘To reap prestige and financial support ...’, Moore writes, ‘scientists must ... demonstrate that their work is ultimately ... useful to a broad constituency’ (p. 54). In this effort, science must demonstrate not its distinctiveness, but its affinity with other interests, even those that might compromise its norms of disinterestedness, generality and scepticism (Merton, [1942]1957). From the 1950s through the 1970s, a period of social and political protest, scientists formed public-interest organizations that could speak politically with a scientific voice while keeping science pure and apolitical. Organizations, such as the Union of Concerned Scientists, Science for the People and the Scientists’ Institute for Public Information, could speak out, lobby or advise on policy matters while research conducted by individual principal investigators (PIs) was shielded from inquiries about its political roots and implications.

The authority of science derives in good measure from this continuous monitoring of what does and does not constitute legitimate science, what is inside science and what lies beyond its sacred spaces. Scholars who study scientists and scientific research practices have adopted the term ‘boundary work’ to describe the social transactions that mediate between science and other institutions, including politics and law (Gieryn, 1995, 1999). Observers vary in the degree to which they see these boundaries as more or less given, or in the process of being built, maintained, defended and broken down (Miller, 2000). Nonetheless, ‘recognizing that there is no unbridgeable chasm between science and non-science and that the flexibility of boundary work may threaten some important values and interests’, some have suggested that standardized packages, and what some call boundary objects, stabilize this legitimating boundary work by creating shared practices (Guston, 2001, p. 400; Fujimura, 1991; Miller, 2001). The public-interest organizations that Moore describes fulfill these mediating functions, sustaining the autonomy and disinterestedness of science while performing its public utility. David Guston, in his essay ‘Stabilizing the Boundary Between US Politics and Science’ (Chapter 4), describes offices of technology transfer, specifically at the National Institutes of Health, as another set of organizations that mediates the divide between science and its public – here, the law and the market. The office of technology transfer, an organization we turn to more extensively in Part II, becomes an agent, Guston claims, for both political and scientific interests. Because the boundary organization serves two masters, Jasanoff (1996, p. 397) has labelled its work, ‘co-production’, the simultaneous production of knowledge and social order.

Making Markets of/in Science

Part II begins, as did Part I, with a problem in contract. Again, we encounter a controversy concerning title and property in scientific work. Once more, the right to benefit economically from scientific invention is entangled with the state funding of science – in this case, not the modern state through grants and contracting but an emperor’s patronage in the employment of a court mathematician. Although the following four essays in this section address very contemporary issues concerning the patenting and licensing of biological matter and the expansion of the intellectual property regime since 1980, as well as a close look at how one technology licensing office manages its position at the boundary of science and the market, we begin with the story of Johannes Kepler’s effort to capitalize on Tycho Brahe’s work without constraint by, and compensation to, Brahe’s heirs. In ‘Publish or Perish: Legal Contingencies

and the Publication of Kepler's *Astronomia nova*' (Chapter 5), James Voelkel describes the genesis and unusual shape of Kepler's historic narrative in a series of litigations from libel suits among competing scientists to a suit between the emperor and Brahe's heirs who sought back-pay from Emperor Rudolf II and compensation for Brahe's astronomical assets. Those who bemoan the development of a late twentieth-century litigious culture would do well to study the history of intellectual property litigations.

