Chapter 2
The Growing Gap Between Emerging Technologies and the Law

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It is change, continuing change, inevitable change, that is the dominant factor in society today. No sensible decision can be made any longer without taking into account not only the world as it is, but the world as it will be. . . .
– Isaac Asimov

Change is inevitable, except from vending machines.
– Woody Allen

A series of concurrent technological revolutions are rapidly transforming economic, social and personal domains, now and even more so in the imminent future (Roco and Bainbridge 2003; Garreau 2005). These current and pending emerging technological revolutions include information technologies, communication technologies, nanotechnologies, biotechnology, regenerative and reproductive medicine, robotics, neuroscience, surveillance technologies, and synthetic biology. Perhaps even more important than the degree and breadth of these technological changes considered individually or collectively is the exponential pace at which the successive waves of technical change are washing over us (Kurzweil 2005).

In contrast to this accelerating pace of technology, the legal frameworks that society relies on to regulate and manage emerging technologies have not evolved as rapidly, fueling concerns about a growing gap between the rate of technological change and management of that change through legal mechanisms (Moses 2007). Increasingly, the traditional legal tools of notice-and-comment rulemaking, legislation and judicial review are being left behind by emerging technologies, struggling to cope with even yesterday's technologies.

The consequence of this growing gap between the pace of technology and law is increasingly outdated and ineffective legal structures, institutions and processes to regulate emerging technologies. The two basic options for addressing this problem are (i) to slow or stop the pace of scientific progress; or (ii) to improve the capacity

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of the legal system to adapt to rapidly evolving technologies (even if this means departing from traditional forms of legal regulation into broader forms of governance, as discussed below). History indicates that the first option is highly unlikely, especially with technologies that have significant economic, psychological, or military value. Therefore, implementation of the second option becomes critical and is the focus of this introductory chapter. As Benjamin Cardozo noted almost half a century ago, "with new conditions there must be new rules" (Cardozo 1960, p. 137).

This chapter first summarizes evidence of the accelerating pace of science and technology, followed by evidence of the lagging efforts of law to keep up with emerging technologies. It then briefly describes some basic approaches and options to make the law more dynamic and responsive to accelerating technologies.

2.1 Accelerating Technology

Over the past half-century, we have witnessed the discovery of the structure of DNA, the mapping of the human genome, the development, refinement, and widespread adoption of computing systems, the advent of new communication and information technologies that are fundamentally changing economic and social relations, and the prevalent use of new technologies such as nanotechnology and neuroimaging that were not widely known just a decade ago.

Various statistical measures give a sense of the accelerating pace of science and technology. For example, one analysis concluded that over the last 250 years, the number of scientific journals has doubled approximately every 15 years and the number of "important discoveries" has doubled every 20 years (Price 1986; Tuomi 2003). Further, a study performed at the University of California-Berkeley showed that the total information in the world doubled from 1999 to 2002 (Lyman and Varian 2003). It has been estimated that we have created more scientific knowledge in the past four decades than was created in the previous 5,000 years (Garreau 2001). These exponential increases in information may be correlated with the available scientific workforce, which expanded dramatically and in some cases, exponentially. The number of engineers in the United States has doubled approximately every ten years (Price 1986; Tuomi 2003) and it has been estimated that 90 percent of all scientists who have ever lived are alive today (Garreau 2001).

The exponential growth of technology is demonstrated by several examples, one of which is Moore's Law, a 1965 observation of Gordon Moore, who subsequently co-founded Intel. Essentially, the observation suggests that at the current rate of technological development, the number of transistors that can fit on an integrated circuit (and hence, computing power) will double every 12 months (Moore 1965). (Moore revised this law in the 1970s to suggest that computing power would double every 18–24 months instead). Despite the exponential growth projected by Moore's Law, the rate of computer development has kept pace with these ambitious projections for nearly 50 years (Lundstrom 2003). It has been postulated that with the acceleration of Moore's law, transistors will reach their limit on "smallness" within the next decade; however, another 30 years of exponential progress is attainable and likely due to the rapidly increasing rate of advancement of technologies such as silicon nanoelectronics and quantum computing (Lundstrom 2003). Exponential improvements have also been demonstrated for computational power and for computer processing speed. Specifically, the value of $1,000 of computational power has doubled every two years through five paradigm shifts and most recently (the past 30 years) has doubled every year (Jurvetson 2004). Over the next 20 years, technological growth will be equal to that of the entire twentieth century (Jurvetson 2004). Further, desktop computer processing speed has seen exponential growth (Berndt et al. 2000).

Another area in which rapid technological advancement can be demonstrated is the biological sciences. An observation known as Monsanto's Law supports the theory of the increase of biological technology at an exponential rate. This law is derived from an observation made by the Monsanto Corporation in 1997: "The ability to identify and use genetic information is doubling every 12–24 months. This exponential growth in biological knowledge is transforming agriculture, nutrition and healthcare in the emerging life sciences industry" (Brand 1999).

