CAN TECHNOLOGICAL INNOVATION SURVIVE GOVERNMENT REGULATION?

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In this Article, I will offer a few observations on the troublesome relationship between technological innovation and government regulation. That relationship is neither simple nor linear. In many instances, regulation is strictly necessary because the alternative—a form of case-by-case-litigation—can easily prove to be worse.[1] In other cases, regulation is necessary to secure the creation of property rights in individuals that are good against the rest of the world—a state of affairs that no system of voluntary contracts can hope to create.[2] In other

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1. Edward L. Glaeser & Andrei Shleifer, *The Rise of the Regulatory State*, 41 J. ECON. LITERATURE 401, 402–03 (2003) (positing market regulation as response to dissatisfaction of litigation).

2. SIMEON DJANKOV, THE WORLD BANK, DOING BUSINESS IN 2004: UNDERSTANDING REGULATION 111 (2004), *available at* http://www.doingbusiness.org/~/media/FPDKM/Doing%20Business/Documents/Annual-Reports/English/DB04-FullReport.pdf. *See also* Glaeser & Shleifer, *supra* note 1, at 419 (explaining how increased government regulation led to "significant social progress" between 1887 and 1917); Margaret Jane Radin, *Property and Personhood*, 34

situations, the security of various transactions may depend on regularizing contractual relations by creating state registries.[3] Every system of law needs a system of regulation. Even in purely competitive markets, a system of property rights must be established. Systems of recordation and a statute of frauds are needed to make the system operate properly, and taxes and other income streams are required to support the public activities that are needed to make the system work. The belief that a disembodied free market, one which does not rest upon government force, will function effectively is certainly a mistake of epic proportions, if not an anarchist myth. At bottom, the proper inquiry never poses the stark choice of regulation versus no regulation. Instead, the inquiry is much more modulated; it seeks to find what kinds of regulation are desirable due to the positive consequences they bring about and, conversely, what kinds of regulations are generally dubious because of the negative consequences they bring about.

So we need to find some test that allows us to sort regulations into those which should be welcome and those which should be opposed. For the business activities at issue in this discussion, I propose one test that should go a long way to organize this inquiry. In virtually every case, desirable regulations are those that are designed to fortify a system of competitive markets through reverse engineering. Robust (but never pure) competition is what is desired. Which regulations, then, will move the overall operation of the legal system in that direction? Strong property rights protected by regulation, statutes of frauds on formalities of contract, prevention of inducement to breach of contract, and the use of force against contracting parties all fortify a competitive market system. No one can quarrel with the need for regulation in these areas nor treat such regulation as part of a vast regulatory state that should be the object of our collective wrath.

This Article discusses two important fields within technology. Each field requires at least some deviation from, or at least some modification of, the kinds of solutions that are welcome in competitive markets involving standard goods and services. The first of these two fields is the intellectual property system, which

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STAN. L. REV. 957, 1013 (1982) (discussing the importance of the right to personal property, particularly the home, as a significant part of a society).

3. Juan Botero et al., *The Regulation of Labor* 2 (Nat'l Bureau of Economic Research, Working Paper No. 9756, 2003), *available at* http://www.nber.org/papers/w9756.

chiefly comprises copyrights, patents, trademarks, and trade secrets. The other field is the network industry system, which deals with railroads, telecommunications, and other related technologies. What makes these two areas unique? What kinds of regulations ought we to welcome in them? And what kinds of regulation should be rejected as excessive or counterproductive?

I. INTELLECTUAL PROPERTY

I begin with intellectual property, a field in which the first possession rule—invariably used to acquire title in land, chattels and animals—cannot do the job.[4] It is simply not enough to allow people to take first physical possession of property and then announce that they own it. Recognizing this fundamental point, Congress in 1790 passed the Patent[5] and the Copyright Acts.[6] What makes these statutes, at least in large measure, a long-term success? First, neither statute is meant to be technologically coercive within its respective domain. The Patent Act provides a system in which priority goes either to the first to invest for the first to file—there is a dispute as to which of these two is more important—the law will furnish an examiner, through the Patent and Trademark Office (PTO),[7] who makes an initial determination as to whether or not the patent is valid.[8] If the patent is protected, it falls into the sphere of ordinary property rights that should be protected by injunctions and damages in the event of infringement.[9] This protection against infringement is the intellectual property analog to the ordinary tort of trespass, and it provides the institutional framework that allows patentees to sell or license an invention. Because the Patent Act creates a decentralized system that al-

4. *See, e.g.*, Anupam Chander, *The New, New Property*, 81 TEX. L. REV. 715, 733–36 (2003) (discussing the tendency of a first possession rule for intellectual property to exacerbate distributional inequalities by providing windfalls to established actors); *see also* Richard A. Epstein, *Addison C. Harris Lecture Nov. 9, 2000*, 76 IND. L.J. 803, 815 (2001) (discussing difficulties inherent in applying a first possession rule to patents).

5. Patent Act of 1790, ch. 7, 1 Stat. 109–12 (1790).

6. Copyright Act of 1790, ch. 15, 1 Stat. 124 (1790) (Westlaw 2012).

7. 35 U.S.C. § 3(b)(3) (2012) (allowing the Director of the USPTO to appoint examiners).