Kepler had not been the obvious successor to Tycho Brahe. Only two years before his death, Brahe's household laboratory had been employing a half-dozen or more assistants with various pecuniary relationships – some self-supported noblemen, some employed directly by Brahe, some on commission from collaborating courts. Because of a rapid and coincidental depletion of Brahe's staff immediately before his death, Kepler found himself in the role of the primary assistant with specific responsibility for completing the calculations for the *Rudolphine Tables* of planetary motion, the major project of the moment. When Kepler first wrote to Brahe, seeking access to Brahe's measurements to substantiate his own astronomical model, Brahe invited him to the laboratory, more interested in securing Kepler's co-operation in an ongoing libel litigation than in aiding Kepler's own work. Indeed, Brahe had become more than cautious regarding his assistants' interests, believing that two of his assistants had stolen his work and had published it as their own. Thus, when Kepler arrived to join Brahe's research group, Brahe attempted to confine Kepler's work, through a series of written pledges, to a narrow range focused exclusively on measurements of Mars. Only when the current assistants departed, for a variety of unrelated reasons, did Kepler rise in 1601 to the status of primary assistant. This role had been achieved as part of Brahe's efforts to secure additional funding from the emperor: 'The originality and significance of his ideas could translate into lavish support' (p. 39) from the emperor – much more than from the direct capitalization of his results or honoraria (which were relatively insignificant for this very wealthy man). Most of the emperor's largesse was bestowed on Brahe as a consequence of prestige rather than a direct purchase of intellectual property. The *Rudolphine Tables* were an exception, however. Here, Brahe sought to secure funds in exchange for writing the emperor into history by attaching his name to the best, most accurate astronomical data, just as King Alfonso X of Castile's name had been attached to the Ptolemaic data in the *Alfonsine Tables* and Duke Albrecht of Prussia's name had been attached to the Copernican *Prutenic Tables*. Unfortunately, Brahe died before the task had been hardly begun, and Kepler was immediately appointed as court mathematician with responsibility for 'caring for Tycho's instruments and completing his remaining publications' (p. 125). Thus Kepler was left in charge while the emperor negotiated with Brahe's family for title to the instruments and data. Although an agreement was finally reached to pay the family approximately one-fifth of their original demand, the emperor insisted that this be a government, rather than a personal, payment and that was not forthcoming. This inevitably led to extended litigation in which the family sought to recover the primary assets of the instruments and the observations, succeeding in due course in recovering the lucrative responsibility for the *Rudolphine Tables*. Consequently, to sustain the emperor's commission, Kepler was compelled to produce another work, which we know today as the *Astronomia nova*. To avoid conflicts with Brahe's family, Kepler first framed his findings in terms of an elaboration of his work on Mars, but this did not prove a sufficient strategy to withstand further litigation in which he was ultimately bound to allow Brahe's son-in-law, one of his earlier assistants, to edit and censor his work for publication. Out of respect

and legal necessity, Kepler ended up interweaving the Ptolemaic, Tyconic and Copernican world systems in a ‘long narrative of his [Kepler’s] failures using classical mathematical techniques’ (p. 136), so that the censor of the text would be unable to excise Kepler’s particular contributions and essential reliance on celestial physics, rather than mathematics, to make his particular understanding and contribution. The context of Kepler’s work is the stuff of a long, complex and compelling romance, but, as Voelkel concludes, ‘beginning with the law, which determined in a quite specific way what Kepler could and could not publish, we can look at one of the masterpieces of modern science with new eyes’ (p. 141).

We then skip more than 370 years to Stanford and Berkeley, California, to the first major patent of biological matter, with Sally Smith Hughes’s essay, ‘Making Dollars out of DNA’ (Chapter 6), and to another scientifically significant litigation, *Moore v. Regents of the University of California*² which sustained the University of California’s patent to a cell line derived from John Moore’s spleen. Just as Kepler was forced by Tycho Brahe’s heirs to establish his innovative astronomy by creating discontinuity between his work and that of his predecessors, in order to sustain the patent and licensing rights the University of California had to establish a discontinuity between natural biological matter and invented biological matter. Hannah Landecker’s essay, ‘Between Beneficence and Chattel: The Human Biological in Law and Science’ (Chapter 7) unpacks this artfully constructed distance by displaying how the scientific process that is being patented as a discontinuous invention relies for its scientific validity on the establishment of continuity between the original cells and the line in use in subsequent experiments. She shows how arguments about the continuity of the person – John Moore – and the cell line were left out of the litigation which relied on government expertise that had originally been provided by the defendants in the case. Landecker’s essay offers an example of the economic, legal and rhetorical practices that institutionalize contemporary science by legitimating the resources and conditions of its practice.

The patenting of scientific procedures and products was resisted for most of the twentieth century, although ‘by the 1920s hard-line opposition to patenting among academic scientists was beginning to be modified in favor of a more flexible approach’ (Weiner, 1987, p. 50). Some felt that patenting was an efficient way of controlling the quality of products and protecting the public. That patenting could also provide revenue to support expanding academic research was, of course, an added incentive. Critics, however, argued that patenting undermined the free exchange of ideas essential for research, encouraged unhealthy competition and fed product development that was not always in the public interest. We have already encountered some of these issues in the opening essay, ‘MIT and the Federal “Angel”’. Debates about academic patenting, consistent throughout most of the twentieth century, were most intense during periods of economic crisis and at times when new research seemed to make socially beneficial applications possible. In 1957 Seymour Melman, Professor of Industrial Engineering at Columbia University, completed a study initiated by the US Senate Subcommittee on Patenting, in which he suggested ‘not only that there were problems with the way the patent system was running, but also that there were serious questions about the viability of the system per se’ (Weiner, 1987, p. 57). Melman addressed the issues put forward by both the supporters and critics of patenting academic research. He found that the system was fundamentally incompatible with academic research. First, patenting law required a single inventor, or small