The technology for DNA sequencing has also been improving at an exponential rate (Carlson 2003), with the cost of DNA sequencing dropping by a factor of 100,000-fold over the past decade (Carr 2010). Further, the growth of DNA sequence data that has been added to Genbank, a database of sequences, has been noted to be exponential as well. The amount of DNA sequence data has increased from 606 sequences in 1982 to 108,431,692 in 2009 (GenBank 2010).

Another area of biological technology that has advanced and evolved rapidly in the twentieth century is that of medical product innovation. In particular, the twentieth century has witnessed dramatic advances in pharmaceuticals, materials science, medical device engineering, and biologics. The advances in these individual technologies have culminated in the creation of an entirely new area of innovation, that of the technology of combination medical products (Bartlett Foote and Berlin 2005). Initially, combination medical products involved the addition of an existing pharmaceutical agent to a medical device. One example of an early combination medical product is the addition of a steroid drug to a pacemaker electrode in order to promote healing and decrease scarring of cardiac tissue. More recently, however, combination product innovation involves the addition (to medical devices) of agents that regenerate tissue (LaForte 2004; Bartlett Foote and Berlin 2005), target cells for delivery of gene sequences (Shea and Houchin 2004; Bartlett Foote and Berlin 2005), and detect illnesses in the body and target delivery of drugs and biologics to the illness locale (Miller 2003; Bartlett Foote and Berlin 2005). These innovative new combination products are the result of the rapidly increasing growth and advancement of the fields of tissue engineering, gene therapy, and nanotechnology, respectively (Bartlett Foote and Berlin 2005).

In the last 30 years, exponential advancement has also been demonstrated in noninvasive brain scanning technology. Specifically, exponential improvements in resolution of neuronal features have been demonstrated for computed tomography (CT) brain scanners (Trajtenberg 1990; Kurzweil 2003). In 1972, resolution capability was approximately 4.0 millimeters, and by 1999, resolution had decreased (improved) to approximately 0.06 mm (Kurzweil 2003).

Further, exponential growth has been demonstrated by advancements in internet connectivity (Jurvetson 2004) and in number of internet hosts (Internet Systems Consortium 2008). Specifically, the number of internet hosts has risen from 213 in 1981 to 541,677,360 in 2008 (Internet Systems Consortium 2008).

The field of nanotechnology has exhibited exponential growth as well. The number of nanotechnology science citations has increased from approximately 400 in 1990 to greater than 10,000 in 2002, with a doubling time of 2.4 years. As a result of increasing research and innovation in this particular area, the number of US nanotechnology-related patents has risen from approximately 45 in 1990 to approximately 500 in 2002 (http://www.etcgroup.org/documents/TheBigDown.pdf). Between 1997 and 2004, the number of patents granted in the area of nanotechnology has increased by a factor of three (Jurvetson 2004). As a result, IBM for example, has more lawyers involved in nanotechnology than engineers (Jurvetson 2004).

Finally, a review of patent applications indicates an increasing technological growth. Between 1995 and 2005 a total of over 1.6 million patent applications have been filed worldwide with an average annual growth rate of 4.7% (WIPO 2007). Nor has the growth rate been linear; between 1883 and 1959 the growth rate was a meager 1.99%, whereas between 2004 and 2005 it was 7% (WIPO 2007). A closer examination reveals that certain technical fields are growing at an even greater rate; between 2000 and 2004, medical technology (+32.2% increase in patent applications filed), audio-visual technology (+28.3%), and information technology (+27.7%) were the three fastest growing technical fields (WIPO 2007). Even when controlling for gross domestic product in the United States, the data show that there was a 6.3% increase in patent filings by residents in a one-year period from 2004 to 2005 (WIPO 2007).

2.1.1 Pace of Law vs. Pace of Science and Technology: Can Law Stay Current?

With the increasingly rapid progression of science and technology, a major challenge that arises is the capability of legislation, regulation, and judicial case law (collectively "law") to keep pace with rapidly developing science and technologies (Moses 2007). As far back as 1986, the US Office of Technology Assessment (OTA) noted that "[o]nce a relatively slow and ponderous process, technological change is now outpacing the legal structure that governs the system, and is creating pressures on Congress to adjust the law to accommodate these changes" (OTA 1986). A subsequent analysis from the RAND Corporation echoed this concern: "We see a growing divergence between time cycles of government and those of technology development. Quite simply, this presents government operations with a Hobson's choice: Either live within a shorter response time and run the concomitant risk of ill-considered actions (or inactions) or see government input become less relevant and assume reduced stature" (Popper 2003, p. 86).

The pacing problem facing the legal system has at least two dimensions. First, many existing legal frameworks are based on a static rather than dynamic view of society and technology. A textbook example of a legal provision that fails to anticipate likely change involves the ozone non-attainment provisions of the 1990 Amendments to the US Clean Air Act. After Congress had repeatedly failed in previous amendments to force states to comply with health-based ambient air quality standards, Congress determined in the 1990 amendments to hold states' feet to the fire by imposing a graduated series of progressively more onerous mandatory requirements scaled to the degree of non-compliance and the length of time the state needed to attain compliance. The problem was that Congress tied this graduated scale of requirements to the extent of non-attainment with the existing ozone standard (0.12 ppm averaged over one hour), with no flexibility or anticipation that the EPA ozone standard may change. In fact, the statute required EPA to review and revise as appropriate its ozone standard every five years, and so not unexpectedly, EPA significantly revised its ozone standard seven years later in 1997, changing both the stringency and form of the standard. The new attainment requirements no longer made sense in view of the revised standard, and extensive litigation and regulatory revisions resulted to try to resolve the mess made by Congress' failure to recognize that the world would not stand still.