8. 35 U.S.C. § 131 (2002) (prescribing examination of patent applications).

9. 35 U.S.C.A. §§ 283–84 (2012).

lows anyone to participate,[10] the only real questions involve fine-tuning that system to make it as efficacious as possible.

In dealing with this question, the Patent Act of 1952[11]—the governing statute before the America Invents Act of 2011 (AIA)[12]—was reasonably effective at determining which type of advances in particular subject matters were eligible for patent protection. The 1952 Patent Act also specified what level of advancement over previous inventions was required to obtain protection, among its requirements.[13] Of course, some features of this system were controversial and resulted in systems that tended to drive a wedge between the ordinary rules of property and those for patents. Two notable decisions illustrate this tension. First, *eBay Inc. v. Mercexchange, L.L.C.*[14] weakened the ability of patentees to obtain injunctive relief as a matter of course and thus emboldened infringers to engage in activities for which monetary damage is hard to determine. Second, *Quanta Computer, Inc. v. LG Electronics, Inc.*[15] undermined the efficacy of the licensing system by imposing unnecessary restraints on the principle of freedom of contract.[16] Unfortunately, the patent system has only been weakened further with the passage of the AIA,[17] whose elaborate and complicated reexamination provisions are likely to increase the level of uncertainty about patent validity.[18] In addition, the AIA has the further demerit of fragmenting patents by hiving off business

10. *See, e.g.*, B. Zorina Khan, Innovations in Intellectual Property Systems and Economic Development 19 (Jan. 2002) (unpublished manuscript) (on file with author), *available at* http://www.econ.yale.edu/seminars/echist/eh02/khan-020328.pdf.

11. Patent Act of 1952, ch. 950, 66 Stat. 792 (current version at 35 U.S.C. (2006)).

12. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

13. 35 U.S.C. § 103 (2006); *see also* Dan Hoang, Prometheus Laboratories v. Mayo Clinic*'s Gift to the Biotech Industry: A Study of Patent-Eligibility of Medical Treatment and Diagnosis Methods after* Bilski, 9 NW. J. TECH. & INTELL. PROP. 457, 459 (2011).

14. 547 U.S. 388, 388 (2005) (holding that courts of equity should apply the same standard for granting permanent injunctive relief in a patent case as they do in other types of disputes).

15. 553 U.S. 617 (2008).

16. For my views on these cases, see Richard A. Epstein, *The Disintegration of Intellectual Property? A Classical Liberal Response to a Premature Obituary*, 62 STAN. L. REV. 455, 488–95, 508–10 (2010).

17. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

18. Jason Rantanen & Lee Petherbridge, Commentary, *Toward a System of Invention Registration: The Leahy-Smith America Invents Act*, 110 MICH. L. REV. FIRST IMPRESSIONS 24, 24–27 (2011).

method patents for special treatment.[19] The simplicity and robustness of the older system under the 1952 Act was superior.

The current level of dissatisfaction with the system has led to calls for a wholesale reorientation of the patent system, including the sharp truncation or even abolition of software and business method patents, which are said to have a blocking potential that exceeds their use value.[20] I tend to be very cautious about accepting major changes of this sort. One sensible incremental change would be to increase the resources available to the PTO to deal with the onslaught of patents, both to weed out weak patents and to speed production under strong protection to market. Another response is to give infringers more time to bargain with patent holders or to invent around patents. Yet another response is to hit frivolous law suits (some of which surely exist) with harder sanctions in discovery and after trial. But large changes could easily prove counterproductive, for despite all the anti-patent angst, the software industry, which is the subject of much wrath, has done well in spite of its extensive litigation burden, which in my view has been aggravated by the weakening of the property rights regime. Moreover, at most only some of this litigation has been far-fetched and unsound. My fear is that any systematic effort to change the shape of the patent system will have a fair measure of negative unintended consequences. Any changes will upset settled expectations with regard to existing patents, including the many patents that have led useful if uneventful lives that never reached the level of urban legend.

The issue with copyrights is quite different. Copyrights also need some system of registration, but they do not require intensive examination akin to that given patents before the PTO.[21] The

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19. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 18, 125 Stat. 284, 329–31 (2011).

20. For one outspoken anti-patent piece, see Charles Duhigg and Steve Lohr, *The Patent, Used as a Sword*, N.Y. TIMES, Oct. 8, 2012, at A1, *available at* http://www.nytimes.com/2012/10/08/technology/patent-wars-among-tech-giants-can-stifle-competition.html?nl=todaysheadlines&emc=edit_th_20121008. For one recent scholarly critique, see ROBIN FELDMAN, RETHINKING PATENT LAW (2012).