² 51 Cal. 3d 120, MC 1990.

number of named inventors, while modern scientific research and technology ‘had become a group-based endeavor in which it was often difficult to identify the individual or individuals responsible for a discovery or invention’ (Weiner, 1987, p. 57). Second, rather than spurring innovative research, Melman argued that patenting impeded research by inviting extended litigation about property rights, thereby reducing, rather than encouraging, further research. Aggressive patenting policies in academia (as well as industry) were backfiring because increased managerial control of research ‘impeded the university scientist in the free pursuit of knowledge as an end in itself and thus weakened the universities as centers of basic research’ (Weiner, 1987, p. 58). Third, information-sharing and rapid publication, which had become an engine of research productivity, was being limited by the secrecy required for the patenting process. Melman’s report was basically ignored while the patent lawyers association independently published their own report challenging the claims, but they were unsuccessful in their attempt to rebut Melman’s findings.

The passage of the 1980 Bayh-Dole Act by the US Congress transformed the landscape of academic research by permitting universities, non-profit institutions and small businesses to retain the property rights to inventions derived from federally-funded research. Although the intent of Congress was to encourage collaboration between commercial and non-profit organizations, the result was a profound change in the culture of academic research (Powell and Owen-Smith, 1998). Although the statutory change responded most directly to the development of biotechnology, the consequences spread beyond the biosciences to almost every discipline in science and engineering, with a growing divide between what Powell and Owen-Smith (1998) call the ‘have’ and ‘have-not’ universities. The chasm between haves and have-nots escalates because of a spiralling feedback loop of federal funding, lucrative licences for innovations produced from federally-funded research, and then additional research funding on the basis of prior productivity. Although federal funders provide incentives for young and minority investigators and special awards for educational, rather than research, institutions while attempting to geographically balance the distribution of funds, the number of patents and the volume of research support is concentrated in a small number of institutions.

In ‘Dockets, Deals, and Sagas: Commensuration and the Rationalization of Experience in University Licensing’ (Chapter 8) Jason Owen-Smith provides a close-up look at how science is transformed into property at the interface between university and market. Recent studies of scientific practice have described the heterogeneously assembled and contingent character of facts and artefacts (Bijker, 1995; Callon, 1986; Latour, 1987; Silbey, 2006), but Owen-Smith demonstrates how, in the effort to stabilize the scientific object so that it can be specified in a patent, the technology licensing office makes transparent the contingent, circumstantial character of scientific knowledge. The technology-licensing officers develop local epistemologies and rules of thumb for representing, distinguishing and comparing scientific results and inventions. There is little that is necessary or predetermined in the particular licences other than that they identify the specific technology in such a way as to ensure broad public access and benefit while securing revenue for the university. To achieve these purposes, the technology licensing officers sometimes combine disparate patents in a single licence; at other times they disentangle pieces of a single patent into distinctive licences. Owen-Smith shows the social and organizational arrangements that help constitute technologies, how the objects and processes ‘take their form and acquire their attributes as a result of their relations with other entities’ (Law, 1999, p. 3, quoted on p. 207), such as

the technology licensing officers' discussion rituals, interpretations of university policies, or perceptions of potential public relations problems.

Governing Science: Law in the Lab

In a straightforward sense, patent law provides maps for the journey of science from the laboratory to the market. But this simple metaphor effaces a more complicated nexus between law and science. Law does not supply merely an environment surrounding the boundary of scientific spaces; it also inhabits science not only metaphorically, but also quite materially and behaviourally. However, the role of legal regulation within the procedures as well as in the spaces of science is perhaps one of the least explored or understood aspects of the relationship between law and science. Part III of this collection addresses this link between law and science within the very processes of data collection and analyses that are the hallmarks of empirical science.