Second, legal institutions are slowing down with respect to their capacity to adjust to changing technologies. This problem applies across the board to legislatures, regulatory agencies, and the courts. The *legislative* process is notoriously slow, with federal and state legislatures only capable of addressing a small subset of the plethora of potential issues before them in any legislative session. Issues are often not addressed on the basis of their importance, but rather as a function of headlines and perceived political urgency and expediency. Thus, a given issue may only be addressed by the legislature during an infrequent "window" when various factors combine to elevate the issue to the front of the priority line (Kingdon 1995). It often takes some type of crisis or disaster to open this legislative window and "shock" the legislature into taking legislative action (Kahn 2007). Once the legislative body has acted on an issue during the window of opportunity, it may be years or even decades before it revisits the issue, creating the risk of outdated legislation that remains in effect simply as a reflection of legislative inertia. For example, every US environmental statute is now past (in many cases well past) its stated reauthorization time (Campbell 2008). Statutes also fail to adapt because of political gridlock, where legislators agree that an existing statute is out-of-date, but cannot agree on how it should be changed, resulting in the prolonged life of an outdated statute. The legislative process is also heavily determined by the scale of relevant political and ideological structures, which in many cases are smaller than the increasingly global technological enterprise.

Regulatory processes by federal and state agencies have become slower at the same time that science and technology are speeding up. In the United States, regulatory agencies are required, both to meet legislatively imposed requirements and to survive judicial review, to undertake an ever-increasing burden of analytical requirements to support their regulatory decisions. The increasing complexity of the European Union regulatory processes similarly slows regulatory initiatives. As issues involving technology become more complex, more stakeholders become involved in regulatory processes, further slowing the potential for rapid regulatory action. These and other requirements have resulted in what is referred to as the "ossification" of rulemaking (McGarity 1992; Pierce 1995), whereby promulgation of new regulations becomes increasingly delayed and difficult, resulting in ineffective and out-dated regulations. Not only do agencies fail to adopt timely regulations to address new issues and problems (e.g., nanotechnology), but they fall into "rulemaking ruts" where they fail to update existing regulations in response to new scientific and technological knowledge (Blais and Wagner 2008). Although there remains empirical uncertainty and disputes about some aspects of the extent and causes of the ossification of rulemaking (e.g., Johnson 2008; Jordan 2000), there is no question that the evidentiary and legal burdens on agencies seeking to promulgate regulations has increased dramatically over time, contributing to a notable slowdown in rulemaking activities by some agencies (e.g., OSHA) and an apparent retreat from rulemaking altogether by other agencies (e.g., NHTSA) (Mashaw and Harfst 1991; Blais and Wagner 2008; McGarity et al. 2010).

The system of *judicial* case-law is deliberately structured to provide a conservative brake on rapid change in order to provide stability and predictability in the legal system. Thus, common law courts adhere to precedent, under the doctrine of stare decisis, often following the legal principles and holdings set down in cases decided decades or even centuries earlier (albeit with some flexibility to depart from such historical decisions in light of new facts, laws, and social views). The process of litigation is also often lengthy, as a single case can take many years to progress through the process from filing of a complaint to a final appellate decision, further increasing the likelihood that a judicial opinion might be outdated even at the time it is issued.[1]

These dynamics of legislative, regulatory and judicial legal actors all suggest that the law may have problems keeping pace with exponentially changing technologies. There are at least anecdotal examples of such a problem. In the Microsoft antitrust case in the United States, for example, the D.C. Circuit Court of Appeals noted that it was being asked to judge alleged anticompetitive conduct of Microsoft that took place six years earlier (US v. Microsoft 2001, at 49). The court expressed concern

[1] A (hopefully) trivial yet illustrative example of the slow pace of courts is a legal action in the European Court of Human Rights to stop the start up of the Large Hadron Collider in Europe because of an alleged risk it could start a runaway reaction that could destroy the earth. After the court denied an interim order to delay the experiment, a news report quoted a court spokesperson as saying it could "take several years" to decide the merits of the case, leading the reporter to caustically remark "[s]o, if a black hole is swallowing up the Earth by 2012, we might have the consolation of knowing it was illegal, at the conclusion of an apocalyptic version of Jarndyce v Jarndyce." (Warner 2008).

that "six years seems like an eternity in the computer industry," and "[b]y the time a court can assess liability, firms, products, and the marketplace are likely to have changed dramatically." (Id.). The court noted "the enormous practical difficulties" that resulted from the slow response of the legal system relative to the rapid pace of technology that, in this case, left the court evaluating what should be done about an earlier generation of now-obsolete software.