21. Under 17 U.S.C. § 408(a) (2006), registration of works is not a condition of copyright protection. The copyright attaches as soon as the author fixes the work in a "tangible medium of expression," as long as the other requirements for copyright—authorship and a modicum of originality—are met. *See* 17 U.S.C. § 102 (2006). Under 17 U.S.C. § 411 (2006), however, in order to commence an infringement suit, copyright owners must register their work by depositing a copyright claim in the Copyright Office.

copyright and patent systems have widely parted company in that regard.[22] The durability of copyrights does not lend itself to one simple solution. In general, copyrights for software (like all patents) are short-lived, but the protection afforded literary works such as Shakespearean sonnets should be substantially longer, for they are far more unique than any scientific invention.[23] But any gratuitous extensions of the length of the patent should be considered very cautiously. Therefore, the Copyright Term Extension Act[24] was, and remains, a major policy mistake.[25] Throughout history, copyrights and patents have hewed closely to the privatized model. The more closely that copyright and patent law track traditional forms of property can be made, the better off society will be.[26]

II. NETWORK INDUSTRIES

In contrast to intellectual property, the regulation of network industries technology should be modeled on the traditional rules for common carriers. This model allows all parties to gain access to a single integrated network, such that any user anywhere on the network can directly communicate with any other user.[27] Picking the right solution can make a huge differ-

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22. Under § 1 of the 1790 Patent Act, patent applications were examined by the Attorney General, the Secretary of State, and the Secretary of War. Patent Act of 1790, ch. 7, § 1, 1 Stat. 109, 109–10 (1790). This system quickly proved unworkable. For the subsequent evolution, see Andrew P. Morriss & Craig Allen Nard, *Institutional Choice & Interest Groups in the Development of American Patent Law: 1790-1865*, 19 SUP. CT. ECON. REV. 143, 149–51 (2011). From 1793 to 1836, patents—like copyrights—operated under a registration system, which did not screen patents, but left the determination of their validity to after the fact by the district courts. *Id.* at 152–61. The Patent Office reinstituted the earlier patent examination system under the Patent Act of 1836, ch. 357, § 1, 5 Stat. 117, 117–18 (1836).

23. Under 17 U.S.C. § 302(a) (2006), the term of copyright protection for most works published after 1977 is generally the life of the author plus seventy years. Under 35 U.S.C. § 154(a)(2) (2006), patents are protected for twenty years from the date on which the patent application was filed.

24. Sonny Bono Copyright Term Extension Act, Pub. L. No. 105-298, § 102, 112 Stat. 2827, 2827–28 (1998) (codified as 17 U.S.C. § 302) (extending the duration of copyright terms from fifty years to seventy years).

25. *See generally* Richard A. Epstein, *The Dubious Constitutionality of the Copyright Term Extension Act*, 36 LOY. L.A. L. REV. 123 (2002).

26. Epstein, *supra* note 16, at 456 (explaining that intellectual property is best treated as "a coherent subset of a larger body of property law").

27. Richard A. Epstein, *Before Cyberspace: Legal Transitions in Property Rights Regimes*, 73 CHI.-KENT L. REV. 1137, 1145–47 (1998) (explaining that regulation may

ence. For example, the Telecommunications Act of 1996[28] was passed a bit too soon and caused trillions of dollars in losses[29] because it adopted the wrong solution. It incorrectly assumed as its fundamental postulate that local exchange carriers would retain their monopoly power for a long period of time. The Act therefore designed a complex system that sought to jump start competition by allowing the formation of new companies, Competitive Local Exchange Carriers (CLECs), that were allowed to buy network elements from one another on what turned out to be highly favorable terms.[30] The Telecommunications Act successfully reflected the elements of the basic technology as it existed in 1996. But by 1998, the Act's implicit assumption—the dominance of the exclusive power of the local exchange carriers (LECs)—was clearly wrong. Allowing the government to force the sale of particular network elements at bargain prices created distortions in that market, which ultimately helped nobody.[31] The CLECs competed away the subsi-

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be necessary to ensure that "all persons . . . [have] access to the network," and that "no class of users . . . be required to subsidize another.").

28. Pub. L. No. 104-104, 110 Stat. 56 (1996).

29. *See* COMMON CAUSE EDUC. FUND, THE FALLOUT FROM THE TELECOMMUNICATIONS ACT OF 1996: UNINTENDED CONSEQUENCES AND LESSONS LEARNED 3–5 (2005), http://www.commoncause.org/atf/cf/%7BFB3C17E2-CDD1-4DF6-92BE-BD4429893665%7D/FALLOUT_FROM_THE_TELECOMM_ACT_5-9-05.PDF.

30. The Act was structured on the assumption that local exchange carriers (LECs) would continue to dominate the telecommunications industry. It failed to anticipate the transformative impact of cellular technology. *See* Richard A. Epstein, *The AT&T Consent Decree: In Praise of Interconnection Only*, 61 FED. COMM. L.J. 149, 154–56 (2008); *see also* Richard A. Epstein, *Takings, Commons, and Associations: Why the Telecommunications Act of 1996 Misfired*, 22 YALE J. ON REG. 315, 319–20 (2005); Press Release, Mediamark Research Inc., Telecom Milestone: More Cellphone-Only Than Landline-Only Households (Sept. 12, 2007), *available at* http://www.gfkmri.com/PDF/Telecom%20Milestone%20More%20Cell%20Phone%20Only%20Than%20Landline%20Only%20Households.pdf (showing that, by mid-2007, households with only cell phone connections outnumbered those with only landline connections).