Powerfully shaping contemporary life, science is perceived to be dangerous, both in terms of its potential to produce physical harm and in its insistence on an independent source of authority. Although legal regulations focus on material and physical dangers, most leave unchallenged the authority of scientists to determine what constitutes scientific knowledge (Gieryn, 1999). Of course, the history and development of modern science has not been a story of total immunity from the influences of competing social institutions. As the chapters in this volume and Volume I attest, the law has been constitutively present, sometimes centrally so, in the expansion and organization of modern science. 'But, in its efforts to promote (as well as contain) the development and consequences of science, the law has, over the centuries, certified areas of scientific autonomy, putting them beyond the law's reach' (Silbey and Ewick, this volume, p. 273). Since the middle of the twentieth century, however, the law's reach has increased considerably into all sorts of activities, relationships and spaces that had heretofore been privileged as private. By the end of the twentieth century, the regulatory state also included scientific spaces and practices within its embrace.

Under the mandate to secure the health and well-being of the nation, under the state's residual police powers, legal regulation has crept into just about every form of human action from the certification of health-protecting pharmaceuticals to the composition of children's pajamas or the construction of infants' cribs and carriages:

What the law regulates, constrains, and enables is influenced, if not determined, in large part by science's methods and conclusions ... The law's deference to science's claim – to have access to something that is independent of its own activities – [thus] helps construct scientific authority and legitimacy at the same time as it instantiates and legitimates law's authority to regulate. (Silbey and Ewick, this volume, p. 273)

While science provides the impetus and justification for legal regulation in the name of health and safety,

... *how* that regulation takes place, through what sorts of procedures and sanctions, are the law's specific prerogative. Thus, we manage the dangers of radiation through an elaborate system of continuous surveillance that can lead to mandatory cessation of operation or

personal exclusion from work. On the other hand, we respond to the dangers of smoking by requiring notices on cigarette packages, prohibit advertising and sale to minors, but taxing rather than prohibiting consumption for adults. And, in most American states, we respond to the dangers of sexually transmitted diseases not by providing or requiring surveillance or mandated notices, nor by monitoring the sexual practices of infected persons; we do, however, permit and certify marriages only after screening for disease. In each of these instances, the dangers have been identified through scientific research; the modes and forms of regulation are legal inventions. (Ibid.)

In the early twentieth century, chemistry laboratories began to install ventilation hoods to exhaust the chemical fumes. They were not required by law, at first, but were merely examples of good research practice. By the end of the Second World War, radioisotopes were familiar research substances, the control of which was delegated to the Atomic Energy Commission that later became the Nuclear Regulatory Commission. Under the auspices of these agencies, licences were issued to universities and other laboratories to work with radioactive materials. The licences specified safe conditions of operation through architecture, training and self-monitoring. Again, there was no regulatory surveillance or enforcement except when an accident was reported. Some universities established in-house offices to provide service to those using radioactive materials. These offices usually assumed the role of consulting advisors supporting researcher self-policing.

Thus, for most of the twentieth century, universities acquiesced to national priorities for research and development, in exchange for which the government funded the research and deferred to historic traditions of academic self-governance. By the end of the twentieth century, however, science's collaboration with the regulatory state led back, in an almost perfect feedback loop, into the sanctified spaces of science (the laboratories and research practices of scientists) through regulations concerning health, safety, environmental protection and conditions of employment. Although such regulations were, in principle, universal, with very few exempt categories, scientists and academic institutions nonetheless retained a good measure of the organizational autonomy they had been used to. In 1991 OSHA (Occupational Health and Safety Administration) enacted the lab standard, exempting research facilities from regulations designed for high-production enterprises. The new rules delegated to the regulated organizations themselves authority to determine how these more generally applicable federal and state regulations would be implemented within universities and research laboratories. Thus a compromise was struck between the regulator's interests in safety and the universities' interest in self-governance. This pattern of adaptive regulation would characterize the legal regulation of laboratory practices for at least the last quarter of the twentieth century and into the twenty-first.

Beginning in the 1970s this unspoken bargain between regulators and scientists began to wither in the face of a series of scientific inventions and embarrassments that awakened public notice and political institutions to what seemed like unnecessarily risky, if not evil, scientific enterprises. As a consequence, demands for more direct regulation of the processes of doing science escalated, beginning with attention to human subjects of and in research. Following the Second World War, the Nuremberg Code established voluntary consent by human subjects as the fundamental principle of ethical scientific or medical research. Nonetheless, for 40 years (1932–72) the US public health service had been conducting an experiment on 400 African-

American men in the late stages of syphilis without their consent. The public health service did not tell the men from what disease they were suffering, nor was the disease treated; the men were told only that they were being treated for ‘bad blood’. The doctors merely observed as the patients’ disease proceeded along its course and monitored the men’s progress until death with the aim of constructing a complete model of the disease’s ravages. A newspaper story in the *Washington Star*, on 25 July 1972, broke the story. Although the doctors and state officials are reported to have been unrepentant, claiming that someone was making a mountain out of a molehill, ‘under the glare of publicity, the government ended their experiment, and for the first time provided the men with effective medical treatment for syphilis’.³ Ten million dollars was paid in an out-of-court settlement.

