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INTELLECTUAL AND REGULATORY PROPERTY

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Introduction

Conventional accounts of the relationship between intellectual property (IP) and public health regulation depict distinct regimes at cross-purposes with each other. IP is construed as a means to promote technological progress, while regulation is viewed as a drag on innovation.[1] By these accounts, extensive scrutiny by the U.S. Food and Drug

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[1] Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. TECH. L. REV. 345, 345-46 (2007), *available at* http://www.mttlr.org/volthirteen/eisenberg.pdf (summarizing conventional accounts of the relationship between patents and FDA regulation, and observing, "This framing suggests a symbiotic tension between patents and drug regulation…In this picture, patents promote innovation by making it profitable, while drug regulation deters innovation, in furtherance of the competing goal of public health, by making it costly.").

Administration (FDA) compels inventors of medical technologies to incur costs that the government offsets with grants of IP rights.[2] Yet this simplistic framing breaks down upon closer examination. Public interest concerns cabin IP protection,[3] and regulation erects barriers to competition that benefit innovators.[4] Moreover, a broad conception of innovation encompasses not only the creation of new inventions, but also the accumulation of new information about the risks and benefits of existing technologies.[5]

An expansive view of innovation exposes functional similarities between IP and FDA regulation. Both systems create incentives to produce socially valuable information, albeit different types of information at different points in technology development timelines. IP is designed to bring forth inventions that meet specified novelty and inventiveness criteria, while FDA regulation is structured to generate additional information about particular embodiments. IP exerts a pulling effect on would-be inventors, and regulation pushes developers to move nascent discoveries downstream along innovation pathways. Importantly, interplay between IP and regulation creates feedback loops of cumulative technological innovation.

This Article uses the term "regulatory property," in contradistinction to regulatory takings (and givings) of private property, to highlight the ways in which regulatory oversight gives rise to the creation of valuable information.[6] Regulatory takings and

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[2] *See, e.g.,* Michael Abramowicz, *Orphan Business Models: Toward a New Form of Intellectual Property*, 124 HARV. L. REV. 1362, 1381-82 (2011) ("Private sector research depends on the patent reward because of the extraordinary costs associated with research into new drugs and the relative ease with which generic drug manufacturers can copy drugs.").

[3] Michael A. Carrier, *Cabining Intellectual Property Through a Property Paradigm*, 54 DUKE L. J. 1, 4 (2004) (noting that IP's exclusionary rights provide incentives to create, but that IP is limited by competing social goals).

[4] Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, *supra* note 1, at 348 ("Indeed, as the role of the patent system in drug development has become more complex and ambiguous, drug regulation has become an increasingly important source of market exclusivity for innovating firms.").

[5] *Id*. at 347 (asserting that conventional framing of the relationship between patents and FDA regulation "is seriously incomplete and out of date," because "[i]t misses the important structural role that drug regulation has come to play in *promoting* a valuable form of pharmaceutical innovation – the development of credible information about the effects of drugs.").

[6] The term "regulatory property" has been used in the context of land use regulation to describe "a property right created and allocated by a government entity, such as a right to emit specified pollutants into the atmosphere under the terms of a permit issued by a government regulator." Bruce Yandle & Andrew P. Moriss, *The Technologies of Property Rights: Choice Among Alternative Solutions to Tragedies of the Commons*, 28 ECOL. L. Q. 123, 129 (2001). Such rights to use physical resources alternatively may be referred to as privileges, or, in the terminology developed by Abraham Bell and Gideon Parchomovsky, regulatory givings. *See* Abraham Bell & Gideon Parchomovsky, *Givings*, 111 YALE L. J. 547, 550 (2001).

givings involve government redistributions of *preexisting* resources that effect wealth transfers between affected members of society.[7] By contrast, regulatory property refers to the process whereby government regulation leads to the generation of *new* information resources. The Article's novel application of the property label serves to underscore the ways in which IP and regulatory systems interoperate to create incentives to produce intangible goods.

As regulatory property is generated, both federal and state regulations manage its dissemination across proprietary and public domains. Whether modifications to these laws effect takings or givings depends upon baseline assumptions regarding ownership of newly created regulatory property. Ownership questions surrounding regulatory property are thornier than those for information goods that firms independently amass during the course of doing business. Developers assert proprietary rights in data that government regulators mandate they produce, but since such information is generated for a specific public purpose, and may be derived from contributions by members of the public who participate as research subjects, it lacks the classic attributes of private property. Rules governing the exclusion and use of regulatory property influence innovators' decisions to invest additional rival resources into activities directed toward creating new technologies, and activities directed toward expanding knowledge about existing inventions. These iterative decisions have disparate effects on technology users.

In the biomedical field, patent and trade secrecy laws interrelate with FDA regulation to govern knowledge production and distribution. Minimal utility requirements and stringent novelty and nonobviousness requirements under patent law induce inventors to seek patents at very early stages of product development.[8] The FDA subsequently leverages its market gatekeeping powers to elicit the generation of information beyond that which is disclosed in patents. The scope of trade secret

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By contrast, the term regulatory property as used in this Article describes the process whereby regulation leads to the creation of new information resources.

[7] The Fifth Amendment of the U.S. Constitution states: "[N]or shall private property be taken for public use, without just compensation." U.S. CONST. amend V. *See also* Abraham Bell & Gideon Parchomovsky, *Givings*, *supra* note _ (advocating development of a converse doctrine that recognizes government givings of private property).

[8] *See* In re Brana, 51 F.3d 1560, 1562-63, 1566-67 (Fed. Cir. 1995) (holding that patent law's utility requirement is satisfied by demonstrating that a chemical compound has a beneficial effect in animal models of disease and that it is not necessary to show that the compound has a desirable effect in humans); Part IIIB, *infra*.

protection for these data in turn influences how manufacturers coordinate development activities and communicate information to others. Absent regulatory mandates, firms have economic incentives to produce and reveal safety and efficacy data only to the extent that doing so increases private payoffs. Hence a primary function of FDA regulation is to compel firms to aggregate and disclose socially valuable information about their products that would not be distributed in an unregulated market. This includes positive clinical results whose value manufacturers cannot sufficiently appropriate through exercise of IP rights, as well as negative clinical results that lead the FDA to withhold licensing approval, reduce consumer demand for licensed products, or expose manufacturers to tort liability.[9]

FDA requirements dictate the type and amount of regulatory property that manufacturers must create, as well as its disposition upon a product's market entry. When the FDA approves a product, the agency determines which information remains proprietary, and which information must be placed into the public domain through disclosures to patients, physicians, and researchers. In addition, FDA regulations on advertising and labeling influence manufacturers' decisions to undertake post-market data gathering activities. Federal regulatory preemption of state products liability laws further alters innovators' incentives to invest in costly efforts to develop new intellectual and regulatory property.

Functional connections between IP and FDA regulation are most apparent at the common pressure points currently stressing both systems. The essential output of much contemporary R&D, such as genomic discoveries and diagnostic algorithms, is knowledge that is not tied to new compositions or machines. Additionally, the boundaries between producers and consumers of new information resources are increasingly indistinct. Many of the central governance challenges in both IP and regulatory law are variations on common problems related to these transformations in the nature of innovation. Within both regimes, courts and agencies are struggling to adapt paradigms

[9] Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, *supra* note 1, at 347 ("In addition to the spillover problems that dampen R&D incentives for many information-enriched products, market incentives to generate rigorous information about the effects of drugs are distorted by the risk that better information could as readily undermine the commercial value of the products under study as enhance it.").

suited to physical creations to new information goods. In each context, decision makers are confronting new sets of tradeoffs between static and dynamic costs and benefits.

Part I of this Article reviews contemporary debates over the "propertization" of information and advocates expansive application of the property label to intangible resources. This Part notes that property need not connote absolute rights to exclude and can be a useful vehicle for allocating rights in information across proprietary and shared creative spaces. Part II delineates the ways in which IP and regulatory laws are functionally intertwined by examining the interplay between patents, trade secrecy, and FDA regulation. It explains the overlapping roles of intellectual and regulatory property in the iterative process of cumulative innovation. Part III highlights contemporary governance challenges that span across IP and regulatory regimes and suggests that common problems stem from similar difficulties in managing information resources that are not tied to newly created tangible things. Part IV suggests ways in which intellectual and regulatory property may be coordinated and calibrated to develop more coherent biomedical innovation policy. A brief Conclusion summarizes the Article's main observations and arguments.

I. Innovation Within and Without IP

A. IP and Regulation As Property Regimes

Commentators hotly debate the essence and contours of IP. While one camp embraces the characterization of IP as a species of property,[10] another has argued that IP is more accurately described as a public regulatory regime.[11] In some quarters, these conceptual disagreements stem from differing underlying views about the rhetorical significance of the property designation. Those who associate property with Blackstonian

[10] *See, e.g.*, Stephen L. Carter, *Does It Matter Whether Intellectual Property Is Property?*, 68 CHI.-KENT L. REV. 715, 723 (1993) (rejecting distinctions between tangible and intangible property); Frank H. Easterbrook, *Intellectual Property Is Still Property*, 13 HARV. J. L. & PUB. POL'Y 108, 118 (1990) (arguing that society "should treat intellectual and physical property identically in the law.").

[11] *See* Mark A. Lemley, *IP in a World Without Scarcity* *46, *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2413974 ("IP is essentially a form of regulation. The government restricts entry into the market, or alternatively controls the price at which that entry can occur, in order to serve valuable social ends."); Mark A. Lemley, *The Regulatory Turn in IP*, 36 HARV. J. L. & PUB. POL'Y 109 (2013); Mark A. Lemley, *Taking the Regulatory Nature of IP Seriously*, _ TEX. L. REV. (forthcoming 2014).

notions of "sole and despotic dominion"[12] assert that IP is not truly a form of property.[13] Others who take a more expansive view of property argue that the property label can be accommodated to encompass an ever-broadening range of subjects, such as spectrum frequencies and pollution credits.[14] The latter view rejects the need to draw sharp distinctions between private property and public regulatory regimes.[15]

Scholars who differ over the breadth of the property umbrella express differences of opinion on how to characterize trade secrets and privacy interests. Although trade secrets generally are referred to as IP, the only attribute that they clearly share in common with patents and copyrights is their intangibility.[16] Trade secret law's protection of uncreative work that companies produce in the ordinary course of business and guard against disclosing is at odds with the federal IP laws' purpose to promote the generation and dissemination of innovative goods.[17] Those who disfavor extending the bounds of property in information resist construing trade secrets as IP.[18] For similar reasons, scholars have pushed back against the notion that privacy laws that protect against the disclosure of sensitive personal information grant individuals property rights.[19]

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[12] William Blackstone famously referred to property as "that sole and despotic dominion which one man claims and exercises over the external things of the world, in total exclusion of the right of any other individual in the universe." 2 WILLIAM BLACKSTONE, COMMENTARIES *2. However, his later writings extensively qualified this hyperbole. *See, e.g.*, Carol M. Rose, *Canons of Property Talk, or Blackstone's Anxiety*, 108 YALE L.J. 601, 603 (1998) ("Blackstone himself was thoroughly aware of these pervasive and serious qualifications on exclusive dominion.").

[13] *See, e.g.*, Tom W. Bell, INTELLECTUAL PRIVILEGE: COPYRIGHT, COMMON LAW, AND THE COMMON GOOD (2014) (arguing that copyright should not be considered a form of property but rather a privilege bestowed by the government).

[14] *See, e.g.*, John F. Duffy, *Intellectual Property Isolationism and the Average Cost Thesis*, 83 TEXAS L. REV. 1077, 1078 (2005) ("A unified theory of property – one broad enough to account for the similarities *and differences* among species of property as diverse as Blackacre and patents – promises to increase rather than diminish our understanding of property and intellectual property.").

[15] *See* John F. Duffy, *Rethinking the Prospect Theory of Patents*, U. CHI. L. REV. 439, 509-10 (2004) (drawing an analogy between the patent system and natural monopoly regulation).