31. 47 U.S.C. § 251(c)(3) (requiring local exchange carriers to sell off unbundled network elements to competing entrants "on rates, terms, and conditions that are just, reasonable, and nondiscriminatory" and "in a manner that allows requesting carriers to combine such elements in order to provide such telecommunications service"); Julian Epstein, *A Lite Touch on Broadband: Achieving the Optimal Regulatory Efficiency in the Internet Broadband Market*, 38 HARV. J. ON LEGIS. 37, 57–60 (2001); Epstein, *The AT&T Consent Decree*, *supra* note 30, at 162 (explaining that Section 251(c)(3) of the Telecommunications Act of 1996 frequently forced incumbent carriers to sell components at a price too low for them to recover the cost of their investment).

dies and could not survive.[32] The LECs were forced to enter into credit transactions with the CLECs, draining the LECs of valuable resources.[33] Here, the mistake was to have the government create a system of forced exchanges rather than supervise interconnection agreements, which it could have done relatively easily.[34]

In today's new age, entry into the telecommunications market has become relatively easy because of the decline of the local monopolies under the LECs.[35] Instead of trying to force people to interconnect, the better plan, as it turned out, would have been for the government to allow private investors to build and strengthen other kinds of networks, and, in the course of using those networks, enter into competition with one another.[36] In many cases interconnection may be necessary; but in many other cases, it will not—for instance, the many networks designed to transmit huge amounts of data that do not require universal connectivity, which can easily impair the sensitive task of data protection.

What principles determine the appropriate system of regulation? If new technology facilitates the creation of competitive networks, the established firm or firms should no longer be treated as holding the monopoly power normally attributed to a single supplier or a dominant firm in a particular market. Instead, the industry as a whole should be treated as competitive.

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32. *See* Ron Hubert, *The CLEC Train Wreck*, CONNECTED PLANET ONLINE, Oct. 10, 2001, http://connectedplanetonline.com/news/telecom_clec_train_wreck/.

33. *See* STEPHEN POCIASK, TELESCAM: HOW TELECOM REGULATIONS HARM CALIFORNIA CONSUMERS 11 (2003), *available at* http://special.pacificresearch.org/pub/sab/techno/telescam/Telescam%20Oct.pdf (noting that "[a]cross all states and the District of Columbia, ILECs [incumbent local exchange carriers, also known as LECs] stand to lose $38 billion in revenues if they are forced to sell all their retail services at bargain wholesale rates").

34. Epstein, *The AT&T Consent Decree*, *supra* note 30, at 163 (interconnection agreements would be superior to forced sales because "[t]he key decisions on how to expand the network would be made by market players" rather than through the administrative process, which is "filled with major uncertainties and lengthy delays.").

35. *See* Press Release, Mediamark Research Inc., *supra* note 30.

36. *See* Jeffrey A Eisenach & Thomas M. Lenard, The Progress & Freedom Fund, *Telecom Deregulation and the Economy: The Impact of "UNE-P" on Jobs, Investment and Growth*, PROGRESS ON POINT, Jan. 2003, at 4, *available at* http://ssrn.com/abstract=1260407 (predicting that "immediate elimination of obligations to provide unbundled network elements at below cost rates would raise GDP growth by between $14 and $34 billion this year, and create 282,000 to 669,000 jobs over the next three years.").

Therefore, government actors should let market players determine both the composition of the traffic that runs over their networks and the prices they charge for the traffic they agree to carry. In effect, whenever alternative networks are available, the last thing government regulators should attempt is to impose any kind of network neutrality requirement on these systems. This type of requirement becomes a new form of wealth transfer from those who built the infrastructure to content providers.[37]

The dangers of network neutrality depend in large measure on the structure of the information market. If the information sent over the network is relatively homogenous, and the cost of providing it is relatively low, the losses of running a pro rata system that gives all content providers equal access is likely to be small. Indeed, in many cases, firms in voluntary markets employ a pro rata system when it is not worthwhile for them to engage in any form of discrimination.[38] But once the amount, type, or value of information that is sent over networks begins to vary, the prohibitive costs of the pro rata policy make access and pricing essential for maintaining sound network operations.[39] AT&T's decision to limit the amount of data that any one customer could access or send through the network illustrates this trend.[40] Unless other telecommunications providers

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37. Robert E. Litan & Hal J. Singer, *Unintended Consequences of Net Neutrality Regulation*, 5 J. TELECOMM. & HIGH TECH. L. 533, 558–60 (2007) (imposing a one-size-fits-all pricing policy on ISPs would likely result in higher prices for the average consumer, who would be forced to subsidize heavy users); Dennis L. Weisman & Robert B. Kulick, *Price Discrimination, Two-Sided Markets, and Net Neutrality Regulation*, 13 TUL. J. TECH. & INTELL. PROP. 81, 95 (2010) (observing that allowing Internet service providers (ISPs) to charge differential prices is efficient and encourages ISPs to invest capital in their network: "[P]rotecting less-efficient content providers by prohibiting access-tiering would harm society by impeding more-efficient content providers and limiting the choices available to the Internet subscribers they serve. This outcome would involve an arbitrary transfer of economic wealth to less-efficient content providers.").