Subsequently, other examples of irresponsible science became public. During the 1940s, 800 pregnant women, patrons of a prenatal clinic at Vanderbilt University, were given a cocktail including a tracer dose of radioactive iron as a means of establishing the iron requirements of pregnant women. Several universities participated in an experiment in which terminally ill patients were injected with plutonium to determine how the radioactive chemical would spread through the body. During the 1950s mentally retarded boys at the Fernald School in Waltham, Massachusetts, were fed radioactive calcium and iron with their breakfast cereal in exchange for extra milk and trips to baseball games. In the 1960s patients with incurable cancers were exposed to heavy doses of full-body radiation – a procedure that had largely been abandoned by that time.

In 1974 the US Congress passed the National Research Act that created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Social science, as well as medical research, was to be included under new rules for conducting scientific research. It turned out that social scientists had also been conducting experiments on unwitting subjects who had been recruited without full disclosure or consent into experiments as prison inmates, counterinsurgency agents, or as mock researchers conducting experiments using electric shock discipline as a learning technique. Barrie Thorne, in “‘You Still Takin’ Notes?’ Fieldwork and Problems of Informed Consent’ (Chapter 9) analyses the dilemmas that have arisen for ethnographic fieldworkers who study people in their natural environments. The rules of informed consent that were promulgated as a result of experiments on humans imagine all research as risky interventions that disrupt ordinary lives. Thorne, however, deconstructs consent as itself a subject worthy of intensive examination. The reliance on what is fundamentally a medical model of observational research has created, some observers claim, serious impediments to important social science observational research (see Wax, 1977; Bosk and DeVries, 2004).

At the same time as Congress and the public were responding to the unfolding stories of out-of-control scientists, biologists were inventing the means of unpacking and reconfiguring DNA. When rDNA (recombinant DNA) was first announced, the public mobilized to oppose the research and succeeded in securing a moratorium on research in Cambridge, Massachusetts, while negotiations took place between local authorities and researchers. Biologists organized themselves, following a call in *Science* magazine (Berg *et al.*, 1974) for a worldwide voluntary moratorium, to respond to the growing concerns and reservations

³ For full details see ‘The Tuskegee Syphilis Experiment’ (3 July 2007), at: www.infoplease.com/ipa/A0762136.html.

echoed by scientists themselves at previous conferences. The ability to clone DNA segments from virtually any organism on our planet and recombine them with other DNA segments triggered a level of unprecedented concern. As a result, 140 scientists, lawyers and members of the press met at Asilomar Conference Center on California's Monterey peninsula to draw up voluntary guidelines to ensure the safety of DNA research and technology. The conference was notable not only for the initiative by the scientists, who certainly had an interest in seeing research resumed, but also because it was an application of the precautionary principle of regulation – a principle that is less frequently applied in the United States than in Europe. In the United States, regulation more often follows a demonstrated negative consequence than in Europe where regulation attempts to anticipate or prevent negative impacts before they occur. The precautionary principle is a moral and political injunction: in circumstances that might cause severe or irreversible harm to the public, and where scientific consensus does not preclude such harm, the burden of proof for undertaking such action lies with those who advocate the action.

In the end, protocols were established nationally and internationally, with even more stringent regulations imposed in Cambridge, Massachusetts, where citizens had been first mobilized. The regulations sought to protect laboratory personnel, the general public and the environment from any hazards that might be generated by biological experiments. The first principle for dealing with potential risks focused on containment, while the second principle asserted that the effectiveness of containment should match the estimated risk as closely as possible. This led to the categorization of hazards with commensurate physical containment through the use of hoods, limited access or negative-pressure laboratories. The signs that label spaces according to the level of biohazard (BL1, BL2, BL3, BL4) are now familiar signs along the corridors of scientific research buildings. The conference also suggested the use of biological, as well as physical, barriers to limit spread of recombinant DNA, such as hosts unable to survive in natural environments and non-transmissible and fastidious vectors (plasmids, bacteriophages and other viruses) that were able to survive only in specified hosts. Philip Bereco, in 'Institutional Biosafety Committees and the Inadequacies of Risk Regulation' (Chapter 10) describes the experiment of self-regulation of biological hazards within its first decade of operation, but points to long-term uncertainties.