Another example of the legal system responding too slowly to changes in science and technology is the Delaney Clause, a 1958 amendment to the Food, Drugs, and Cosmetic Act sponsored by Congressman James Delaney of New York. The Delaney Clause prohibited any food additive that was "found to induce cancer in man, or, after tests, found to induce cancer in animals." At the time the clause was enacted, carcinogens were viewed as relatively rare substances that could be completely eliminated from the human diet. Soon thereafter, though, evolving scientific knowledge suggested that at least half of all chemicals could cause some form of cancer in animal tests at very high doses, and that almost every food additive and most "natural" foods contained some level of potential carcinogens at trace levels. Regulatory agencies such as FDA and EPA attempted to circumvent the harsh, extreme language of the Delaney Clause by suggesting that additives with trivial cancer risks should be exempted, but were repeatedly rejected by the courts that insisted only Congressional action could change the outdated assumptions underlying the Delaney Clause (Merrill 1988). It was not until 1996 that Congress finally stepped in to update the statute, decades after it was known to be scientifically obsolete and untenable in practice.

In some cases, lethargic development of new legislation or adaptation of existing legislation in response to scientific discovery or development can impede research and innovation, resulting in blocking of new technology. An example of this dilemma is the US patent system. While the purpose of patent law is to promote the progress of useful arts by providing inventors with incentives to innovate, thereby driving technological advancement, is has been suggested recently that US patent policy may, in fact, be impeding innovation (Mireles 2005; Jaffe and Lerner 2004). In particular, patent law has failed to recognize that different emerging technologies may require unique patenting rules, thereby continuing to apply an increasingly obsolete "one size fits all" policy to vastly different technologies (Thurow 1997; Burk and Lemley 2003).

Other examples of new technologies that have developed in a legal void with no comprehensive regulatory framework include embryonic stem cell research, artificial reproductive technologies (ART), preimplantation genetic screening, genetic testing, new surveillance technologies, and privacy on the internet. According to the co-chair of an American Bar Association committee studying the need for regulation of ARTs, "[w]ith each advancement in technology, the law grows further behind" (Baker 1999).

In addition to these anecdotal examples, there appears to be a common sentiment among experts in a variety of different technologies that regulatory systems are not keeping pacing with the rapidly developing technology. For example, such expert statements in the field of nanotechnology include:

- Innovation in the field of nanotechnology development is far ahead of the policy and regulatory environment, which is fragmented and incomplete at both the national and international levels. (Roco and Renn 2007)
- We have moved into . . . a . . .world dominated by rapid improvements in products, processes, and organizations, all moving at rates that exceed the ability of our traditional governing institutions to adapt or shape outcomes. If you think that any existing regulatory framework can keep pace with this rate of change, think again. (Rejeski 2004)
- [L]aw, regulations, and policy are going to have to take a giant leap if they are to keep up with the pace of nanotechnology development. (Kelly 2008)
- Currently, governments are not able to set up or modify comprehensive regulatory structures quickly enough to match the pace of innovation and product introduction. (IRGC 2007)
- The slow movement to regulate nano in the face of legitimate yet manageable risks is an example of the broader social issue of how regulation is sorely lagging behind advances in technology generally. (Laws 2008)

Likewise in the life sciences, commentators express concern about the ability of law to keep pace with new scientific developments:

- [B]iomedical technologies are quickly outpacing the development of appropriate policies to inform the decision-making of researchers and the general public on many issues, including genetic testing, medical privacy, genetic discrimination and others. (Terry 2001)
- Science and technologies are outpacing the development of appropriate policies for decisionmaking. Genetic testing, medical privacy, genetic discrimination and others are some of the issues we face without having the right policies in place. (Eibert 2002)
- Although advances in genomics hold the potential for a range of preventive medical interventions of great value, risks to patients are also emerging. Laboratory regulation and accreditation measures have not kept pace with the growing demand for genetic tests. (WHO 2008)
- [R]egulatory institutions have not kept pace with our rapid technological advance. Indeed, there is today no public authority responsible for monitoring or overseeing how these [reproductive] technologies make their way from the experimental to the clinical stage, from novel approach to widespread practice. There is no authority, public or private, that monitors how or to what extent these new technologies are being or will be used, or that is responsible for attending to the ways they affect the health and well-being of the participants or the character of human reproduction more generally. (President's Council on Bioethics 2004)
- The synthetic life sciences seem to have emerged from nowhere, and their potential uses and misuses have taken the scientific and regulatory community by surprise . . .. [I]t is a reminder of how scientific development might leave moral, social, legal discourse in its wake. . .. (Samuel et al. 2009)

The same observation of lagging legal oversight is frequently made for information and communication technologies:

- As applied to the Internet, the traditional legal issues of property rights, commerce and trade, national sovereignty, and international remedy, are being examined in this new context. The old rules do not well apply, for this technology has outpaced the law. (Newman 2003)
- [E]lectronic surveillance law ... has failed to keep pace in adapting to new technologies, and ... provides for insufficient judicial and legislative oversight. (Solove 2004)
- Legislation ... is a slow process, often at pains to keep pace with rapid technological advance .... Technologies, after all, change faster than laws can. (Garfinkel 2002)
- The Internet has given the government powerful 21st-century tools for invading people's privacy and monitoring their activities, but the main federal law governing online privacy is a 20th-century relic. Adopted in 1996, it has had trouble keeping up with technological advances and is now badly out of date. (NY Times 2010)

This concern that law is badly trailing rapidly evolving technologies has been repeated literally dozens of time by experts working on dozens of technologies (See Moses 2007 for examples). Of course, there may be examples where it is preferable to delay writing new laws for regulating emerging technologies until the direction and risks of the new technology have been better determined. Premature regulation of a developing technology could result in poorly aligned regulations that inappropriately "lock in" inferior technological choices (Fong 2001). For example, attempts to regulate nanotechnology at the present time would likely be premature because the future direction and risks of this emerging technology (and, indeed, even an appropriate definition given the breadth of the term) are so uncertain.