38. This has not, however, been the case in network industries: "[I]n the telecommunications industry, regulated carriers have long been permitted to offer their customers a variety of service options for both long-distance and local service. Extended area service, local measured service, flat-rate service, and flat-rate calling plans are all examples in which regulators have permitted customers to choose between different price-quality combinations for their telecommunications services." Weisman & Kulick, *supra* note 37, at 96.

39. William D. Rahm, *Watching over the Web: A Substantive Equality Regime for Broadband Applications*, 24 YALE J. ON REG. 1, 17–20 (2007).

40. Jeffry Bartash, *AT&T to end unlimited plans for wireless data*, WALL ST. J. MARKETWATCH, June 2, 2010, http://articles.marketwatch.com/2010-06-02/markets/30722124_1_heavy-data-at-t-customers-data-usage (noting that on June 7, 2010,

adopt that strategy, serious negative externalities will attach as overall network capacity increases: as a telecommunications provider enlarges the pipe, its customers will be able, at no increase in cost, to send larger quantities of data over the network.[41] In 1990 nobody would have tried to send hundreds of movies over the networks; the capacity was simply not available.[42] But now that the networks are large enough,[43] a network user might attempt to do just that.

At this point, tiered access and pacing—in other words, a differentiation in rates—has this key effect: more valuable information will come to the head of the network queue, increasing the overall value of the information sent through the network.[44] Therefore, once two or three carriers are willing to participate in a given market, that market should be treated as competitive and thus not well suited to price regulation. But if only one or two carriers participate in a given market, the market is not yet competitive; in this case, some regulation may be appropriate. But even in a dynamic market, caution should be the rule, so as to encourage new entrants to join the market and reduce the instances of, and need for, any system of direct regulatory control. The risk here is that heavy-handed government regulation, which sets prices and mandates service, will make the technology industry look like the healthcare industry with its manda-

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AT&T replaced its unlimited $30 per month data plan for cellular data usage with a $25 "DataPro" plan, which capped data usage at 2 gigabytes per month, because "[h]eavy data usage by a tiny percentage of customers [had] occasionally clogged networks and reduced the quality of wireless service for other subscribers").

41. Rahm, *supra* note 39, at 17–18 (observing that heavy usage of bandwidth by a "small set of users" imposes negative externalities on other users); *see also* Dionne Searcey, *Consumers Could See New Web Rates: Use More, Pay More*, WALL ST. J., Mar. 2, 2006, at B1, *available at* http://online.wsj.com/article/SB114126093188287053.html (relating a statement from BellSouth Chief Technology Officer William Smith, who claims that "at BellSouth, 1% of broadband customers drive 40% of Internet traffic").

42. *See* BRET SWANSON & GEORGE GILDER, DISCOVERY INST., ESTIMATING THE EXAFLOOD: THE IMPACT OF VIDEO AND RICH MEDIA ON THE INTERNET 4–5 (2008), *available at* http://www.discovery.org/scripts/viewDB/filesDB-download.php?command=download&id=1475 (noting that the explosion in internet usage in the mid-1990s was caused, in part, by "dramatic advances in fiber-optic communications in the core of the network, both of which supplied unprecedented *physical* connectivity").

43. *Id.* at 3 (positing that, according to one study, "[t]he U.S. Internet of 2015 will . . . be [at least] 50 times larger than it was in 2006," in large part because of the proliferation of online video and of practices such as multimedia streaming).

44. Weisman & Kulick, *supra* note 37, at 96–98 (discussing benefits of price discrimination in the context of telecommunications).

tory service requirements, and of course its highly controversial individual mandate.

The adjudication with respect our telecommunications systems in the next generation will determine, for better or for worse, whether or not this nation, or other nations, will maintain its energetic drive. Every time tough regulations apply to networks, content providers will benefit to some extent in the short run but at the cost of retarding additional investment in the network itself.[45] Voluntary arrangements are still the best way to determine the optimal way to structure interactions between content providers and carriers outside the control of the regulatory state.[46] In the short term, the battle over the Internet may well look like some form of second-best monopolistic competition. Nonetheless, in the long run, allowing technology to be free from regulation will make the system both more competitive and more efficient. The weight of the evidence supports light-handed regulation.

III. PHARMACEUTICAL INNOVATION

I also disagree with the huge expansion of federal power in the health sector, and I will relate a specific story as to why. When it was founded in 1906, the Food and Drug Administration (FDA) lacked the authority to regulate the manufacture of drugs within the states.[47] Congress granted that power to the FDA in 1938 in the aftermath of the 1937 constitutional transformation of the federal commerce power.[48] One of the most notable advances in medicine in the years between those two legislative landmarks was the isolation and purification of insulin as a viable treatment for diabetes. At that time, diabetes was always fatal to those it afflicted.[49] The story of this great event could not be repeated today. From 1921–1922, at the University of Toronto in Canada, Frederick Grant Banting, working with the assistance of medical student Charles Best, figured out how

45. *Id.* at 95–96.