[16] *See* Michael Abramowicz & John F. Duffy, *Intellectual Property for Market Experimentation*, 83 N.Y.U. L. REV. 337, 380 (2008) (noting that trademark and trade secret law "have fallen under the same umbrella of 'intellectual property' solely because of the intangible nature of the property right, despite differences in the underlying theoretical justification.").

[17] *Id.* at 389-91 (suggesting that the goal of trade secret law is to encourage market experimentation by protecting business data and thereby increasing first mover advantage).

[18] *See, e.g.*, Pamela Samuelson, *Information as Property: Do Ruckelshaus and Carpenter Signal a Changing Direction in Intellectual Property Law?*, 38 CATHOLIC U. L. REV. 365, 375 (1989) (arguing that "[i]t is simply unnecessary to call trade secrets 'property'").

[19] *See, e.g.*, Pamela Samuelson, *Privacy as Intellectual Property?*, 52 STAN. L. REV. 1125, 1129 (2000) ("Deep differences in the purposes and mechanisms of traditional intellectual property regimes and the proposed property rights regime in personal data raise serious doubts about the viability of a property rights

Though many observers decry the "propertization" of information over the past several decades, applying the property label to rights in intangible resources need not bestow upon its holders absolute rights to exclude.[20] To the contrary, designating rights to information goods as property enables policymakers to rely on established doctrines to calibrate their scope in furtherance of social goals.[21] For example, recognized limitations on physical property, such as eminent domain, easements, adverse possession, and zoning laws provide templates for cabining intangible property.[22] Indeed, many of the fundamental principles underlying restrictions on tangible property have been modified to limit the scope of IP.[23] These basic limitations on the exclusion and use of IP can be further adapted to shape other forms of intangible goods. The malleability of property makes it a useful vehicle through which to calibrate interrelated public and private rights in information.

A rich body of literature has advanced the argument that IP's primary goal is not to reward invention, but to create incentives to develop and commercialize nascent discoveries.[24] Such incentives are unnecessary where the costs of bringing embodiments to market are insubstantial, and the inherent lead-time advantage that inventors enjoy

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approach and its prospects of achieving information privacy goals."); Mark A. Lemley, *Private Property*, 52 STAN. L. REV. 1545, 1554 (2000) ("In short, a properly designed [privacy] right would look rather more like a system of regulation than a system of property rights.").

[20] *See* Joan Williams, *The Rhetoric of Property*, 83 IOWA L. REV. 277, 280-83 (1998) ("Many commentators have noted the gap between the political rhetoric of absolute property rights and the practice of limited property rights.").

[21] Michael A. Carrier, *Cabining Intellectual Property Through a Property Paradigm*, *supra* note _, at 4-5 ("Although scholars have lamented the propertization of IP, they have failed to recognize a hidden promise of the transformation: the *narrowing* of IP.").

[22] *Id*. at 80-81 (providing a chart that summarizes numerous restrictions on property rights, and categorizing them as development-, necessity-, or equity-based limits that restrict rights to exclude, transfer, or use property).

[23] *Id*. at 144 (providing a chart that summarizes recognized restrictions on rights in copyright, patent, trademark, and rights of publicity, using the same development-, necessity-, or equity-based taxonomy).

[24] See generally F. Scott Kieff, Property Rights and Property Rules for Commercializing Inventions, 85 MINN. L. REV. 697 (2001); Michael Abramowicz & John F. Duffy, Intellectual Property for Market Experimentation, 83 N.Y.U. L. REV. 337 (2008) (arguing that IP should encourage commercial experimentation as well as technological innovation); Edmund W. Kitch, The Nature and Function of the Patent System, 20 J. L. & ECON. 265, 265 (1977) (developing a "prospect theory" of patents). See also Oren Bar-Gill & Gideon Parchomovsky, Essay, A Marketplace for Ideas?, 84 TEX. L. REV. 395, 397 (2005) (advocating very limited and narrow legal entitlements in naked ideas in order to promote development and commercialization).

over competitors enables them to recoup their R&D investments.[25] However, for other inventions, such as pharmaceuticals[26] and agricultural chemicals,[27] post-invention follow on work requires costly, risky capital expenditures. To the extent that development and commercialization investments yield significant net social benefits, structures should be in place to encourage them.[28]

Often research that enhances the value of particular embodiments of known inventions does not produce outputs that meet the criteria for formal IP protection. For example, data on the risks and benefits of previously disclosed uses for known products is not copyright- or patent-eligible information.[29] Scholars have proposed creating separate proprietary rights specifically to induce downstream innovation.[30] Yet such

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[25] *See* Robert Mazzoleni & Richard R. Nelson, *Economic Theories About the Benefits and Costs of Patents*, 32 J. ECON. ISSUES 1031, 1048 (1998) (noting that in many circumstances head start advantages provide sufficient incentives to perform follow-on work); Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (Or Not)* 6, 10 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000), *available at* http://www.nber.org/papers/w7552.pdf (reporting that in many industries lead-time advantage recoups R&D costs more effectively than patents).

[26] *See, e.g*, Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is It Really $802 Million?*, 25 HEALTH AFF. 420, 420 (2006) (estimating a total cost to bring a new drug to market of $868 million); Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 164-66 (2003) (estimating the costs of performing FDA-mandated clinical trials at $467 million per drug, which is more than half of the total estimated cost per drug); Jim Gilbert et al., *Rebuilding Big Pharma's Business Model*, 21 IN VIVO: BUS. & MED. REP., Nov. 2003, at 1, *available at* http:// www.bain.com/ bainweb/ PDFs/ cms/ Public/ rebuilding_ big_ pharma.pdf (estimating cost of discovering, developing, and launching new drugs at $1.7 billion by factoring in costs of failed projects).

[27] *See* 7 U.S.C. § 136a (2011) (establishing a regulatory regime for pre-market approval of agricultural chemicals).

[28] Several economic studies have shown that expenditures to develop medical technologies yield significant net social benefits. *See, e.g*., David M. Cutler & Mark McClellan, *Is Technological Change in Medicine Worth It?: When Costs and Benefits Are Weighed Together, Advantages Have Proved to Be Worth Far More than Their Costs*, 20 HEALTH AFF. 11, 23 (2001). Of course, it does not follow that investments in particular inventions necessarily yield net social benefits. For example, there likely is a net social cost to developing drugs that offer trivial therapeutic advantages over existing therapies. Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomic Era*, 2001 U. ILL. L. REV. 173, 205-206.

[29] *See* Feist Publications, Inc. v. Rural Telephone Service Co., 499 U.S. 340, 344-45(1991) (explaining that raw data is not copyrightable, because "[t]he *sine qua non* of copyright is originality"); Digitech Image Technologies v. Electronics For Imaging, Inc., *9 (Fed. Cir. July 11, 2014) ("Data in its ethereal, non-physical form is simply information that does not fall under any of the categories of eligible subject matter under section 101 [of the Patent Act]."). Raw data itself cannot be protected as intellectual property in the U.S. *See* Daniel J. Gervais, *The Protection of Databases*, 82 CHI.-KENT L. REV. 1109, 1133-1148 (2007) (discussing several failed bills introduced in Congress in the late 1990s and early 2000s to create *sui generis* intellectual property in data).

[30] *See* Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341, 400-405 (2010) (proposing "commercialization patents" that would be limited to particular products and would be used primarily for defensive purposes); Michael Abramowicz & John F. Duffy, *Intellectual Property for Market*

downstream entitlements need not take the form of conventional IP, with the prescribed panoply of exclusionary interests. Moreover, a sui generis property regime may not be necessary in regulated areas like the biomedical industry, since the means to tailor downstream innovation incentives are built into the existing legal scheme.

Patent law's low utility threshold enables inventors to patent eligible discoveries at embryonic stages of development.[31] Early patenting yields social benefits, because it fosters competition that leads to the earliest possible patent expiration and concomitant dedication of inventions to the public domain.[32] Yet much remains unknown about the social value of nascent, patented technologies. In the biomedical arena, FDA regulation aims to fill this void by compelling the generation and disclosure of additional information about the safety and efficacy of particular embodiments. Through its licensing process, FDA scrutiny gives rise to the creation of a distinct species of intangible property.

Government directives that induce the generation of regulatory property are qualitatively different from laws that effect regulatory takings or givings. Takings and givings involve government redistributions of preexisting resources that effect wealth transfers between affected members of society.[33] Regulatory takings occur when strengthened government regulations deprive owners of "all economically beneficial use" of their private property.[34] It logically follows that loosened government regulations can effect a giving to property owners by enabling them to engage in a broader range of economic uses.[35] By contrast, regulatory property refers to the process whereby government regulations give rise to the creation of new information resources. Like other

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Experimentation, *supra* note _, at 405-408 (proposing modification of the patent system to allow for patents on products that are not novel but that have never been effectively commercialized, but cautioning that the PTO may lack institutional competence to judge commercial nonobviousness); *id*. at 409 (questioning "whether, in the future, a branch of intellectual property should be developed that more precisely targets the encouragement of undertaking of entrepreneurial risk and market experimentation.").

[31] *See* In re Brana, *supra* note _; U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2107.03 (8TH ed. 2001) (stating that animal testing is generally sufficient to support therapeutic utility).

[32] John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 445-46 (2004) (noting that "the overarching goal of the patent system…is not to curb rivalry but merely to channel it into a relentless quest for earlier patenting and thus earlier dedication to the public.").

[33] Abraham Bell & Gideon Parchomovsky, *Givings*, *supra* note _, at 563 (noting that "[a]ny government redistribution of private property necessarily involves givings and takings").

[34] Lucas v. South Carolina Coastal Council, 505 U.S. 1003, 1027 (1992).

[35] Abraham Bell & Gideon Parchomovsky, *Givings*, 111 YALE L. J. 547, 550 (2001).

types of information goods, these resources are allocated across private and public domains according to formal and informal rules governing access and use.

B. Managing Resources Across Information Semicommons

While scholars disagree over IP's precise boundaries, issues surrounding rights in information uncontrovertibly touch upon an increasingly diverse set of creative activities. Eric von Hippel has observed that technology enables increased democratization of innovation.[36] In the medical field, this trend is apparent in the "citizen science" and participatory health movements, which aim to democratize medical research.[37] PatientsLikeMe, an online community whose members self-organize to exchange and produce clinical knowledge, exemplifies the advent of user-generated biomedical innovation.[38] Another example is Harvard Medical School's Personal Genome Project, which plans to sequence the genomes of 100,000 volunteers and contribute their genomic and medical record information to enable "public genomics."[39]

Multi-faceted governance strategies are necessary to manage democratic innovation, regardless of whether one locates particular interactions within or without IP.[40] Dynamic, distributed collaborations require a mix of legal and extra-legal tools to sustain them and enable them to thrive. Drawing upon Elinor Ostrom's approach to commons arrangements in the physical environment, Michael Madison, Brett Frischmann, and Katherine Strandburg have developed a framework for examining information-sharing arrangements in "cultural" commons environments.[41] They note that

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[36] Eric von Hippel, DEMOCRATIZING INNOVATION 1 (2005) ("When I say that innovation is being democratized, I mean that users of products and services – both firms and individual consumers – are increasingly able to innovate for themselves.").
[37] See Melanie Swan, Health 2050: The Realization of Personalized Medicine through Crowdsourcing, the Quantified Self, and the Participatory Biocitizen, 2 J. PERS. MED. 93 (2012).
[38] PatientsLikeMe, http://www.patientslikeme.com/ (urging individuals to "take control of your health" and "contribute to research that can advance medicine for all").
[39] John M. Conley, Adam K. Doerr, & Daniel B. Vorhaus, *Enabling Responsible Public Genomics*, 20 HEALTH MATRIX 325 (2010).
[40] *See* Mark A. Lemley, *IP in a World Without Scarcity* *45, *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2413974 ("IP regimes have always coexisted with areas of innovation not protected by IP, governed instead by open competition or informal norms of sharing.").
[41] Michael J. Madison, Brett M. Frischmann, & Katherine J. Strandburg, *Constructing Commons in the Cultural Environment*, 95 CORNELL L. REV. 657, 676 (2010) ("A key insight of Ostrom's approach to the natural environment was recognition of the important role for institutions intermediate between private

a significant portion of innovative activity takes place in areas in between proprietary domains of exclusion and an openly accessible public domain in which exclusion is prohibited.[42] In contrast to physical resource environments, where the focus is on developing sharing arrangements that facilitate *conservation* of rival resources, in cultural environments the goal is to facilitate sharing of inherited information resources in ways that encourage the *production* of new resources.