Moreover, one of the key functions of law is to serve as a stabilizing mechanism to restrain rapid change based on human dynamics and preference shifts (Van Alstine 2002). Former Supreme Court Chief Justice Warren Berger once wrote: "It should be understood that it is not the role and function of the law to keep fully in pace with science" (Berger 1967). In some cases, then, the slow pace of legal evolution may provide important benefits by preserving stability and certainty. Finally, there may be cases where the law is too far in front of science rather than trailing behind it. Such an example might be the early litigation over silicone breast implants, where judges and juries were required to decide the safety of the implants before adequate scientific data on the safety of the devices had been generated (Jasanoff 1995).

These counterexamples, however, do not undermine the suggestion that, especially with foundational technology systems such as biotechnology, nanotechnology, and information and communication technologies, there is a substantial generic and novel problem caused by the inability of law to keep pace with rapidly developing science and technologies. As Waldmeir (2001) noted, "Throughout history, technology has always outpaced the law. In the end, the law catches up. But now, faced with technologies of unprecedented power, there is a risk . . .. that things could be different." Lyria Bennett Moses (2007) has identified four potential problems that may result from the failure of law to keep pace with technology, including: (i) the failure to impose appropriate legal restrictions and precautions to control the risks of new technologies; (ii) uncertainties in the application of existing legal frameworks to new technologies; (iii) the potential for existing rules to either under– or over-regulate new technologies; and (iv) the potential for technology to make existing rules obsolete.

Legal and regulatory systems have generally been oblivious to the growing lag between legal oversight mechanisms and the rapid pace of emerging technologies. One notable exception is the European Union's "Better Regulation" initiative, an integrated series of undertakings to improve the European regulatory system (European Commission 2010). A key objective of this initiative is "to identify overlaps, gaps, inconsistencies, obsolete measures, and potential for reducing regulatory burdens" without sacrificing the level of protection provided by the regulatory system (Commission of the European Community 2009, at 3). Even this initiative, however, has not achieved major successes in addressing the pacing problem, other than reducing some regulatory redundancies and overlaps.

A variety of potential legal mechanisms might provide a more flexible and adaptive regulatory system that can avoid or minimize some of the problems identified above. Some possibilities include:

1. *Innovations for Expediting Rulemaking*: As regulatory rulemaking has become increasingly lengthy and burdened with analytical and procedural requirements, regulatory agencies have recently begun exploring possible approaches for streamlining rulemaking. An example of such a measure is direct final rulemaking, whereby an agency issues a final rule without going through public comment, but will withdraw the rule and go through full notice-and-comment rulemaking if substantial public comments in opposition to the direct final rule are received (Levin 1995). This and other recent innovations attempted by federal or state regulatory agencies or proposed by administrative law scholars will be evaluated as strategies for keeping regulation more up-to-speed with science and technology.
2. *Self-Regulation or "Cooperative" Regulation*: In recent years, regulatory agencies such as the US Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA) have increasingly relied on "cooperative regulation" approaches under which industry essentially self-regulates under the supervision of the relevant federal agency (Pedersen 2001). The European Union and its member states are likewise increasingly recognizing and relying on self-regulatory approaches to fill the gaps and supplement traditional regulatory frameworks (Falkner et al. 2005). A prominent example is the covenant system of environmental regulation in the Netherlands, which is based on voluntary agreements between industry, government, and environmental organizations (Allenby 1999). Such self-regulatory approaches have the

benefit of achieving more expedited results without having to comply with all the formalities of official regulation, but also raise concerns about accountability and the lack of opportunity for public participation in regulatory decisions (Caldart and Ashford 1999).