Three essays focus specifically on the laboratory as an object of governance and as a spatial means to regulate the dangers of science. The essay by Susan Silbey and Patricia Ewick, 'The Architecture of Authority: The Place of Law in the Space of Science' (Chapter 11), describes a shift in the more general processes of liberal governance from legal constraint on the individual (who is made vulnerable to surveillance and control by her own freedom as an actor) to self-regulation by an institution – science (which is made both dangerous and vulnerable through its claims of autonomy and universality). Silbey and Ewick describe governance as an ensemble of spatial processes that operate alongside the person who is free to circulate within regulated spaces: '... because the laboratory plays a crucial role in the production and governance of science, it has become an important locus for the legal regulation of science and the various material and cultural dangers science poses' (p. 300). The next essays by Cyrus Mody and Benjamin Sims respectively delve directly into the laboratory to uncover exactly how safety and contamination become critical sites of scientific discovery and epistemology. Mody's 'A Little Dirt Never Hurt Anyone: Knowledge-Making and Contamination in Materials Science' (Chapter 12) uses the work of anthropologist Mary

Douglas to identify the multiple, overlapping and contradictory meanings of dirt and shows how contaminants function as positive resources as well as threatening pollutants. In, 'Safe Science: Material and Social Order in Laboratory Work' Sims argues that the particular safety protocols in a pulsed-power laboratory mimic the physicists' efforts to create transparency and thus control of physical matter. The physical knowledge and safety protocols exhibit, he suggests, a kind of homology, one almost epistemologically internal to the other. Physicists enact safety protocols in ritualized compliance with technical standards, their behaviour displaying fidelity to rules that trace their origins and legitimacy to physicists' special knowledge of the structure of matter. The ideal of both the safety regime and the physics is just this traceability or transparency among both visual and logical components of the laboratory and the atom.

Governing Scientists: Social Control and Scientific Misconduct

If legal regulations have only recently focused on the dangerous spaces of science, appropriate scientific practice has more often been governed by professional norms rather than legal regulations. The role of professional, as opposed to legal, norms for governing misconduct has, however, been a subject of lively debate, some of which we include here.

In his canonical definition of science as an institution, Robert Merton ([1942]1957) named four central norms: universalism, communism, disinterestedness and organized scepticism. We have already encountered the consequences of universalism – the ambition that scientific knowledge be universally true – for the historical and architectural specificity of the scientific laboratory. Communism refers to the ambition that scientific knowledge is, in a very ordinary sense, a shared good, that the findings are the result of a shared process and belong to collective humanity. Disinterestedness refers not so much to the motives of actors as to the internal policing by the institution of the claims put forth by the actor/scientists. Disinterestedness is an institutional practice, according to Merton, such that base motives of profit, priority and reward are constrained by the epistemological insistence on replication and the fourth norm of organized scepticism. Merton first produced this account in the 1940s when awareness of scientific fraud was not common. By the 1970s, however, examples of fraud were abundant. Nachman Ben-Yehuda, in 'Deviance in Science' (Chapter 14) presents a brief, almost chatty inquiry into the Mertonian model and the conditions for the production of deviance in science. Elsewhere, Harriet Zuckerman (1984) explains that social control as understood by sociologists (including Merton, Ben-Yehuda and herself), refers not to the motives of one or another person, but to the patterns of behaviour in particular organizations and institutions. To the extent that 'the system of science does not require scientists to forgo career advancement while making disinterested contributions to knowledge' (Zuckerman, 1984, p10) the system operates to reward disinterestedness. Conventional theories explaining deviant behaviour – for example, differential association, anomie, social structure and control theory – are sufficient to explain the variations along a continuum of deviant behaviours in science ranging from departures from cognitive norms involving 'disreputable' errors or negligence to departures from social and moral norms, including plagiarism and secrecy.