Information production and exchange takes place across "semicommons" of overlapping and interacting common and private property.[43] Semicommons are shaped through formal operation of IP law, and through private ordering among members of cultural communities to modify default IP rules.[44] Such mixed ownership arrangements create opportunities for strategic behavior at the interfaces between individually and commonly owned property.[45] Two different types of "common interest tragedies"[46] threaten to undermine cooperation within the information semicommons. A tragedy of the commons occurs where individuals fail to use a resource system in a socially productive way because the private costs of doing so outweigh the private benefits and individual users cannot sufficiently capture positive externalities. Conversely, a tragedy of the anticommons occurs where the private benefits of using a resource system in a socially productive way exceed the private costs, but individuals hold out in the hopes of

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property and the state in solving problems of collective action."). The authors broadly define "cultural" environments to include all environments in which the resources to be produced, conserved, and consumed are pieces of information. *Id*. at 659.

[42] *Id*. at 667-668.

[43] *See* Henry E. Smith, *Semicommon Property Rights and Scattering in the Open Fields,* 29 J. LEGAL STUD. 131, 131-32, 138-44 (2000) (explaining that a semicommons exists where private and common property regimes overlap and interact, and that legal entitlements help to constrain strategic behavior within the overlapping areas); Robert A. Heverly, *The Information Semicommons*, 18 BERKELEY TECH. L. J. 1127, 1130-31 (2003) ("Information ownership can better be described as a semicommons, a form of ownership that acknowledges the dynamic relationship between private and common uses.").

[44] Michael J. Madison, Brett M. Frischmann, & Katherine J. Strandburg, *Constructing Commons in the Cultural Environment*, *supra* note _, at 668-69 (noting that neither patent nor copyright law grant absolute rights of exclusion, and that individuals modify default IP rules with contracts and through development of social norms).

[45] Lee Anne Fennell, *Commons, anticommons, semicommons*, RESEARCH HANDBOOK ON THE ECONOMICS OF PROPERTY LAW 38-39 (Kenneth Ayotte & Henry E. Smith eds., 2012) (illustrating that, "[a] rescaling and associated ownership change can shift that line [dividing individually and commonly owned elements] in one direction or the other, but it will not eliminate the line itself or the incentive problems that can occur when privately and commonly owned elements interact.").

[46] *See* Lee Fennell, *Common Interest Tragedies*, 98 NORTHWESTERN L. REV. 907 (2004).

obtaining a disproportionately large surplus.[47] Importantly, a fine line separates these two tragic situations, which tend to converge when taken to their logical conclusions.[48]

The possibility for incentive misalignment is inevitable so long as individual labor remains privately owned and privatizing the entire resource system is infeasible or inefficient.[49] However, common interest tragedies stemming from uncooperative behavior can be averted either through government-wielded coercion, or through mechanisms that recalibrate private payoffs in ways that facilitate the internalization of social costs and benefits. For example, the government can subsidize socially productive behavior or tax socially unproductive behavior. Alternatively, norm-based sanctions and rewards, such as shaming and accolades, can alter community members' perceived payoffs in ways that induce them to engage in socially beneficial resource production and exchange.[50]

Cooperative sharing arrangements provide middle-way alternatives to purely proprietary and purely open schemes to encourage the creation of intangible goods. Importantly, however, there is no "one-size-fits-all panacea approach" that is appropriate for all innovation contexts.[51] By the same token, there is no singularly superior overarching government structure to support different forms of innovation.[52] A wide variety of means is available to encourage resource production across the information semicommons. Government interventions extend beyond binary choices between the IP system and models designed to directly supply information to the public domain through awards of grants and prizes. In addition to these mechanisms for incenting the production

[47] *Id*. at 954-55 (illustrating the distinction using as an example the problem of replacing a burnt-out light bulb in a community laundry room).
[48] *Id*. at 909 (explaining that "a potential anticommons problem stands between every garden-variety commons tragedy and its solution.").
[49] Lee Anne Fennell, *Commons, anticommons, semicommons*, *supra* note _, at 39 (explaining that the possibility of incentive misalignment cannot be eliminated as long as labor remains privately owned).
[50] *See Id*. at 40.
[51] *Id*. at 670 ("[S]cholarly discussion…increasingly extol[s] community production as a solution to the free-rider problems of cultural production. The danger is that the amorphous idea of 'community production' will become the new one-size-fits-all panacea approach in rivalry with privatization, public subsidy, and the public domain.").
[52] *Id*. at 669-70 ("The question for both public policy and legal theory becomes how best to use legal and other tools to encourage the growth and persistence of creative, sustainable, and equitable cultural environments.").

of information resources, regulatory bodies can foster innovation by allocating rights in agency-mediated information.

Government institutions compel regulated entities to generate distinct forms of socially valuable intangible resources. Once regulatory property is created, both formal legal rules and informal sharing arrangements govern its distribution among knowledge consumers and producers. Through these processes, it becomes scattered across the information semicommons – that is, partially excluded within proprietary spaces and partially deposited into (semi-) public domains.[53] In the medical context, tracing the history of FDA regulation in the U.S. sheds lights on the malleable, versatile nature of regulatory property and its utility as a tool for engineering innovation policy.

II. Functional Linkages Between IP and FDA Regulation

A. Historical Co-Evolution

1. The FDCA and the Rise of Patenting

Historians generally characterize the enactment of federal food and drug regulations as triumphs of consumer activism and Progressivism, exemplifying government efforts to overcome market failures and harness science to improve public welfare.[54] Before the passage of federal food and drug laws, Americans consumed substances at their own peril.[55] Mounting concerns about dangerously unsafe food and drugs, stoked by articles documenting medical product sellers' fraudulent practices and

[53] *See* Robert A. Heverly, *The Information Semicommons*, *supra* note _, at 1146 (noting that there is no uniformly accepted definition of the public domain, and that expansive definitions of the "information commons" encompass arrangements involving restrictions on use, or the requirement that fees be paid in exchange for access, so long as the information is indiscriminately made available to all comers).
[54] PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION xi (2003); Richard Curtis Litman & Donald Saunders Litman, *Protection of the American Consumer: The Congressional Battle for the Enactment of the First Federal Food and Drug Law in the United States*, 37 FOOD DRUG COSM. L.J. 310, 310 (1982); CHARLES O. JACKSON, FOOD AND DRUG LEGISLATION IN THE NEW DEAL vii (1970) (describing the 1938 FDCA as a result of the "significant and dramatic impact of science").
[55] *See* SAMUEL HOPKINS ADAMS, THE GREAT AMERICAN FRAUD (5th ed. 1912) (containing reprinted articles from *Collier's Weekly* warning Americans about the dangers of unknown medicines); JAMES HARVEY YOUNG, PURE FOOD: SECURING THE FEDERAL FOOD AND DRUGS ACT OF 1906, at 31-39, 110-12 (1989) (discussing food and drug concerns before passage of the Pure Food and Drugs Act).

Upton Sinclair's widely read exposé of the Chicago meat-packing industry,[56] led to the enactment of the Pure Food and Drugs Act of 1906.[57] Significant expansions of federal regulation followed in 1938 with passage of the Food, Drug, and Cosmetic Act (FDCA),[58] in 1962 with the Kefauver-Harris Amendments,[59] and in 1976 with the Medical Device Amendments to the FDCA.[60] Each of these expansions to the federal regulatory system came on the heels of a nationally publicized tragedy involving medical products.[61]

Yet outrage over public health disasters was not the only impetus behind the development of the federal regulatory scheme. The origins of the current regime trace back to early 20th century objections to the use of IP in medical products markets.[62] Mapping the historical linkage between IP concerns and the evolution of the FDA reveals an underappreciated role for regulation in shaping innovation policy.

Before federal regulations were introduced, most "patent medicines" in the United States were in fact *un*patented medicinal products. Manufacturers relied on a combination of trademark, copyright, and, most importantly, trade secret protection to maintain the

[56] Upton Sinclair, The Jungle (1906). The popular pressure leading up to the passage of the 1906 Pure Food and Drugs Act is recounted in Philip J. Hilts, Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation 46-55 (2003).
[57] Pure Food and Drugs Act, ch. 284, 34 Stat. 768 (1906) (granting enforcement powers to the precursor of the modern FDA, the Chemistry Bureau within the Department of Agriculture). The Food, Drug and Insecticide Administration was formally established in 1927 and gained its present name in 1930. Act of Jan. 15, 1927, Pub. L. No. 69-551, 44 Stat. 976, 1002 (1927); Act of May 27, 1930, Pub. L. No. 71-272, 46 Stat. 392, 422-23 (1930).
[58] Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).
[59] Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962).
[60] Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976).
[61] The 1938 legislation passed after a scandal over deaths caused by a preparation of the drug sulfanilamide. CHARLES O. JACKSON, FOOD AND DRUG LEGISLATION IN THE NEW DEAL, *supra* note _, at 152-74. Enactment of the 1962 Amendments followed shortly after reports linking devastating birth defects to pregnant women's use of the drug thalidomide to prevent miscarriage (an indication for which the drug proved to be ineffective). PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION, *supra* note _, at 144-65. The 1976 Medical Device Amendments were passed in the wake of widespread infections, and several deaths, linked to the Dalkon Shield intrauterine device. *Riegel v. Medtronic*, 128 S.Ct. 999, 1003 (2008).
[62] Kara W. Swanson, *Food and Drug Law as Intellectual Property Law: Historical Reflections*, 2011 WIS. L. REV. 331, 335 ("[C]ontemporary concern about intellectual property in food and drugs has historical antecedents that influenced the structure of modern food and drug law.").

market for their pills, liquids, and ointments.[63] Critics of the patent medicine industry cited secrecy as both the foundation of its success and the primary cause for concern:

> Secrecy of composition is to the "patent medicine" maker what the silk handkerchief and the wand are to the vaudeville thaumaturgist. Take away the element of secrecy from the "patent medicine" business and this gigantic monument to human credulity will crumble and decay.[64]

During this time, "ethical" medicine manufacturers competed with "patent" medicine sellers by supplying doctors and pharmacists with publicly disclosed drugs listed in nationally published formularies. Formulary medicines were sold under brand names that were protected as trademarks, and ethical manufacturers built their businesses upon reputations for consistent, high quality products.[65]

The Pure Food and Drugs Act and the subsequent, more comprehensive FDCA effectively imposed federal anti-secrecy prohibitions on drug manufacturers. The 1906 Act outlawed interstate shipment of "adulterated" or "misbranded" drugs.[66] Adulteration was defined as a failure to conform to published formulary standards.[67] Proprietary medicines did not fit the legal definition of adulteration, because they were not included in published formularies. Nonetheless, the Act deemed them misbranded if labeled with false or misleading statements.[68] But since federal agents lacked statutory authority under the Pure Food and Drugs Act to examine regulated products, they lacked the means to assess the accuracy of manufacturers' claims. The 1938 FDCA gave teeth to these provisions by granting the FDA the power to evaluate information about the ingredients

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[63] Kara W. Swanson, *Food and Drug Law as Intellectual Property Law: Historical Reflections*, *supra* note _, at 352-53 (noting an historian's assertion that only the least savvy entrepreneurs sought patent protection for their nostrums).
[64] Arthur J. Cramp, *"Patent Medicines": IV. Secrecy and Mystery – The Essentials*, 1 Hygeia 243 (1923). *See also* James Harvey Young, The Medical Messiahs: A Social History of Health Quackery in Twentieth-Century America 22 (1967) (noting that entrepreneurs during this time sought profits by buying and selling trade names rather than patents or manufacturing know-how).
[65] Jeremy A. Greene, *What's in a Name? Generics and the Persistence of the Pharmaceutical Brand in American Medicine*, 66 J. HIST. MED. & ALLIED SCI. 468 (2011). *See also* JAN R. MCTAVISH, PAIN AND PROFITS: THE HISTORY OF THE HEADACHE AND ITS REMEDIES IN AMERICA 46-60 (2004) (noting that "ethical" manufacturers also sold proprietary medications, and the line between ethical and non-ethical manufacturers was not always clear).
[66] Pure Food and Drugs Act, ch. 384, § 2m 34 Stat. 768 (1906).
[67] Kara W. Swanson, Food and Drug Law as Intellectual Property Law: Historical Reflections, supra note _, at 363.
[68] *Id*. at § 8.

contained in medical products and their effects on the human body.[69] The 1938 Act also mandated more comprehensive and specific disclosures in product labels, including lists of contents and statements about risks.[70]

The advent of the federal regulatory scheme contributed to an industry shift toward a reliance on patents as a means for medicinal product sellers to maintain competitive advantages.[71] The information-forcing provisions of the FDCA, along with advances in laboratory science, limited manufacturers' ability to protect their substances as trade secrets. These changes undercut the "patent" medicine industry's business model. Beginning in the first half of the 20th century, "ethical" drug companies rose to market dominance by transforming into the science-driven, patent-intensive businesses that characterize the contemporary pharmaceutical industry.[72]

Although patents are essential assets for today's manufacturers, trade secrets continue to play a vital role in the biomedical industry. In fact, the rise of the modern regulatory regime has heightened the importance of trade secrecy in medical products markets. Amendments to the FDCA over the past several decades illustrate how trade secrets mark a contemporary intersection between IP and FDA regulation.