3. *Issue-Specific Legislative Initiatives*: Congress recently enacted new statutes in several subject matters with the express purpose of making the statutes more current with changing technologies. Examples include the FDA Modernization Act of 1997 and the Digital Millennium Copyright Act of 1998. The process, effectiveness, and feasibility of such issue-specific statutory approaches remain to be evaluated.
4. *Specialized Courts*: In recent years, states such as Michigan and Maryland have taken steps to establish technology or cyber-courts to provide speedier and more sophisticated legal decisions in cases involving rapidly changing technologies (Maryland Business and Technology Court Task Force 2000; Ponte 2002). The feasibility and design of these specialized technology courts need to examined with respect to their potential for providing speedier legal resolution of technological disputes.
5. *Sunset Clauses*: One mechanism that legislatures can use to prevent statutes from becoming out-dated is to insert a sunset clause that results in the automatic expiration of the legislation after a given time-period (Mooney 2004). As the President's Council on Bioethics stated when recommending a four-year moratorium on therapeutic cloning rather than a permanent ban, a temporary ban that expires after a given period "make[s] it impossible for either side to cling to the status-quo," because the sunset of the legislation would force legislators to revisit the issue de novo (President's Council on Bioethics 2002).
6. *Periodic Reviews*: Some regulatory programs build in mandatory periodic reviews to assess the current status of the problem being regulated and to evaluate whether programmatic adjustments are warranted. An example of such a requirement is California's adoption of the zero emission vehicle mandate in 1990, scheduled originally to commence implementation in model year 1998. Recognizing the technology forcing challenge this mandate imposed on manufacturers, California regulators provided for a biennial program review that resulted in numerous delays and revisions to the applicable requirements. This periodic review provision resulted in considerable program instability, uncertainty and strategic behavior, but also allowed the program to adjust to changing expectations about the feasibility of zero emission vehicles.
7. *Independent Institutions*: Another strategy might be to create and delegate decision-making authority over an issue to a new free-standing commission or other institution that can make efficient, speedy adjustments in policy as a technology evolves. Such an entity would be less burdened by the political and bureaucratic restrictions that apply to existing political institutions. An example of such an institution might be the Commission on Base Closure and Realignment established by Congress in 1991 to determine which military bases should be closed which, according to at least one analysis, was able

to successfully protect professional norms from political pressures and make efficient decisions on the merits of the issue (Koven 1992). Independent institutions overseeing emerging technologies at the international level may also provide appropriate flexibility and adaptability. A good example is the Internet Corporation for Assigned Names and Numbers (ICANN), an independent entity given responsibility for managing the internet domain system and the many related technical and policy issues. According to ICANN, it's independent status gives it the flexibility to respond quickly to fast moving technological change: "ICANN's independence enables rapid response to changes within the commercial, technical and geopolitical landscape of the Internet and DNS. While rapid and flexible, the ICANN process also requires and considers input from all interested and affected constituencies." (ICANN undated).

8. *Adaptive Management*: Adaptive management was developed initially in ecology to provide an iterative approach for regulating complex ecosystems subject to frequent change. The premise of such adaptive management approaches was to use continual feedback to adjust policy in parallel with changing facts. In recent years, legal scholars have proposed that law could adopt a similar adaptive management approach (Ruhl 1997).
9. *Principles Based Regulation*: "Principles Based Regulation" is a new approach to regulation that involves the promulgation of general principles of expected behavior rather than detailed prescriptive rules. Regulated parties are then expected to implement the general principles in their own regulatory programs. The reliance on more general principles rather than detailed rules can provide greater flexibility for adjustments in response to new developments without the need to promulgate new regulations. This new approach has primarily been attempted in the financial services sector particularly in the United Kingdom to date, but a broader application has been proposed to provide a more adaptive regulatory system.

References

Allenby, Braden R. 2005. *Reconstructing earth: Technology and environment in the age of humans*. Washington, DC: Island Press.

Allenby, Braden R. 1999. *Industrial ecology: Policy framework and implementation.* Upper Saddle River, NJ: Prentice-Hall.

Baker, Debra 1999. Catching up to science. *American Bar Association Journal* 88 (Dec.): 88.

Bartlett Foote, Susan, and Robert J. Berlin. 2005. Can regulation be as innovative as science and technology? The FDA's regulation of combination products. *Minnesota Journal of Law, Science & Technology* 6: 619, 620–623.

Berger, Warren E. 1967. Reflections on law and experimental medicine. *UCLA Law Review* 15: 436–442.

Berndt, Ernst R., E.R. Dulberger, and N.J. Rappaport. 2000. Price and quality of desktop and mobile personal computers: A quarter century of history, 17 July 2000).

Blais, Lynn E., and Wendy E. Wagner. 2008. Emerging science, adaptive regulation, and the problem of rulemaking ruts. *Texas Law Review* 86: 1701–1739.

Brand, Stewart. 1999. *The Clock of the long now.* New York, NY: Basic Books.

Burk, Dan, and Mark Lemley. 2003. Policy levers in patent law. *Virginia Law Review* 89: 1575, 1575–1696.

Caldart, Charles C., and Nicholas A. Ashford. 1999. Negotiations as a means of developing and implementing environmental and occupational health and safety policy. *Harvard Environmental Law Review* 23: 141–202.

Campbell, Bradley M. 2008. Landmarks and land mines. *The Environmental Forum* (Nov./Dec.): 30–35.

Cardozo, Benjamin N. (1960). *The nature of the legal process* (Yale Paperbound ed 1960).

Carlson, Robert. 2003. The pace and proliferation of biological technologies. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 1: 203, 203–14.

Carr, Geoffrey 2010. Biology 2.0. *The Economist* (June 19, Supp: 1–3).

Commission of the European Communities. (2009). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Third Strategic Review of Better Regulation in the European Union, COM(2009) 15 final.

Eibert, Mark D. 2002. Human cloning: Myths, medical benefits and constitutional rights, *Hastings Law Journal* 53: 1097.