46. *Id.* at 94–98.

47. *A History of the FDA and Drug Regulation in the United States*, FDA, http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm093550.pdf (last visited Nov. 10, 2012).

48. *Id.*

49. *See* Richard A. Epstein, *The Tale of How Insulin Came to Market*, HOOVER INST. (Jan. 2, 2011), http://www.hoover.org/publications/defining-ideas/article/61436.

to isolate and purify insulin.[50] Initially, many of the dogs whom Banting and Best injected with insulin died.[51] Moreover, once Banting and Best unlocked the original formula, they managed to forget key elements of their process, which they regained only after frantic efforts.[52] Nonetheless, progress was rapid, especially once Banting obtained the backing of Eli Lilly and Company, a great American pharmaceutical company.[53] By 1923, Eli Lilly as able to bring insulin to the entire North American market.[54] Banting and Best—despite being regarded as unqualified to conduct serious research[55]—made the requisite technological breakthough by a combination of keen insight and dumb luck.[56] Despite the difficulties, it took less than three years for insulin to go from an idea hatched in one of Banting's dreams[57] to being a marketable product.[58] The key transformation took between two and three years to accomplish.

The gain from this invention was enormous. Before 1921, the treatment for diabetes was slow starvation.[59] Essentially, doctors slowed the metabolic processes, and patients were forced to endure a starvation diet.[60] The case of Elizabeth Hughes, the daughter of the great Charles Evans Hughes, illustrates the breakthrough that the introduction of insulin into the market accomplished. Diagnosed with diabetes in 1919 at age eleven,[61] she weighed only forty-eight pounds in 1922, having survived until the age of fifteen.[62] When, in the nick of time, her caretakers

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50. *Frederick Grant Banting (1891-1941): Codiscoverer of Insulin*, 198 JAMA 660, 660 (1966); *The Discovery of Insulin*, NOBELPRIZE.ORG: THE OFFICIAL WEB SITE OF THE NOBEL PRIZE, http://www.nobelprize.org/educational/medicine/insulin/discovery-insulin.html (last visited Nov. 10, 2012).

51. *See* Louis Rosenfeld, *Insulin: Discovery and Controversy*, 48 CLINICAL CHEMISTRY 2270, 2274 (2002).

52. *Id.* at 2279.

53. *Id.* at 2279–80.

54. *Id.* at 2280.

55. *See id.* at 2277.

56. *See id.* at 2271.

57. *See id.* at 2271.

58. *Id.* at 2271, 2280.

59. LEWIS WEBB HILL & RENA S. ECKMAN, THE STARVATION TREATMENT OF DIABETES 9–13 (1915); *see also* Robert Tattersall, *Pancreatic Organotherapy for Diabetes, 1889–1921*, 39 MED. HIST. 288, 310–11 (1995).

60. Tattersall, *supra* note 59, at 289.

61. THEA COOPER & ARTHUR AINSBERG, BREAKTHROUGH: ELIZABETH HUGHES, THE DISCOVERY OF INSULIN, AND THE MAKING OF A MEDICAL MIRACLE 20–23 (2010).

62. *Id.* at 185.

administered insulin, it was like Lazarus rising from the dead. She started to gain weight,[63] married at age twenty-three,[64] bore several children,[65] managed to self-administer insulin and lived until the age of seventy-three.[66] The government played only one role in this story, and that role was a near tragic byproduct of prohibition. When Banting's work was continued in the United States, researchers had difficulty obtaining the pure ethanol necessary to isolate insulin: Federal officials sought to block the use of ethanol on the grounds that methanol could do as much good for patients as insulin.[67] The Rockefeller family had to wield its sizable influence to obtain permission to use the ethanol needed for the process to go forward.[68] By 1924, insulin was in general production and, by 1930, its price had dropped twentyfold, or by ninety-five percent.[69]

This episode presents some clear lessons about the dynamics of production. One lesson is that the invention and discovery of insulin, which went from idea to commercialization in a mere three years, contributed more to human beings and their welfare than every single other advance, taken together, with respect to diabetes in the following ninety years, perhaps by an order of magnitude. Similarly, in technology, the first round of innovation results in huge gains, whereas ten times the amount of effort and money is required for the next advancement, resulting in one-tenth the improvement. The FDA has dampened the innovation cycle, because of its belief that aggressive regulations will protect people from abuse and crackpot medicines.[70] The fate of insulin would have been uncertain if the

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63. *Id.* at 206.

64. *Id.* at 239.

65. *Id.* at 244.

66. *See id.*

67. *See* Epstein, *How Insulin Came to Market*, *supra* note 49.

68. *Id.*

69. *See* Christopher J. Rutty, *Couldn't Live Without It: Diabetes, the Cost of Innovation and the Price of Insulin in Canada, 1922-1984*, 25 CAN. BULLETIN OF MED. HIST. 407, 418 (2008).