2. The Hatch-Waxman Act and the ANDA Pathway

The history behind the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the "Hatch-Waxman Act") reflects the important ways in which government management of regulatory property affects incentives to create and develop new technologies. Prior to passage of the Hatch-Waxman Act, the FDA required manufacturers of generic copies of previously approved

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[69] Anna B. Laakmann, *Collapsing the Distinction Between Experimentation and Treatment in the Regulation of New Drugs*, 62 ALA. L. REV. 305, 308-09 (2011) (summarizing the 1938 FDCA provisions that required pre-market notification and authorized the FDA to assess safety, and the 1962 Amendments that implemented the modern scheme of pre-market approval and FDA review of both safety and efficacy).
[70] Kara W. Swanson, *Food and Drug Law as Intellectual Property Law: Historical Reflections*, *supra* note _, at 365-66 (noting that the FDCA further limited, but did not eliminate, manufacturers' ability to protect recipes and formulae as trade secrets).
[71] Kara W. Swanson, Food and Drug Law as Intellectual Property Law: Historical Reflections, supra note _, at 336.
[72] Kara W. Swanson, *Food and Drug Law as Intellectual Property Law: Historical Reflections*, *supra* note _, at 385 ("Indeed, the ethical manufacturers of the nineteenth century, Eli Lilly, Parke-Davis, Squibb, and others, became the successful U.S.-based pharmaceutical giants of the twentieth century known as 'Big Pharma.'").

drugs to produce their own clinical data establishing their products' safety and efficacy. Since generic manufacturers could not recoup high R&D costs by selling off-patent drugs, FDA regulations produced barriers to entry that insulated brand manufacturers from competition even after their patents had expired. The FDA treated clinical trials data submitted to the agency as proprietary information, which enabled pioneers to rely on valuable regulatory property acquired through the approval process to effectively deter competitors. Generic manufacturers lobbied Congress to lower regulatory barriers, while pioneers argued that it was only fair that regulation effectively extended their periods of exclusivity, since regulation significantly shortened their patents' effective lives.[73]

In passing the Hatch-Waxman Act, Congress brokered a series of compromises between generic and brand manufacturers. The Act's most transformative provision was the creation of a streamlined process for generic manufacturers to gain approval to sell products. By filing an abbreviated new drug application (ANDA) showing that the applicant's drug is "bioequivalent" to a previously approved product, the Hatch-Waxman Act enabled generic manufacturers to bring off-patent products to market without performing costly clinical trials.[74] This provision essentially authorized the FDA to mediate structured information exchange between competing drug manufacturers by preserving pioneer firms' data as trade secrets while simultaneously facilitating indirect free riding. As a result of this modification to the regulatory regime, generic manufacturers that utilize the ANDA pathway need only spend about $2 million to complete the approval process, in stark contrast to the hundreds of millions of dollars that pioneers must invest to generate safety and efficacy data.[75] To compensate pioneer firms, the Hatch-Waxman Act directed the PTO to grant patent term extensions for loss of patent life engendered by regulatory delays.[76]

The Hatch-Waxman Act also set up a complex scheme whereby generic manufacturers can challenge the validity of unexpired patents. A generic manufacturer may file an ANDA application certifying that it does not believe that its product infringes a valid patent. If the patent owner files an infringement action within 45 days, the FDA

[73] Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, *supra* note 1, at 356-57.
[74] Federal Food, Drug, and Cosmetic Act § 505(j); 21 U.S.C. § 355(j).
[75] *Big Generic Pharma*, THE ECONOMIST, July 30, 2005, at 58.
[76] 35 U.S.C. § 156.

will issue a 30-month stay of regulatory approval of the ANDA, which effectively acts like an FDA-administered preliminary injunction in favor of the patentee.[77] The first ANDA filer to successfully invalidate a pioneer's patent receives 180 days of exclusivity as the only generic manufacturer of the previously approved reference product.[78] Through this scheme, IP and regulatory laws work in tandem to calibrate innovation incentives, making it "difficult to tell just how much work is being done by patents and how much by drug regulation in deferring generic entry."[79]

3. FDA-Administered Exclusivities

Other amendments to the FDCA expressly harness the regulatory regime to encourage innovation. Pursuant to these statutes, the FDA leverages its market gatekeeping authority to award "pharmaceutical pseudo-patents" to manufacturers in exchange for performing certain types of R&D.[80] The Orphan Drug Act of 1983[81] authorizes the FDA to award seven years of market exclusivity to the first manufacturer that succeeds in gaining approval to sell a drug to treat rare diseases and conditions that affect fewer than 200,000 patients in the United States.[82] Additionally, the Hatch-Waxman Act directs the FDA to grant five years of data exclusivity for approved new chemical entities,[83] and three years of data exclusivity for approved new indications or formulations of licensed drugs that require submission of additional clinical data.[84]

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[77] Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy, supra* note 1, at 358.
[78] 21 U.S.C. § 355(j)(5)(B)(2006). This scheme has given rise to "pay for delay" agreements between generic and brand manufacturers whereby the brand manufacturer compensates the ANDA filer in exchange for their agreement to concede the validity of the challenged patent and delay seeking FDA approval to enter the market. The Federal Trade Commission has contended that these agreements violate the antitrust laws. *See* Federal Trade Commission v. Actavis, Inc., 570 U.S. __, at *20-21 (2013) (holding that the FTC should have the opportunity to challenge "pay for delay" settlements on a case-by-case basis under the rule of reason).
[79] Rebecca S. Eisenberg, The Role of the FDA in Innovation Policy, supra note 1, at 359.
[80] *Id*. at 359.
[81] Pub. L. No. 97-414, 96 Stat. 2049.
[82] 21 U.S.C. § 360cc(a). The exclusivity conferred by the Orphan Drug Act does not preclude approval of either (1) another drug for the same disease or condition, or (2) the same drug for another disease or condition. Genentech, Inc. v. Bowen, 676 F. Supp. 301 (D.D.C. 1987); Sigma-Tau Pharms. V. Schwetz, 288 F.3d 141 (4th Cir. 2002).
[83] 21 U.S.C. § 355(j)(5)(F)(ii).
[84] 21 U.S.C. § 355(j)(5)(F)(iii). Pharmaceutical companies frequently use the three-year data exclusivity provision toward the end of a drug's patent life to obtain exclusive rights to market their products over-the-counter.

Finally, the Food and Drug Administration Modernization Act of 1997 (FDMA) provides for six months of market exclusivity as a reward for conducting pediatric clinical drug trials.[85] This market exclusivity is not contingent upon approval of pediatric use of the tested drug; it simply extends any other exclusivity period held by the submitter, whether under a patent or another FDA-administered exclusivity provision.[86]

An important distinction between FDA-administered market and data exclusivities highlights the qualitative differences between intellectual and regulatory property. *Market* exclusivities provided under the Orphan Drug Act and the FDMA operate like patent extensions by granting additional rights in particular patent-eligible compositions of matter. By contrast, FDA-administered *data* exclusivities provided under the Hatch-Waxman Act grant temporary proprietary rights in regulatory property to eligible recipients before permitting free riding by others. Data exclusivities do not prevent competitors from performing their own clinical trials to generate requisite data for FDA approval.[87]

Notably, even after all exclusivity periods end, the creators of regulatory property retain valuable residual proprietary rights. The FDA does not disclose manufacturers' raw, patient-level data about the safety and efficacy of their products, which firms perpetually hold as trade secrets. As discussed in Part IIB(1), *infra*, recent calls for the government to publicly reveal more information developed during the regulatory review process raise questions as to whether compulsory disclosure rules would constitute takings of privately owned regulatory property.

B. Current Interplay of Intellectual and Regulatory Property

1. Regulatory Takings of Trade Secrets

[85] Pub. L. No. 105-115, 111 Stat. 2296. This provision was extended by the Best Pharmaceuticals for Children Act of 2002, Pub. L. 107-109, 115 Stat. 1408 (codified as amended in scattered provisions of Titles 21 and 42 of U.S.C.).
[86] Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy, supra* note 1, at 361.
[87] *Id*. at 360 ("In effect, these provisions amount to FDA-administered proprietary rights in regulatory data, awarded to encourage particular kinds of innovation in drug development rather than to protect consumers from unsafe or ineffective drugs.").

The desirability of leveraging government agencies' gatekeeping authority to compel dissemination of product sponsors' data submissions is a debatable matter of innovation policy. Such proposals also raise constitutional concerns. Takings doctrine is implicated where a government directive reduces the value of a regulated entity's private property.[88] Generally, the determination of whether government regulation effects a taking turns on historical regulatory practices toward the resource at issue, and the extent of the private loss incurred by the government intervention.[89] Regulated entities are deemed on constructive notice of agencies' statutory authority.[90] But tying licensing approval to others' free riding on submitted data invokes the related doctrine of "unconstitutional conditions," which places limits on the government's ability to require individuals to waive their constitutional rights, including those to property under the Takings Clause, to escape a regulatory burden.[91]

Of course, all takings claims are based on a predicate determination that private property is affected by the challenged government action. Unlike situations involving land, discerning the bounds of private property is more difficult where intangible goods are involved.[92] Indeed, the very notion that information can be private property is a controversial idea.[93] As compared to trade secrets that firms independently amass during

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[88] *See* Abraham Bell & Gideon Parchomovsky, *Givings*, *supra* note _, at 552 (noting that takings doctrine is based on assessing whether government action diminishes the absolute value of private property).

[89] *See* Penn Central Transportation Co. v. New York City, 438 U.S. 104 (1978) (setting forth a three-factor test to determine whether a regulation effects a taking that instructs courts to consider the owner's reasonable investment-backed expectations, the nature of the government action, and the degree of diminution in property value). *See also* Nolan v. California Coastal Commission, 483 U.S. 825 (1987) (requiring a rational nexus between the government's goal and the means chosen to pursue it); Dolan v. City of Tigard, 512 U.S. 374, 391 (1994) (holding that there must be rough proportionality between the government's means and ends).

[90] *See* Ruckelshaus v. Monsanto, 467 U.S. 986, 1006 (1984) (observing that "Monsanto was on notice of the manner in which EPA was authorized to use and disclose any data turned over to it by an applicant for registration.").

[91] *See* Richard A. Epstein, BARGAINING WITH THE STATE 23 (1993).

[92] *See* Richard A. Epstein, *The Constitutional Protection of Trade Secrets under the Takings Clause*, 71 U. CHI. L. REV. 57, 58 (2004) (noting that understanding the Takings Clause is difficult in ordinary cases involving land, and "we should not be surprised to find that these problems will surface in the more specific context of trade secrets where the intangible nature of the right adds yet another layer of interpretive uncertainty.").