By including social structural explanations for misconduct, sociological analyses predict an increase in scientific fraud as a consequence of the transformations in the intellectual property regime. Edward Hackett, in 'A Social Control Perspective on Scientific Misconduct' (Chapter

15), argues, however, that each of the explanations for the increase in misconduct illuminates only a facet, not the composite problem. Rather than focusing on the causes of misconduct, Hackett suggests adopting a focus on the social response to deviance, which would associate variations in reported fraud with varying relationships between public attention and scandal, or among science and political interests and power. Marcel LaFollette's essay, 'The Politics of Research Misconduct' (Chapter 16), however, locates the discussion of scientific fraud within a history of Congressional oversight, marking precisely that increased public notice, commercial success and political consequence which Hackett refers to as conditions of the recognition, if not emergence, of misconduct. LaFollette concludes with reference again to Mukerji's (1989) notion of the fragile bargain between science and public institutions with which we began this volume. The conversion of knowledge into economic wealth comes with demands for efficiency in the use of, and accountability for, the consequences of financial support. Although Congress remains generally supportive, that encouragement and accommodation is provided with a closer eye on the general public's reception and approval of scientific knowledge.

Governing the Products of Science

Finally, Part V of this volume addresses the ways in which law attempts to constrain the consequences, rather than the processes, of scientific research and invention. We began this two-volume set with essays on the use of scientific knowledge as testimony in courts, as data for judicial decision-makers. By focusing on the regulation of scientific products, we end this second volume with essays on the use of scientific knowledge as data for policy, rather than litigation, decisions. If the rituals of the trial exacerbate the distinctions between making facts in science and building cases in law (Fuchs and Ward, 1994), public policy deliberations may provide a more hospitable, but no more certain or problem-free arena for scientific discourse. The essays in Part V describe the strains that policy-making discourses place on science. As Sheila Jasanoff explains in 'Contested Boundaries in Policy-Relevant Science' (Chapter 17), because '[k]nowledge claims are deconstructed during the rule-making process, exposing areas of weakness or uncertainty and threatening the cognitive authority of science ... the legitimacy of the final regulatory decision depends upon the regulator's ability to reconstruct a plausible scientific rationale for the proposed action' (p. 447). During policy deliberations members of the public, the policy-makers and the scientists compete to define the problem and the relevant knowledge. Each group mobilizes disqualifying and legitimating discourses to 'further their own interests' (p. 447).

Les Levidow's essay, 'Precautionary Uncertainty: Regulating GM Crops in Europe' (Chapter 18), explores the ways in which regulation governed by the precautionary principle highlights scientific uncertainty and sets limits to the role of science in policy-making. Beginning with uncertain parameters within which to estimate the consequences of genetically modified crops, debates focused on the normative, value-laden assumptions within the risk assessments. Uncertainties in the assessments escalated during the debates until it became more and more apparent that uncertainty was not merely contextual, but was constitutive of the problem of GM crops. Levidow concludes that precaution, as a principle of governance, 'offers a means to justify uncertainty' (p. 483) rather than uncertainty justifying precaution in the regulation of scientific innovations.

Hugh Gusterson, in 'How Not to Construct a Radioactive Waste Incinerator' (Chapter 19), delves inside the public's understandings of, and responses to, risk assessment as important pieces of the policy-making process. He shows how activists were able to mobilize media coverage of environmental degradation caused by the US nuclear weapons complex to transform the public's perception of the risks associated with the building of a waste incinerator. The end of the Cold War provided an historical opening for transforming the responses of business and the public. Gusterson describes how non-professional actors can actively shape the networks through which scientific knowledge passes in the policy-making process.

Conclusion

Law and science are probably the two most significant sources of authority in modern, especially Western, societies. Although law and science are often thought of as different and even divergent institutions, I have suggested that science and law are broadly similar epistemologically, that their historical interactions are long, and that their present-day connections are close. There are, however, significant differences. Unlike legal disputes, scientific debates have no closure. There is no Supreme Court of Science whose rulings are final. In addition, science claims its authority through its foundations in reason alone, whereas law's authority derives from both reason and force (Bobbio, 1965; Cover, 1986). It is possible, Nick Buchanan (2006) argues, that 'intensifying connections between science and law are blurring the differences between the two institutions'. The more scientific debates enter legal arenas, the more closure is provided to scientific debates, that closure being achieved not in the laboratory but through court rulings. Court rulings are legitimated not only by their historical institutional authority, but also by legal reasoning that amalgamates expert scientific evidence and state force. 'In other words, the convergence of science and law means that scientific truths are now legally enforceable with state violence. This represents a fundamental change in the character of the scientific enterprise' (Buchanan, 2006).

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