European Commission. 2010. Better Regulation. available at http://ec.europa.eu/governance/better_regulation/key_docs_en.htm#_br.

Falkner, Gerda, Oliver Treib, Miriam Hartlapp, and Simone Leiber. (2005). *Complying with Europe: EU harmonisation and soft law in the member states*. Cambridge: Cambridge University Press.

Kong Fong, I. 2001. Law and new technology: The virtues of muddling through. *Yale Law & Policy Review* 19: 443, 443–461.

Garfinkel, Simson. Oct 2002. An RFID bill of rights. *Technology Review* 35 *available at* http://www.simson.net/clips/2002/2002.TR.10.RFID_Bill_Of_Rights.pdf.

Garreau, Joel. 2001. *Science's mything links: As the boundaries of reality expand, our thinking seems to be going over the edge.* Washington Post Cl (July 23).

Garreau, Joel. 2005. *Radical evolution*. New York, NY: Random House).

Genbank 2010. GenBank Overview: What is Genbank? available at http://www.ncbi.nlm.nih.gov/genbank/. Accessed 14 July 2010.

ICANN (undated). ICANN Factsheet. available at http://www.icann.org/en/factsheets/fact-sheet.html.

International Risk Governance Council (IRGC). 2007. *Nanotechnology risk governance*. IRGC: Geneva.

Internet Systems Consortium, *ISC Domain Survey: Number of Internet Hosts.* 2008. http://www.isc.org/index.pl?/ops/ds/host-count-history.php.

Jaffe, Adam B., and Josh Lerner.2004. *Innovation and Its discontents: How our broken patent system is endangering innovation and progress, and what to do about it*. Princeton, NJ: Princeton University Press.

Jasanoff, Sheila. 1995. *Science at the bar: Law, science, and technology in America.* Cambridge, MA: Harvard University Press.

Johnson, Stephen M. 2008. Ossification's demise? An empirical analysis of EPA rulemaking from 2001–2005. *Environmental Law* 38: 767–792.

Jordan, W.S., III. 2000. Ossification revisited: Does arbitrary and capricious review significantly interfere with agency ability to achieve regulatory goals through informal rulemaking? *Northwestern University Law Review* 94: 393–450.

Jurvetson, Steve. 2004. *Transcending Moore's law with molecular electronics and nanotechnology. Nanotechnology Law & Business* 1: 70–90.

Kahn, Matthew E. 2007. Environmental disasters as risk regulation catalysts? The role of Bhopal, Chernobyl, Exxon Valdez, Love Canal, and Three Mile Island in Shaping US environmental law. *Journal of Risk and Uncertainty* 35: 17–43.

Kelly, James J. 2008. President of the Food and Drug Law Institute, *quoted in* David J. Hanson, *FDA Confronts Nanotechnology*, Chemical & Engineering News, 17 March 2008, at 32–34.

Kingdon, John W. 1995. *Agendas, alternatives, and public policies,* 2nd ed. New York, NY: Addison Wesley Educational Publishers.

Koven, Steven G. 1992. Base closings and the politics-administration dichotomy revisited. *Public Administration Review* 52: 526–531.

Kurzweil, Ray. 2003. Exponential growth an illusion?: Response to Ilkka Tuomi, essay (September 23) http://www.kurzweilai.net/meme/frame.html?m=1.

Kurzweil, Ray. 2005. *The singularity is near: When humans transcend biology*. London: Penguin.

LaForte, Amy J. 2004. Bone Morphogenetic Protein Combination Products and Orthopedic Repair, in Nat'l Research Council. *Proceedings From The Workshop On Science-Based Assessment: Accelerating Product Development Of Combination Medical Devices* 15 (Bonnie A. Scarborough ed).

Laws, Elliott P. 2008. Regulators facing a brave new world, The environmental forum. July/August 2008, at 14.

Levin, Ronald M. 1995. Direct final rulemaking, *George Washington Law Review* 64: 1, 1–34.

Lundstrom, Mark. 2003. Moore's Law forever? *Science* 299: 210, 210–211.

Lyman, Peter, and Hal R. Varian. 2003. *How much information.* available at http://www2.sims.berkeley.edu/research/projects/how-much-info-2003/ on 2 Nov. 2005.

Maryland Business and Technology Court Task Force, Final Report. 2000. available at http://www.courts.state.md.us/finalb&treport.pdf.

Mashaw, Jerry L., and David L. Harfst. 1991. *The struggle for auto safety.* Cambridge, MA: Harvard University Press.

McGarity, Thomas O. 1992. Some thoughts on deossifying the rulemaking process. *Duke Law Journal* 41: 1385, 1385–1462.

McGarity, Thomas, Rena Steinzor, Sidney Shapiro, and Mathew Shudtz. 2010. Workers at risk: regulatory dysfunction at OSHA, Center for Progressive Reform White Paper #1003.

Merrill, Richard A. 1988. FDA's implementation of the delaney clause: Repudiation of congressional choice or reasoned adaptation to scientific progress? *Yale Journal on Regulation* 5: 1, 1–88.