[93] *See* Pamela Samuelson, *Information as Property: Do Ruckelshaus and Carpenter Signal a Changing Direction in Intellectual Property Law?*, *supra* note _, at 365 ("Informed by the Enlightenment tradition that influenced the drafters of the United States Constitution, American intellectual property law has generally resisted regarding information as something in which its discoverer or possessor can have a property interest.").

the ordinary course of doing business, regulatory property poses even thornier ownership issues. Product developers assert proprietary rights in government-mandated data, but since such information is generated for a specific regulatory purpose, and often is the result of trials involving members of the public who participate as research subjects, its designation as private property is contestable.

Underlying assumptions about the nature of agency-mediated regulatory property affect whether changes to administrative data disclosure rules contemplate regulatory takings (or givings). The constitutionality of government decisions to publicly disclose or permit additional free riding on clinical data largely turns on one's priors as to who owns submitted information upon its creation. If safety and efficacy data are considered private property owned by the firms that fund its production, then mandating disclosure creates positive externalities for which sponsors may need to be compensated.[94] But if one assumes that these data rightfully belong within the public domain, then no constitutional violation occurs if the government unilaterally discloses submitted information. According to this position, allowing firms to retain proprietary rights in safety and efficacy data creates negative externalities for which they do not sufficiently pay.[95]

The Supreme Court adopted the former view in *Ruckelshaus v. Monsanto*,[96] in which it concluded that research data submitted to the Environmental Protection Agency (EPA) constituted private property within the meaning of the Fifth Amendment of the U.S. Constitution. The Court held that, under some circumstances, a federal agency's use or public disclosure of submitted data could constitute a taking of property for which the government must pay just compensation.[97] The takings issue in *Ruckelshaus* arose as a result of a series of legislative amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), a statute that authorizes the EPA to compel pesticide manufacturers to produce data showing that their products will not harm the environment

[94] For an argument that trade secrets and land should be treated analogously for purposes of takings law, *see* Richard A. Epstein, *The Constitutional Protection of Trade Secrets under the Takings Clause*, *supra* note _, at 64, 73 ("Whether we deal with partial government takeovers of land or trade secrets, it is still necessary to consider any police power justification that the state may offer for its actions.").
[95] *See* Harold Demsetz, *Toward a Theory of Property Rights*, 57 AM. ECON. REV. 347, 347-57 (1967) (arguing that property arises to effect internalization of positive and negative externalities).
[96] 467 U.S. 986 (1984).
[97] *Id*. at 1003-04.

in order to gain approval to sell them.[98] Congress amended FIFRA in 1978 to provide ten years of data exclusivity for certain submissions to the EPA, and a fifteen year period in which the original submitter was entitled to "reasonable compensation" from subsequent applicants for the EPA's use of the original submitter's research data in connection with approval of subsequent products.[99] The 1978 amendments also authorized the EPA to publicly disclose data where necessary to protect the public health. These changes overrode an earlier regulatory scheme that had provided stronger trade secret protection for submitted research data.[100]

Monsanto argued that these modifications to the federal rules governing use and disclosure of government-mandated data contemplated an uncompensated taking of trade secrets in violation of the Fifth Amendment.[101] In considering this claim, the Supreme Court found that Monsanto's safety data were property under Missouri law, and noted statements in the legislative history of FIFRA suggesting congressional recognition of a property interest in data submitted to the EPA.[102] The Court reasoned that other kinds of intangible rights, such as liens on property and contracts, had been found to be property within the meaning of the Takings Clause, and concluded that Monsanto's trade secrets similarly fell within the scope of the Fifth Amendment.[103] However, the Court held that no taking would occur were the EPA to disclose data submitted by Monsanto after passage of the 1978 FIFRA Amendments, or to use those data when evaluating others' license applications. This was because "Monsanto could not have had a reasonable, investment-backed expectation that EPA would keep the data confidential beyond the limits prescribed in the amended statute itself."[104]

Like the regulatory property dispute at issue in *Ruckelshaus*, revisions to the regulatory regime governing submissions to the FDA can raise takings issues. The biomedical industry has long taken the position that clinical data submitted to the FDA is

[98] 7 U.S.C. § 136a (2011).
[99] Pamela Samuelson, *Information as Property: Do Ruckelshaus and Carpenter Signal a Changing Direction in Intellectual Property Law?*, supra note _, at 377-78.
[100] *Id*. at 378.
[101] *Ruckelshaus*, 467 U.S. at 998-99.
[102] *Id*. at 1001-02.
[103] Id.
[104] *Id*. at 1005-06.

intangible property belonging to product sponsors.[105] Firms rely on federal regulations that prohibit public disclosure of data that is classifiable as trade secrets or confidential information.[106] Additionally, under the Trade Secrets Act, the disclosure by a federal employee of data designated as proprietary to the submitter constitutes a criminal offense.[107] The FDA has consistently treated agency-mandated safety and efficacy data as proprietary information,[108] although the statutory language used to support this position is ambiguous.[109]

The FDA's stance runs counter to a literal interpretation of the FDCA as amended by the Hatch-Waxman Act, which provides that data to support a license application shall be publicly disclosed as soon as all FDA-administered exclusivity periods have ended, "unless extraordinary circumstances are shown."[110] In response to calls for increased transparency, in recent years the agency has put more information about approved products on its website, such as analyses of clinical data by FDA staff and agency letters

[105] *See, e.g.* PHARM. RESEARCH & MFRS. OF AM. PRINCIPLES ON CONDUCT OF CLINICAL TRIALS AND COMMUNICATION OF CLINICAL TRIAL RESULTS 21 (2004) ("As owners of the study database, sponsors have discretion to determine who will have access.").

[106] 21 C.F.R. § 20.61(c) ("Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure."). *See also* 21 C.F.R. § 20.61(a) (defining a trade secret as "any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort"); 21 C.F.R. § 20.61(b) ("Commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.").

[107] *See* 18 U.S.C. § 1905 (prohibiting, on penalty of fines and imprisonment, the disclosure by a federal employee of "information [that] concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association").

[108] *See, e.g.,* Public Information, 42 Fed. Reg. 3094, 3106 (Jan. 14, 1977) (noting that the FDA has treated clinical trials data as trade secrets since 1938); Pub. Citizen Health Research Group v. FDA, 997 F. Supp. 56 (D.D.C. 1998).

[109] Drug sponsors have relied on § 301(j) of the FDCA, which prohibits "[t]he using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section [505]…concerning any method or process which as a trade secret is entitled to protection." 21 U.S.C. § 331(j).

[110] Section 104 of the Hatch-Waxman Act, 98 Stat. 1597 (1984) (codified as amended at 21 U.S.C. § 355(l)). *See* DONALD O. BEERS, GENERIC AND INNOVATOR DRUGS: A GUIDE TO FDA APPROVAL REQUIREMENTS § 5.01 (1999) ("In fact, for almost every application, FDA has been willing to find 'extraordinary circumstances' for refusal to release such data.").

to manufacturers regarding safety concerns.[111] However, the agency does not disclose the underlying raw data used to support licensing and labeling decisions.[112]

The FDA will not approve a generic manufacturer's ANDA until after the reference product sponsor's FDA-administered exclusivity periods have ended. In addition, ANDA filers must either wait until the reference product sponsor's patents have expired or risk a patent infringement lawsuit before marketing a generic version of a licensed product. Hence brand manufacturers do not have an unassailable argument that data nondisclosure is necessary to prevent free riding by competitors.[113] Nevertheless, trade secrecy for clinical data enables product sponsors to capture a significant portion of the social value of the regulatory property developed through the review process. The FDA exercises its licensing and labeling authority to synthesize, distill, and filter complex scientific data to inform patients and physicians about manufacturers' products. Regulatory approval serves to signal the quality of the sponsor's product while allowing sensitive underlying information, including some negative data, to remain proprietary.[114]

Data nondisclosure sustains incentives to develop regulatory property by offering its producers competitive benefits, but simultaneously diminishes the social utility of the information that is generated. For example, other firms may not be alerted to possible dangers of or potential new indications for particular classes of drugs. A lack of publicly available data could lead to inefficient drug development if manufacturers unaware of competitors' past failures repeat clinical trials that are destined to fail. Additionally, non-commercial researchers lack the means to independently re-analyze raw data and verify or refute product sponsors' safety and efficacy claims.[115]

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[111] *See*, *e.g.*, FDA, Label and Approval History, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist (information about injectable Reglan).

[112] Under the Freedom of Information Act (FOIA), anyone may request copies of documents that form the records of agencies of the Executive Branch. 5 U.S.C. § 552 (2006), *amended by* OPEN Government Act of 2007, Pub. L. No. 110-175, 121 Stat. 2524. However, subsection 4 ("Exemption 4") exempts "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). The Supreme Court has held that this exemption permits agencies to withhold company records containing trade secrets. Chrysler Corp. v. Brown, 441 U.S. 281, 292-94 (1979). *See* Pub. Citizen Health Research Group v. FDA, 185 F.3d 898, 901 (D.C. Cir. 1999) (affirming the FDA's authority to withhold submitted information based on Exemption 4 of FOIA).

[113] Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, *supra* note 1, at 381-82.

[114] *Id*. at 382-83.

[115] *Id*. at 383.

Over the past several years, both the FDA and the biomedical industry have faced mounting political pressure to disclose more information about clinical data used to support agency safety and efficacy determinations. In 2000, pursuant to Section 113 of the FDAMA, the National Institutes of Health (NIH), in consultation with the FDA and other agencies, launched the ClinicalTrials.gov website. As originally conceived, the government required posting of information about all clinical trials, whether federally or privately funded, studying investigational products to treat serious or life-threatening diseases or conditions.[116] Shortly after the launch of ClinicalTrials.gov, pharmaceutical companies and their trade associations began to make voluntary commitments to share clinical trial results.[117] The International Committee of Medical Journal Editors (ICMJE) in 2005 began to require public registration of clinical trials as a condition of publication.[118]

In 2007, the World Health Organization (WHO) created the International Clinical Trials Registry Platform, which includes a search portal linked to data listed on ClinicalTrials.gov.[119] That same year Congress enacted the Food and Drug Administration Amendments Act (FDAAA),[120] which expanded the disclosure rules to mandate registration of all clinical trials related to FDA submissions (excluding early exploratory drug trials), not merely those studies pertaining to the treatment of serious or life-threatening conditions. It also mandated the posting of summary results, including adverse events, for certain trials.[121] Furthermore, the FDAAA stipulated penalties for noncompliance, such as the withholding of NIH grant funding and civil monetary penalties of up to $10,000 per day.[122]

Several companies in the United States and Europe recently published commitments to expand access to clinical trial results beyond that required under current

[116] *See* ClinicalTrials.gov Background, https://clinicaltrials.gov/ct2/about-site/background.
[117] Michelle M. Mello et al., *Preparing For Responsible Sharing of Clinical Trial Data*, 369 NEW ENGL. J. MED. 1651, 1651 (2013) (noting that companies and trade associations began to make voluntary data sharing commitments beginning in 2002).
[118] *See* ICMJE, Clinical Trial Registration, http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html.
[119] *See* WHO, Welcome to the WHO ICTRP, http://www.who.int/ictrp/en/.
[120] Food and Drug Administration Amendments Act of 2007, Pub. Law No. 110-85, 121 Stat. 823 (codified as amended at 21 U.S.C. §§ 301 *et seq*.).
[121] 42 U.S.C. § 282(j) (delineating requirements related to the expanded clinical trial registry data bank).
[122] *See* ClinicalTrials.gov, FDAAA 801 Requirements, https://clinicaltrials.gov/ct2/manage-recs/fdaaa.

laws. For example, the pharmaceutical company Roche adopted a policy allowing researchers access to raw data from trials of approved products,[123] and the medical device manufacturer Medtronic partnered with Yale University to provide access to data on a recombinant protein sold by Medtronic for use in bone grafting procedures.[124] In June 2013, the European Medicines Agency (EMA), which approves drugs for marketing within the European Union, announced plans to provide access to some patient-level data used to make licensing decisions, although the agency will not release information that it considers to be confidential, and requesters must pledge to use the data only for non-commercial public health research purposes.[125] The FDA also drafted a proposal to make available to researchers patient-level data on classes of drugs (but not individual products).[126]