70. *See* JOSH MAKOWER, FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION: A SURVEY OF OVER 200 MEDICAL TECHNOLOGY COMPANIES 5 (2010), http://www.nvca.org/index.php?option=com_docman&task=doc_download&gid=668&Itemid=93 (noting that "independent analysis has demonstrated that the current system does an exceptional job at protecting patients . . . [but] that, with regard to the agency's objective of promoting the public health through new innovations, there are increasing concerns from patients, physicians, and innovators that the FDA is falling short").

FDA had oversight of the discovery process back in the early 1920s. The unfortunate result of the FDA's modern incarnation is to cut people off from the very medications and medical devices that might be able save them. The FDA begins with the view that, unless the applicant can prove to the agency's satisfaction that its product or device is safe, no individual—acting alone or with the aid of a physician—is able to make sound judgments, even on matters so close to his personal welfare.[71]

The clash between the FDA and the right of an individual to make healthcare decisions came to a head in the well known case of *Abigail Alliance v. Von Eschenbach*,[72] which raised a sustained challenge to the FDA's power to control the use of drugs by patients. That claim was accepted by the initial panel, by a two-to-one majority. Judge Judith Rogers and Judge Douglas Ginsburg found a constitutional right to use potentially life-saving investigational new drugs that had gone through Phase I trials.[73] The majority rested its holding on the autonomy-based rationale that people are entitled to control their own health care destinies.[74] Judge Thomas Griffith dissented.[75] When the case was heard en banc, Judge Griffith's dissent became the majority opinion, and the Alliance's constitutional claim was denied.[76] The right to *refuse* medical treatment does today have constitutional status, but the converse right to *accept* treatment decidedly does not.[77]

In dealing with the general issue of health care regulation, the U.S. Supreme Court held in *United States v. Rutherford*[78] that the Federal Food, Drug, and Cosmetic Actoffers no exception from compliance with the FDA requirements for terminally ill patients. The drug involved in that case was Laetrile,[79] which

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71. *See, e.g.*, Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. 75-717, § 505(b), 52 Stat. 10, 1052 (1937–1938) (requiring manufacturer to demonstrate a new drug is safe for its proposed used before the FDA may give its approval).

72. 445 F.3d 470 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007).

73. *Abigail Alliance*, 445 F.3d at 486. As explained by the Abigail Alliance Court, FDA Phase I trials determine only that a drug is sufficiently safe to be tested on humans but not that the drug is ready for commercial distribution. *Id.* at 473.

74. *Id.* at 486.

75. *Id.* at 486–500.

76. *Abigail Alliance*, 495 F.3d at 697.

77. For discussion, see Richard A. Epstein, *The Erosion of Individual Autonomy in Medical Decisionmaking: Of the FDA and IRBs*, 96 GEO. L.J. 559 (2008).

78. 442 U.S. 544, 544 (1979).

79. *Id.* at 546.

had a long history of failure.[80] But *Rutherford* surely extends much further, for it applies to many therapies where private initiative can advance the scope of medical progress. My late mother-in-law, who suffered from Myasthenia Gravis, provides an example. The disease eventually killed her, but in the years that she suffered from the disease, she acquired more intimate knowledge about its peculiarities than most of the physicians who treated her. Her knowledge helped her physicians develop protocols for treating other patients. Preventing individuals from obtaining, and physicians and scientists from acting, on this kind of information is wrong. Hayekian knowledge—decentralized knowledge that comes from many disparate places at once[81]—is stifled in favor of top-down regulation that is cut off from nourishment that can enter into the system, only, as it were, through the roots.

The decision to accept the FDA's control over drug usage depends in part on the uneasy judicial attitudes toward assisted suicide. In *Washington v. Glucksberg*,[82] the Supreme Court held (correctly in my view[83]) that terminally-ill individuals do not have the constitutional right to assisted suicide. But *Abigail Alliance* involves people who were trying desperately to *live*, not to die. In dealing with this thorny issue, Judge Griffith's elegant opinion in *Abigail Alliance*, which states that people do not have a right to use a drug that passes a Phase I trial, carried the day in the en banc hearing.[84] Judge Griffith reached that conclusion by stitching together these two lines of authority—*Rutherford* and *Glucksberg*—to deny terminally ill persons access to cancer drugs, even when such drugs have been recommended by preeminent physicians.[85] Under current law, his decision is, most regrettably, correct—if only because of the huge deference the courts show to federal officials on matters that so manifestly relate to the core police power issues of

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80. *See generally* DEP'T OF HEALTH, EDUC., & WELFARE, FOOD & DRUG ADMINISTRATION, HEW PUB. NO. 77-3056, LAETRILE: THE COMISSIONER'S DECISION (1977).

81. *See* William N. Butos, *Knowledge Questions: Hayek, Keynes and Beyond*, 16 REV. OF AUSTRIAN ECON. 291, 298 (2003).

82. Washington v. Glucksberg, 521 U.S. 702 (1997).

83. *See* RICHARD A. EPSTEIN, MORTAL PERIL: OUR INALIENABLE RIGHT TO HEALTH CARE? 299–311 (1997).

84. 445 F.3d at 486–99; 495 F.3d at 31–38.

85. 445 F.3d at 491–97.

health and safety.[86] But, ironically, current law does not seem to distinguish between an individual patient who asserts her autonomy right to try to save her life or who asserts her autonomy right to end it.