Miller, J. 2003. Beyond biotechnology: FDA regulation of nanomedicine. *The Columbia Science and Technology Law Review* 4: 1, 1–2.

Mireles, Michael S. 2005. The United States patent reform quagmire: A balanced proposal. *Minnesota Journal of Law, Science & Technology* 6: 709.

Mooney, Chris 2004. *A short history of sunsets*. *Legal Affairs* 67, 67–71. (Jan.–Feb. 2004), available at http://www.legalaffairs.org/issues/January-February-2004/story_mooney_janfeb04.msp.

Moore, Gordon E. 1965. Cramming more components onto integrated circuits. *Electronics* 38 (8): 114–117.

Moses, Lyria Bennett. 2007. Recurring dilemmas: The law's race to keep up with technological change. *University of Illinois Journal of Law, Technology & Policy* 2007: 239–285.

Newman, P. 2003. Trilateral seminar on science, society and the internet, opening statement by Judge Pauline Newman. A Dec. 14–16, conference sponsored by, inter alia, the NSF, available at www.law.gmu.edu/nctl/stpp/us_japan_pubs/internet-IIAIIB.pdf

New York Times. 2010. Dial-Up law in a broadband world (editorial). *NY Times*, April 9, at A18.

Office of Technology Assessment. 1986. *Intellectual property rights in an age of electronics and information*. Washington, DC: GPO.

Pedersen, William F. 2001. Contracting with the regulated for better regulations. *The Administrative Law Review*. 53: 1067, 1067–1138.

Pierce, Richard J. Jr., 1995. Seven ways to deossify agency rulemaking. *Administrative Law Review* 47: 59, 60.

Ponte, Lucille M. 2002. The Michigan Cyber Court: A bold experiment in the development of the first public virtual courthouse. *North Carolina Journal of Law & Technology* 4: 51, 51–91 (2002).

Popper, Steven W. 2003. Technological change and the challenges for 21st century governance. In *AAAS science and technology policy yearbook 2003*, eds. A.H. Teich et al., 83–103. Washington: American Association for the Advancement of Science.
President's Council on Bioethics. 2002. *Human cloning and human dignity: An ethical inquiry.* Washington, DC: GPO.
President's Council on Bioethics. 2004. Reproduction and responsibility: The regulation of new biotechnologies. Washington, DC: GPO.
de Solla Price, D.J. 1986. *Little science, big science . . .and beyond.* New York, NY: Columbia University Press.
Rejeski, David. 2004. *The next small thing*. The environmental forum, March/April 2004, at 45.
Roco, Mihail C., and William Sims Bainbridge. 2003. *Converging technologies for improving human performance: Nanotechnology, biotechnology, information technology and cognitive science*. Dordrecht: Klewer Academic Publishers.
Roco, Mihail., and Ortwin Renn. 2007. International Risk Governance Council, Policy Brief: Nanotechnology Risk Governance – Recommendations for a Global, Coordinated Approach to the Governance of Potential Risks.
Ruhl, J.B. 1997. Thinking of environmental law as a complex adaptive system: How to clean up the environment by making a mess of environmental law. *Houston Law Review* 34: 933–1002.
Samuel, Gabrielle N., Michael J. Selgelid, and Ian Kerridge. 2009. Managing the unimaginable. *EMBO Reports* 10: 7–11.
Shea, Lonnie D., and Tiffany L. Houchin. 2004. Modular design of non-viral vectors with bioactive components. *Trends In Biotechnology* 22: 429.
Solove, Daniel J. 2004. Reconstructing electronic surveillance law. *George Washington Law Review* 72: 1264.
Terry, Sharon T. 2001. Prepared testimony before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, House of Representatives, 107th Congress, *Issues Raised by Human Cloning Research,* 28 Mar. 2001.
Thurow, Lester C. 1997. Needed: A new system of intellectual property rights. *Harvard Business Review* 75 (5): 94–103.
Trajtenberg, Manuel. 1990. *Economic analysis of product innovation: the case of CT scanners*, Cambridge, MA: Harvard University Press.
Tuomi, Ilkka. 2003. *Kurzweil, Moore, and Accelerating Change*, Joint Research Centre, Institute for Prospective Technological Studies, Working paper 27 (August 2003), http://www.meaningprocessing.com/personalPages/tuomi/articles/Kurzweil.pdf.
United States v. Microsoft Corp. 2001. 253 F.3d 34. (D.C. Cir.).
Van Alstine, Michael P. 2002. The costs of legal change. UCLA Law Review. 49: 789–870.
Waldmeir, Patti. 2001. Lawmakers Struggle to Keep Up, Financial Times, 2 Oct. 2001 at 13.
Warner, Gerald. 2008. If You're Reading This, Perhaps All is Well. *Daily Telegraph* (Sept. 10) at 21.
World Health Organization (WHO). 2008. *Quality & Safety in Genetic Testing: An Emerging Concern.* available at: http://www.who.int/genomics/policy/quality_safety/en/index.html.
WIPO (World Intellectual Property Organization). 2007. Patent Report: Statistics on Worldwide Patent Activity (2007 Edition). http://www.wipo.int/ipstats/en/statistics/patents/patent_report_2007.html#P173_14118.