Data transparency proponents assert that these efforts are steps in the right direction, but do not go far enough.[127] They argue that manufacturers should be required to disclose raw safety and efficacy data as a condition of gaining and retaining regulatory approval to sell their products.[128] The normative judgment underlying this position is that the dynamic costs associated with dampening incentives to invest in the production of regulatory property would be offset by the static and dynamic benefits of mandating that

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[123] *Switzerland's Roche pledges to open up access to drug data*, Reuters.com, Feb. 27, 2013, http://uk.reuters.com/article/2013/02/26/roche-data-access-idUKL6N0BQD3M20130226.
[124] Yale School of Medicine, Yale University Open Data Access (YODA) Project, Medtronic Collaboration, http://medicine.yale.edu/core/projects/yodap/datasharing/medtronic/index.aspx.
[125] Michelle M. Mello et al., *Preparing For Responsible Sharing of Clinical Trial Data, supra* note _, at 1652. See also Rory Watson, *European Medicines Agency Changes Policy on Clinical Trial Data Publication,* 348 BMJ g4073 (2014), available at http://www.bmj.com/content/348/bmj.g4073 (noting that transparency proponents remain concerned about "the broad legal conditions on the access and use of such data and the fact that it only allowed limited access to clinical trial data by redacting significant information.").
[126] *See* Availability of Masked and De-Identified Non-Summary Safety and Efficacy Data; Request For Comments, 78 Fed. Reg. 33, 421 (June 4, 2013).
[127] *See Best Kept Secrets*, 32 NATURE BIOTECH. 499 (2014), June 9, 2014, *available at* http://www.nature.com/nbt/journal/v32/n6/full/nbt.2935.html ("Although these moves to greater transparency are a positive development, they are being played out against a backdrop in which company secrecy – specifically confidential business information (CBI) – is on the rise.").
[128] *See, e.g.,* Joseph S. Ross & Harlan M. Krumholz, *Ushering in a new era of open science through data sharing: the wall must come down*, 309 JAMA 1355 (2013) ("As for the interest of [clinical trial] funders, the privilege of selling a medical product should be accompanied by a responsibility to share all clinical research data relevant to evaluating the product's risks and benefits."); Christine D. Galbraith, *Dying To Know: A Demand For Genuine Public Access to Clinical Trial Results Data*, 78 MISS. L. J. 705, 712 (2009) (calling for "comprehensive disclosure of meaningful clinical trial results data from all studies, including the underlying raw data, regardless of whether FDA approval is ever obtained or even sought.").

regulatory property be deposited into the public domain.[129] Patients and physicians arguably would benefit from more comprehensive information about marketed products, and researchers would have greater access to data with which to perform follow on R&D. On the other hand, large-scale public disclosures would threaten patient privacy and could cause harm stemming from information overload and data misinterpretation. Moreover, mandatory free riding on submitted data could cause the private costs to outweigh the private benefits of performing rigorous clinical trials, leaving product developers with insufficient motivation to generate socially valuable information.[130]

2. Federal Preemption of Failure-To-Warn Claims

Cost/benefit tradeoffs over administrative agencies' exclusion and use of regulatory property are functionally tied to the interplay between federal regulatory and state tort laws in encouraging the production and disclosure of product safety information. In addition to compensating individuals harmed by risky products, tort liability rules for failure-to-warn essentially function as private, *ex post* information-eliciting regulations. Through the penalties imposed by the tort system, firms are discouraged from holding as proprietary information that they owe a duty to reveal.[131] In this way, state products liability laws allocate among producers and consumers rights to information. But federal preemption doctrine modifies these allocations by shielding manufacturers from liability associated with information that they confidentially disclose to agencies and which agency officials elect to hold secret. Federal administrative policies regarding the treatment and management of data submissions thereby have ripple effects on firms' incentives to create and disseminate intellectual and regulatory property.

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[129] *See*, *e.g.*, Ida Sim et al., *Clinical Trial Registration: Transparency is the Watchword*, 367 LANCET 1631, 1631 (2006) (concluding, based on consultations between industry representatives and the WHO's International Clinical Trials Registry Platform group, that, "there is no convincing evidence that disclosure threatens competition and hence innovation. Indeed, openness might promote rather than stifle innovation.").

[130] Katie Thomas, *Medical Journal to Require More Details on Drug Trials*, NY TIMES, Oct. 31, 2012, *available at* http://www.nytimes.com/2012/11/01/business/british-medical-journal-to-require-detailed-clinical-trial-data.html?_r=1& (noting a statement by an industry representative citing concerns about sharing raw patient-level data, which "'could not only lead to misinterpretation of the risks and benefits of medicines, and potentially interfere with patient confidentiality, but would also deter future medical innovation if would-be competitors could access confidential commercial information.'").

[131] Dan R. Cahoy, *Medical Product Information and the Transparency Paradox*, 82 IND. L. J. 623, 637 (2006) ("[T]ort law acts as a supplemental means of punishing those whose secrecy creates unreasonable risks.").

Often the FDA will condition licensing approval on a product sponsor's agreement to complete additional post-marketing studies. The agency has weak statutory authority to enforce such voluntary agreements,[132] but manufacturers of approved products have mandatory, ongoing obligations to timely report to the FDA certain "adverse drug experience" information.[133] In addition, product sponsors must file annual reports to the FDA disclosing any newly acquired post-market information that could affect the agency's previous safety and efficacy conclusions.[134] The FDA occasionally requires manufacturers to alert physicians of suspected, but as yet unconfirmed, side effects.[135] It may prescribe labeling revisions in response to new safety information that accumulates after product approval.[136] Preliminary risk information also must be posted online in advance of potential labeling revisions.[137]

Supplementing the federal regulatory scheme, state tort laws create incentives for manufacturers to develop and disclose information about licensed products. Manufacturers do not have a duty to warn of risks associated with their products that are unknowable on the basis of existing scientific evidence.[138] However, jurisdictions vary in the stringency of their standards regarding sellers' obligations to discover risks that might have become apparent if additional studies were conducted. Several courts have rejected

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[132] *Id*. at 633 n. 39.
[133] 21 C.F.R. § 314.80(a) (defining an "adverse experience" as "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.").
[134] *Id*. at § 314.81(b)(2)(iv)(a).
[135] *See, e.g*., Marc Kaufman, *Impotence Drug Will Get Blindness Warning*, WASH. POST, July 9, 2005, at A6.
[136] 21 U.S.C. § 355(o)(4)(2006).
[137] *See* FDAAA, Pub. L. No. 110-85, § 915, 121 Stat. 823, 958 (2007) (codified at 21 U.S.C. § 355(r)(2)(D) (requiring the Secretary to prepare, "by 18 months after approval of a drug or after use of the drug by 10,000 individuals, whichever is later, a summary analysis of the adverse drug reaction reports received for the drug, including identification of any new risks not previously identified, potential new risks, or known risks reported in unusual number"). Adverse event reports are available to the public via the FDA's MedWatch website, which also includes a portal for reporting incidents. *See* MedWatch: The FDA Safety Information and Adverse Event Reporting Program, http://www.fda.gov/Safety/MedWatch/default.htm.
[138] *See, e.g*., Griggs v. Combe, Inc., 456 So. 2d 790, 791-93 (Ala. 1984) (rejecting tort claims because manufacturer's topical cream had never before been associated with the plaintiff's injury); Toner v. Lederle Labs., 732 P.2d 297, 306-07 (Idaho 1987) (stating that manufacturers are not required "to be clairvoyant"). A couple of jurisdictions impute knowledge to product sellers, thereby shifting the burden of proof on this issue to the defendant. *See* Shanks v. Upjohn Co., 835 P.2d 1189, 1199-200 (Alaska 1992); Feldman v. Lederle Labs., 479 A.2d 374, 387-88 (N.J. 1984).

the argument that manufacturers have tort duties to engage in costly and speculative data generation efforts to identify unknown safety risks of licensed products.[139] But others have suggested that sellers do have ongoing duties to test their products and to ascertain their clinical effects.[140]

Some commentators assert that manufacturers should have perpetual common law duties to research the safety and efficacy of their marketed products.[141] They argue that the tort system, in addition to enforcing duties to warn of known risks, should impose upon firms an affirmative obligation to continuously generate and reveal information during the post-marketing period. As Lars Noah explains, "Frustrated by the inherent limitations of preapproval clinical trials, the failure of the [FDA] to demand rigorous postapproval testing, and the minimal information communicated directly to patients, these commentators have urged judges to draw on the common law tradition in order to remedy these and other alleged failings of the regulatory system."[142] Such proposals would extend manufacturers' product stewardship obligations beyond those generally recognized under tort law.

A primary rationale for enhancing manufacturers' tort exposure is that doing so would create additional incentives for firms to invest in research that they might otherwise lack motivation to perform. However, proposed expansions of the tort system could create perverse effects if they are uncoordinated with changes to the federal regulatory scheme. Initiatives aimed at increasing disclosure of FDA-mediated clinical

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[139] *See* JAMES M. BECK & ANTHONY VALE, DRUG AND MEDICAL DEVICE PRODUCT LIABILITY DESKBOOK § 2.04[1]. *See, e.g.*, Valentine v. Baxter Healthcare Corp., 81 Ca. Rptr. 2d 252, 265 (Ct. App. 1999) (stating that "the imposition of liability for breach of an independent duty to conduct long-term testing, where the causal link to the known harm to plaintiff is the unknown outcome of the testing that was not done, would be beyond the pale of any California tort doctrine we can identify.").

[140] *See, e.g.*, Medics Pharm. Corp. v. Newman, 378 S.E.2d 487, 488-89 (Ga. Ct. App. 1989) (recognizing a duty to test the safety of unapproved "off-label" uses); Feldman v. Lederle Labs., 479 A.2d 374, 386-87 (N.J. 1984) (explaining that a manufacturer "must keep reasonably abreast of scientific knowledge and discoveries" and "may also be required to make tests to determine the propensities and dangers of [its] product."); Kociemba v. G.D. Searle & Co., 707 F. Supp. 1517, 1528-29 (D. Minn. 1989) ("[T]he duty to test is a subpart…of the duty to warn."); Bichler v. Eli Lilly & Co., 436 N.E.2d 182, 188-90 (N.Y. 1982) (allowing plaintiff's claim that manufacturer could have discovered its product's toxicity if it had undertaken rodent testing). *See also* Dan R. Cahoy, *Medical Product Information and the Transparency Paradox*, 82 IND. L. J. 623, 640-41 & nn. 78-81 (2006) (discussing limited judicial recognition of a tort duty to test).

[141] Lars Noah, *Platitudes About "Product Stewardship" in Torts: Continuing Drug Research and Education*, 15 MICH. TELECOMM. TECH. L. REV. 359, 360 (2009), *available at* http://www.mttlr.org/volfifteen/noah.pdf.

[142] *Id*. at 360-61.

trials data could create a "transparency paradox" whereby liability fears cause manufacturers to decrease the amount of publicly available information that they generate.[143] Over the past several years, the Supreme Court has decided a series of cases addressing tensions between state and federal laws that obligate manufacturers to produce and disclose risk information. Recent decisions regarding the extent to which federal regulation preempts state tort claims have altered innovators' incentives to reveal safety information about licensed technologies, and correspondingly their incentives to create new intellectual and regulatory property going forward.