Nonetheless, that constitutional determination does not answer the policy challenge to the FDA's hegemony. The challenge asks why the FDA should be allowed to exercise a veto once routine Phase I trials have been completed, even though a huge network of private voluntary organizations—individual physicians and their own expert organizations—have vastly greater access to the reliable information needed to make relevant treatment decisions on a patient-by-patient basis. As a matter of institutional design, the FDA represents a long-term regulatory misadventure whose tardy decisions create bottlenecks for innovation and bring about large amounts of gratuitous suffering.[87] Its grip is so strong that the companies that might protest the agency's actions remain silent, lest they face retaliation from the FDA on other matters that they have pending before the agency. In practice, therefore, the burden of dealing with the FDA falls on patient advocacy groups like Abigail Alliance, which often must lead the challenge against an entrenched FDA, which all too often does not understand state-of-the-art techniques in areas in which it alone has the final say.

What is at stake in this area is nothing less than the question of how to preserve technical innovation in the face of wall-to-wall regulation. The prognosis is grim. Unless we reform agencies like the FDA and their procedures and operations, this country will suffer from a long-term drag on innovation that could, if the trend is not abated, lead to long-term mediocrity, as inventors and scientists flee our shores for friendlier environments. The pace of regulation is one of the central issues of our time. One of the sad consequences of our courts' broad reading of the Commerce Clause in cases such as *Wickard v.*

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86. *See, e.g.*, Heckler v. Chaney, 470 U.S. 821 (1985) (granting the FDA prosecutorial discretion in determining which parties it would target with enforcement actions); Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973) (granting broad deference to the FDA to determine whether or not a product was a "new drug" within the meaning of the Federal Food, Drug and Cosmetic Act of 1938); Nat'l Eng'g & Contracting Co. v. OSHA, 928 F.2d 762, 764 (6th Cir. 1991) (permitting warrantless workplace inspections by OSHA officials, in deference to the agency's interpretation of 5 U.S.C. § 706(2)(A)).

87. *See generally* MAKOWER, *supra* note 70.

Filburn[88] is that it has broadened the scope of federal regulations in a way that has catalyzed these unfortunate results. In dealing with the long-term future of health care, the constitutional disputes over the individual mandate are a sideshow in the search for medical progress. What really matters is ensuring the long-term flow of technology, and that is what regulation is currently stifling.

The question remains how both private and public sources can cooperate in medical and technological advances. Right now, government funding is largely misplaced. Interestingly, the original bioscience grants were quite small.[89] Since the government grants were first introduced, public expenditures have largely shifted from those in basic infrastructure and scientific research to transfer payments,[90] another dangerous trend. That long-term change has thrown yet further obstacles in the path of scientific innovation. The damage done by the New Deal on structural issues continues to manifest itself and even multiply. As a nation, we need to get back on track in the way in which we organize research in the medical, pharmaceutical, biotech, and alternative energy fields. We need to make sure that such research is free of endless regulatory impediments. Vannevar Bush was basically correct in his proposal that the government subsidize research up to the point of proof of principle, but after that, leave inventions to the patent system.[91]

Lastly, we should ask whether the government could, on its own initiative, make intelligent decisions regarding investments in science and technology. The answer: not unless it can find ways to delegate these decisions to people who know what they are doing. The 535 members in the United States House and Senate do not. Therefore, they cannot be the ideal

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88. 317 U.S. 111 (1942).

89. *See* COOPER & AINSBERG, supra note 61, at 223 (describing how Banting was awarded an annual lifetime stipend of $10,000 by the Canadian government, and how the Rockefeller Foundation provided a grant of $150,000 to fifteen hospitals to promote the use of insulin).

90. *See Profiling Public Expenditures*, RAND Research Brief RB-2500 (Apr. 1995), *available at* http://www.rand.org/pubs/research_briefs/RB2500/index1.html.

91. *See* VANNEVAR BUSH, SCIENCE: THE ENDLESS FRONTIER, A REPORT TO THE PRESIDENT ON A PROGRAM FOR POSTWAR SCIENTIFIC RESEARCH 21, 31–33, 38 (1945), http://www.nsf.gov/od/lpa/nsf50/vbush1945.htm. Bush also suggests that the government's repayment should be a non-exclusive license of any technology that is used with government funds; otherwise, the patentee can do with its invention what it will. *Id.* at 38.

group to decide whether to subsidize a wind technology that shuts down in calm weather and solar power that does not work at night. No lawyer-dominated institution can answer these questions, but by the same token the scientists and technocrats needed to make intelligent decisions at the center must understand the degree of intellectual freedom needed for science and technology to advance. Finding and supporting those people is difficult in the best of circumstances. But it will prove impossible so long as we operate in a world in which our systems of both subsidies and regulation are misguided. On the one hand, subsidizing new technologies that cannot pay their way in the market is dangerous. On the other hand, risk aversion cannot be the dominant mindset of regulators. Unfortunately, both these tendencies are deeply ingrained in the regulatory mindset today. We must change the intellectual climate in order for innovation and growth to regain their footing in the United States.