The Supremacy Clause of the U.S. Constitution stipulates that federal statutes, and the regulations adopted pursuant to them, trump state law.[144] Congress may expressly include a preemption provision in federal legislation. Where Congress is silent as to the preemptory effect of a federal statute, courts will consider whether federal law implicitly preempts state law. Implied preemption exists either where enforcement of state law would impermissibly conflict with the federal scheme ("conflict preemption"), or where it appears that Congress intended federal regulation to exclusively occupy the field ("field preemption").[145] Conflict preemption can be further subdivided into cases in which it is impossible to simultaneously comply with conflicting federal and state requirements, and cases in which enforcing state laws merely would frustrate the goals of the federal statute.[146]

Congress expressly preempted state law when it enacted the 1976 Medical Device Amendments to the FDCA. In *Riegel v. Medtronic*,[147] the Supreme Court held that the Amendments preempted a products liability claim brought against a manufacturer whose medical device had gone through the FDA pre-market approval process.[148] By contrast,

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[143] Dan R. Cahoy, *Medical Product Information and the Transparency Paradox*, *supra* note _, at 625-26 ("This transparency paradox could produce a more dangerous healthcare environment and eventually erode public confidence in the system.").
[144] U.S. Const. art VI, cl. 2.
[145] Richard A. Epstein, *The Case For Field Preemption of State Laws in Drug Cases*, 103 NORTHWESTERN L. REV. 463, 464 (2009).
[146] *Id*.
[147] 552 U.S. 312 (2008).
[148] *Riegel*, 552 U.S. at 322-23. By contrast, the Court in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), ruled that tort claims against a medical device manufacturer were not preempted where the device had been licensed under the FDA's streamlined "510(k)" system, in which the agency certifies products that are substantially similar to those already on the market without requiring independent testing of the new device. *Lohr,* 518 U.S. at 503.

the portion of the FDCA that pertains to drugs does not contain an explicit preemption provision.[149] In a string of decisions involving tort claims against drug companies, the Supreme Court has determined that implied federal preemption doctrine applies differently in cases against pioneers and cases against generic copiers. In *Wyeth v. Levine*,[150] the Court held that a plaintiff could bring a failure-to-warn case under state law against the manufacturer of Phenergen, an antihistamine whose labeling had been approved by the FDA.[151] By contrast, in *Pliva v. Mensing*,[152] the Court held that a plaintiff was barred from bringing a failure-to-warn claim against the manufacturer of a generic version of the drug Reglan. In *Mutual Pharmaceutical Co. v. Bartlett*,[153] it extended the scope of generic manufacturers' protection from tort liability by holding that federal law also preempted claims that generic drugs were defectively designed.[154]

The Supreme Court's uneven application of federal preemption stems from the fact that the FDA currently administers different information disclosure rules for pioneer and generic manufacturers. If a pioneer discovers new risk information about a licensed product, the manufacturer may unilaterally change its label prior to obtaining FDA approval to make the change.[155] The Court in *Wyeth* reasoned that because the defendant did not need FDA preapproval to strengthen its warnings, and there was no evidence that the agency would have prohibited it from making such a labeling change, it was possible for the manufacturer to simultaneously comply with its disclosure duties under both federal and state law.[156] By contrast, in *Pliva* the Court noted that a generic manufacturer would violate federal law if it unilaterally made labeling changes to strengthen its warning. Therefore, preemption applied because it would be impossible for a generic

[149] Indeed, the Drug Amendments of 1962 affirmatively state that preemption shall not apply "unless there is a direct and positive conflict between such amendments and such provision of State law." Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962).
[150] 129 555 U.S. 555 (2009).
[151] *Id*. at 570-73.
[152] 131 S.Ct. 2567-68 (2011).
[153] 133 S.Ct. 2466 (2013).
[154] *Id*. at 2473-77.
[155] The FDAAA of 2007 changed the regulatory landscape significantly by allowing brand manufacturers to update their warnings prior to obtaining FDA approval. *See* Pub. L. 110-85, § 901(a)(4)(B), 121 Stat. 823, 924 (2007).
[156] The Court reasoned that the FDA's "changes being effected" (CBE) regulation, 21 C.F.R. §§314.70(b) and (c), which requires FDA preapproval for most substantive labeling changes, "permitted Wyeth to unilaterally strengthen its [IV-push administration] warning, and the mere fact that the FDA approved Phenergen's label does not establish that it would have prohibited such a change. *Wyeth*, 555 U.S. at 573.

manufacturer to comply with both federal regulations and state tort duties mandating stronger warnings than those contained in FDA-approved labels.[157] For similar reasons, the Court in *Bartlett* found that a generic manufacturer could not be sued on a design defect theory based on inadequate warnings.[158]

The Supreme Court's preemption decisions underscore the complex ways in which FDA regulation affects manufacturers' incentives to create and develop information goods. Under the current regime, pioneers who produce the requisite safety and efficacy data to bring new drugs to market face ongoing sanctions under tort law for failure to sufficiently track accumulated post-market information and uncover emergent trends. Since federal preemption bars the tort system from imposing these duties upon generic manufacturers, generics can free ride on pioneers' efforts to interpret aggregate outcomes data and make necessary labeling changes. However, pioneers can avoid tort liability if they disclose newly acquired risk information to the FDA and the agency explicitly rejects their requests to revise their labels based on such new information.[159] In exercising its licensing authority, the FDA thereby modulates the rewards and penalties associated with regulated entities' information production activities in the post-market period.

Notably, revisions to the regulatory regime can alter the balance of incentives. The FDA recently proposed a new rule that would permit ANDA applicants, like pioneers, to strengthen their warnings in response to new post-market information prior to obtaining regulatory approval to change their labels.[160] If this rule is finalized, impossibility preemption presumably no longer will apply to failure-to-warn claims against generic manufacturers. This would increase generic manufacturers' incentives to generate socially valuable safety information, but likely at the cost of higher prices for consumers who would indirectly pay for generics' enhanced post-market data gathering activities.[161]

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[157] *Pliva*, 2577-78.
[158] *Bartlett*, 133 S.Ct. at 2473-77.
[159] In this case, impossibility preemption would apply. *See Wyeth*, 555 U.S. at 570-73.
[160] *See* Supplemental Applications Proposing Labeling Changes For Approved Drugs and Biological Products, 78 Fed. Reg. 67985-02 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pt. 314 and 601).
[161] *See* Anna B. Laakmann, *The Hatch-Waxman Act's Side Effects: Precautions For Biosimilars*, 47 LOY. L.A. L. REVIEW _ , *12-13 (forthcoming) (unpublished manuscript on file with the author).

III. Common Governance Challenges Across IP and Regulatory Regimes

A. Information Processing Technologies

The functional overlaps between intellectual and regulatory property systems are most striking in areas involving scientific advances that are not linked to the creation of new physical goods. Though it nominally sells chemicals and apparatus, at its heart, the contemporary biomedical industry is in the business of generating and selling information. This is true for conventional products like pharmaceuticals,[162] and even more so for cutting-edge technologies such as genetic diagnostics and mobile health software.[163] The core innovations underlying these new technologies are improvements in the ways in which information is captured, processed, and manipulated. Currently there exists a great deal of uncertainty about the appropriate legal standards to apply to these products and services. Common governance challenges that span across IP and regulatory regimes manifest the ways in which these systems work in tandem to manage the development of socially valuable information.

1. *Heightened Patent Eligibility Standards*

Section 101 of the Patent Act states that a patent may be granted to "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[164] There are, however, longstanding judicially created exceptions to patent-eligible subject matter: "laws of nature, natural phenomena, and abstract ideas."[165] Although the Supreme Court has stated

[162] *See* Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y & ETHICS 717, 717-18 (2005) ("Drugs are information-rich chemicals that in many respects are more akin to other information products…than they are to other chemicals"); Joe Collier & Ike Iheanacho, *The Pharmaceutical Industry as an Informant*, 360 LANCET 1405, 1405 (2002) ("Although the primary function of drug companies is to develop and market drugs, these companies spend more time and resources generating, gathering, and disseminating information."); Lars Noah, *Authors, Publishers, and Products Liability: Remedies for Defective Information in Books*, 77 OR. L. REV. 1195, 1212 (1998) ("[D]rug companies are actually engaged in the business of producing and selling information for use by patients and their physicians.").
[163] *See* Nathan Cortez, *The Mobile Health Revolution?*, 47 UC DAVIS L. REV. 1173, 1176 (2014) ("'Mobile health,' or 'mHealth,' is the use of mobile communications devices like smartphones and tablet computers for health or medical purposes, usually for diagnosis, treatment, or simply well-being and maintenance.").
[164] 35 U.S.C § 101.
[165] Diamond v. Diehr, 450 U.S. 175, 185 (1981).

that a connection to physical objects should not be the litmus test for patent-eligibility,[166] several recent Court decisions have applied the non-statutory exceptions to deny patent protection for information-based technologies. In 2012, the Court held in *Mayo Collaborative Services v. Prometheus Laboratories* that a claimed method of determining optimal drug dosages to treat autoimmune diseases recited unpatentable laws of nature.[167] The following year it decided *Association for Molecular Pathology v. Myriad Genetics*, holding that claims to isolated DNA failed to satisfy the requirements of § 101 because they essentially claimed naturally occurring information.[168] Most recently, in *Alice Corp. v. CLS Bank*, the Court held that a computer-implemented scheme to mitigate settlement risk in financial transactions was drawn to an unpatentable abstract idea.[169]

Numerous commentators observe that the Court's § 101 decisions have increased the threshold requirements for patenting, but have failed to articulate predictable standards to identify whether particular inventions fall within one of the judicially created exceptions.[170] As a result, the combined effects of *Mayo, Myriad,* and *Alice* have cast doubt on the patentability of a wide swath of innovation whose patent eligibility was not disputed just a few years ago. For example, after deciding *Mayo* and *Myriad,* the Supreme Court denied a petition for certiorari to review a Federal Circuit decision finding patent-ineligible a claimed method to determine fetal risk of Down syndrome

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[166] In Bilski v. Kappos, 130 S.Ct. 3218 (2010), the Court stated that the Federal Circuit's "machine or transformation" test should not be the sole test for determining patent-eligibility, because solely relying on such a test "would create uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals." *Bilski*, 130 S.Ct. at 3229-31.

[167] 132 S. Ct. 1289, 1294 (2012).

[168] 133 S. Ct. 2107, 2118 (2013).

[169] 573 U.S. __ (June 19, 2014).

[170] *See, e.g.*, Rob Merges, *Symposium: Go Ask Alice – What Can You Patent After Alice v. CLS Bank?*, SCOTUSBLOG, June 20, 2014 ("To say that we did not get an answer [to the question of whether software is patent-eligible] is to miss the depth of the non-answer we did get."); Rob Merges, *Selected Thoughts on a Myriad of Problems*, SCOTUSBLOG, Feb. 6, 2013, http://www.scotusblog.com/2013/02/selected-thoughts-on-a-myriad-of-problems (describing the Court's § 101 jurisprudence as a "metaphysical morass"); Dan L. Burk, *The Curious Incident of the Supreme Court in Myriad Genetics*, 90 NOTRE DAME L. REV. , *3 (2014), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2407094 (noting the Court's lack of clarity regarding laws and products of nature and their relationship to each other); Arti K. Rai, *Biomedical Patents at the Supreme Court: A Path Forward*, 66 STAN. L. REV. ONLINE 111, 114 (2013) (noting that the Court in *Myriad* missed an opportunity to provide guidance not only to the biopharmaceutical industry, but to industries dependent on software and data processing); Anna B. Laakmann, *The New Genomic Semicommons*, _ UC IRVINE L. REV. _, * 9-10 (forthcoming) (unpublished manuscript on file with the author) (discussing the ambiguities in *Myriad*).

based on measuring two different biochemical and/or ultrasound markers at two different times.[171] The unsuccessful petitioners had argued that the Federal Circuit's ruling rendered unpatentable "most diagnostic, screening, and personal medicine tests, except those involving a man-made cell, a new drug or a new way of using an existing drug."[172] Although it is too soon to ascertain the full precedential impact of the Supreme Court's recent opinion in *Alice*, this decision apparently validates a recent lower court decision finding computer-implemented medical treatment algorithms unpatentable.[173]

The policy rationale underlying the Supreme Court's more rigorous approach to patent eligibility is the need to preserve a robust public domain. The Court explained in *Mayo*, "[E]ven though rewarding with patents those who discover new laws of nature and the like may well encourage their discovery, those laws and principles, considered generally, are 'the basic tools of scientific and technological work.'"[174] But raising patent eligibility thresholds too high risks diminishing the public domain over the long term. One of the main rationales for awarding patents is that it spurs inventors to publicly disseminate knowledge that they might otherwise elect to keep hidden.[175] Inventors of new algorithms for interrogating and interpreting data may turn to secrecy as a means to appropriate the value of patent-ineligible discoveries.[176] Moreover, the IP system does not operate in a vacuum to calibrate incentives to create and disclose intangible resources. Part IIIA(2), *infra*, explains that patent eligibility hurdles are rising against the backdrop of a shifting regulatory landscape for information-based technologies.

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[171] Intema Ltd. v. PerkinElmer, Inc., 134 S. Ct. 102 (Oct. 7, 2013).
[172] PerkinElmer, Inc. v. Intema, 496 F. App'x 65 (2012), *petition for cert. filed*, 2013 WL 2179301 (U.S. May 16, 2013) (No. 12-1372). *See also* Ariosa Diagnostics, Inc. v. Sequenom, Inc., 2013 WL 5863022 (N.D. Cal. Oct. 30, 2013 (finding patent-ineligible claims on a non-invasive test to screen for fetal genetic abnormalities).
[173] *See* SmartGene, Inc. v. Advanced Biological Labs., S.A., No. 2013-1186 (Fed. Cir., Jan. 24, 2014) (unpublished opinion holding that a claim to the use of a computer to select treatment for a patient recites an unpatentable abstract idea).
[174] *Mayo*, 132 S. Ct. at 1301 (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (1972)).
[175] Kevin Emerson Collins, *The Knowledge/Embodiment Dichotomy*, *supra* note _, at 1315-16 ("The inventor gets exclusive rights for a limited period of time, and, in return, the public gets the benefit of access to the knowledge about the invention disclosed in the patent specification – knowledge that, absent patent disclosure, might have remained secret."). *See generally* Michael Abramowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 YALE L.J. 1590 (2011).
[176] *See* Anna B. Laakmann, *The New Genomic Semicommons*, *supra* note _, at *15-17 (discussing the possibility that inventors of patent-ineligible genomic discoveries might turn to secrecy as an appropriation mechanism).

2. Shifting Regulatory Landscape

Medical diagnostics include both *in vitro* tests that are performed outside the human body using tissue samples or bodily fluids, and *in vivo* tests that are performed on or in the body. Historically, the FDA has drawn relatively clear boundaries to mark the scope of its regulatory purview. Conventional *in vivo* diagnostics, such as x-rays and ultrasounds, involve specialized medical equipment that falls squarely within the definition of devices as defined under the FDCA.[177] The FDA has consistently required manufacturers of such diagnostic devices to obtain licenses prior to marketing their products. In addition, the FDA traditionally has distinguished between *in vitro* "test kits" sold by manufacturers and shipped in interstate commerce, and "laboratory-developed tests" (LDTs) performed within clinics and hospitals. Longstanding agency practice has been to regulate the former but to decline to exercise regulatory authority over the latter type of *in vitro* diagnostic test.[178] In order to avoid FDA scrutiny, many commercial diagnostics companies currently develop their tests in-house.[179]

Over the past several years, significant changes in the ways in which health information is generated and exchanged have forced the FDA to reevaluate its regulatory policies. Advances in gene sequencing, data processing, and computational techniques have enabled the development of increasingly sophisticated diagnostic tools.[180] In 2007, the agency published a draft guidance proposing to expand its oversight to a subset of LDTs known as in vitro diagnostic multivariate index assays (IVDMIAs), which apply complex algorithms to interpret multiple recorded variables.[181] One justification for the

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[177] *See* 21 U.S.C. § 321(h) (defining a device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is...(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man.").

[178] *See* PRESIDENT'S COUNCIL OF ADVISORS ON SCI. & TECH., PRIORITIES FOR PERSONALIZED MEDICINE 37 (2008), http://www.ostp.gov/galleries/PCAST/pcast_report_v2.pdf.

[179] *Id*. at 39 ("Based on the FDA's longstanding decision to exercise enforcement discretion with respect to [LDTs]…a number of business plans were based on a path to market via laboratory-based implementation and CLIA regulation, rather than a path of a PMA submission to the FDA, which is perceived to be riskier and more costly.").

[180] *See, e.g.*, Eric J. Topol, *Individualized Medicine from Prewomb to Tomb*, 157 CELL 241, 241-42 (explaining how researchers use laboratory tests, biosensors, scanners, medical records, and social media to obtain multiple layers of data and generate digitized profiles of subject populations).

[181] FDA, DRAFT GUIDANCE FOR INDUSTRY, CLINICAL LABORATORIES, AND FDA STAFF: IN VITRO DIAGNOSTIC MULTIVARIATE INDEX ASSAYS (2007),

proposed regulatory expansion was that the algorithms used in IVDMIAs are often proprietary and users cannot independently verify the results.[182] The draft guidance attracted intense industry criticism, and the agency never finalized it. Instead, in 2010, it announced its intent to regulate all LDTs.[183] The FDA has not yet published proposed changes to its regulation of LDTs, but the agency has indicated that a major overhaul to the current regime is imminent.[184]

The FDA also has been struggling to develop a workable regulatory approach to a rapidly growing array of technologies designed to turn consumer electronics, including smartphones and computer tablets, into medical devices that capture and interpret clinical information.[185] For example, software applications have been developed that take advantage of a smartphone's built-in features, such cameras, accelerometers, and wireless connectivity, to enable patients to track and analyze vital signs, blood-glucose levels, and other biometric data.[186] In September 2013, in order to quell confusion about its regulatory stance, the FDA issued a nonbinding guidance that specifies the types of

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http://www.fda.gov/downloads/MedicalDevices/.../ucm071455.pdf (defining IVDMIA as "a device that 1) combines the values of multiple variables using an interpretation function to yield a single, patient-specific result…that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, and 2) provides a result whose derivation is non-transparent and cannot be independently derived or verified by the end user").

[182] C. Wilson et al., *Biomarker Development, Commercialization, and Regulation: Individualization of Medicine Lost in Translation*, 81 CLINICAL PHARMACOLOGY & THERAPEUTICS 153, 154 (2007).

[183] 75 Federal Register 34462, June 17, 2010.

[184] *See* FDA, PAVING THE WAY FOR PERSONALIZED MEDICINE: FDA'S ROLE IN A NEW ERA OF MEDICAL PRODUCT DEVELOPMENT 32 (October 2013), http://www.fda.gov/downloads/scienceresearch/specialtopics/personalizedmedicine/ucm372421.pdf ("FDA has been developing a risk-based framework for regulatory oversight of LDTs that would assure that tests, regardless of their manufacturer, have the proper levels of control to provide a reasonable assurance of safety and effectiveness, while also fostering innovation and progress in personalized medicine.").

[185] *See* Nathan Cortez, *The Mobile Health Revolution?*, *supra* note_, at 1182-90 (describing the various categories of mobile health technologies).

[186] *See* Aditi Pai, Jonah Comstock & Brian Dolan, *Timeline: Smartphone-Enabled Health Devices*, MOBIHEALTHNEWS (June 7, 2013), http://mobihealthnews.com/22674/timeline-smartphone-enabled-health-devices/ (offering a summary of recent milestones in the development of smart-phone enabled health and fitness devices). *See also* Harry McCracken, *Scanadu Aims to Turn Smartphones into Healthcare Helpers*, TIME (Nov. 19, 2012), http://techland.time.com/2012/11/29/scanadu-aims-to-turn-smartphones-into-healthcare-helpers/ (noting that the tagline of the Silicon Valley company Scanadu is "Sending your smartphone to medical school"); Brian Dolan, *Scanadu Production Backed Up, but FDA Loophole Ready to Go,* MOBIHEALTHNEWS (April 7, 2014), http://mobihealthnews.com/31790/scanadu-production-backed-up-but-fda-loophole-ready-to-go/ (discussing Scanadu's efforts to comply with FDA requirements, and explaining that consumers who want to receive Scanadu's product before it is cleared by the FDA are required to consent to participate as research subjects).

mobile health applications that it will and will not regulate.[187] The agency explained that it would limit its oversight to regulating software developers, and would decline to exercise authority over the manufacturers of the hardware upon which mobile health applications operate.[188] It further clarified that the FDA would assert jurisdiction only over those applications that are intended to diagnose, cure, mitigate, treat, or prevent diseases or other conditions, or affect the structure or function of the body.[189]

Although the FDA's guidance provides some much needed clarity for the mobile health industry, a great deal of regulatory uncertainty persists regarding the agency's plans to manage the means to produce consumer-generated health information. As with conventional medical devices, the FDA's stated goal continues to be the protection of public health and welfare.[190] However, the agency's standard safety and efficacy requirements apply awkwardly to information processing technologies that are not linked to specialized medical equipment. The crux of regulatory decision-making in this area involves striking a balance between enabling access to and ensuring the accuracy of the information created through use of these technologies. The cost/benefit tradeoffs resemble those that come into play within IP law. More stringent regulatory oversight would exclude some health information from users in the short term, but might ultimately enhance the quality of the information goods that are produced by structuring incentives to increase their social value. These regulatory dilemmas lend additional credence to arguments that the FDA is better described as an information intermediary than as a market gatekeeper.[191]

B. New Uses for Old Products

1. Limits of Patent Protection

[187] U.S. FOOD & DRUG ADMIN., MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (September 25, 2013), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf.
[188] *Id*. at 9-10.
[189] *Id*. at 7-8.
[190] *Id*. at 6 ("As is the case with traditional medical devices, certain mobile medical apps can pose potential risks to public health.").
[191] *See* Richard A. Epstein, *Against Permitits: Why Voluntary Organizations Should Regulate the Use of Cancer Drugs*, 94 MINN. L. REV. 1, 31-33 (2009) (noting and critiquing the FDA's role in collecting, processing, and evaluating information).

As with new technologies for processing information, the development of information about new uses for old products presents governance challenges for both IP and regulatory regimes. IP protection is not available for creations that fail to satisfy patent law's novelty and nonobviousness requirements, regardless of the amount of investment required to bring them to market.[192] If innovators lack the means to recoup the costs to develop and commercialize unpatentable inventions, the public can be deprived of beneficial products. This is a particularly acute problem for pharmaceuticals, since mere disclosure of a compound's formula renders the compound and its technically obvious variants unpatentable, and the costs of completing the FDA approval process are substantial.[193] Potentially valuable products that are prematurely deposited into the public domain before their safety and efficacy have been tested risk remaining forever undeveloped.[194] Evidence suggests that the social harm stemming from lack of incentives to develop unpatentable inventions could be severe.[195]

The first product sponsor to gain FDA approval to market an unpatentable drug is entitled to five years of FDA-administered data exclusivity. In additional, drugs that qualify as orphan drugs are entitled to seven years of market exclusivity.[196] However, the prospect of being awarded these proprietary rights upon the successful completion of the treacherous FDA review process may not be enough if firms cannot obtain patents on their products at the outset. Indeed, anecdotal accounts suggest that FDA-administered market exclusivities for orphan drugs provide insufficient incentives to develop products that lack strong patent protection.[197]

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[192] Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 519-20 (2009) (explaining that "the investment necessary to develop and commercialize an invention is irrelevant to its patentability.").

[193] Benjamin N. Roin, Unpatentable Drugs and the Standards of Patentability, supra note _, at 515-16, 521-22.

[194] *Id*. at 545-47 (noting that pharmaceutical companies routinely assess the patentability of drug candidates during the drug development process, and filter out those that they believe are in the public domain).

[195] *Id*. at 553-555 (discussing potential harms caused by insufficient incentives to generate information about the safety and efficacy of using the drug finasteride to prevent prostate cancer, and arguing that, for similar reasons, pharmaceutical companies may lack incentives to develop promising drugs to treat "HIV, cancer, heart disease, stroke, diabetes, malaria, tuberculosis, and diarrhea – conditions that afflict and kill millions of people each year.").

[196] *See* Part IIB(3), *supra*.

[197] Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, *supra* note _, at 566 fn. 335 (discussing telephone conversations with industry executives asserting that FDA-administered exclusivities

Those who discover new methods of using old products may obtain patents on the newly discovered processes. However, process patents generally are much less valuable than patents on machines, manufactures, or compositions of matter, because patentees cannot sue competitors who make and sell the products to be used.[198] Technically, patentees can enforce method of use patents against those who directly infringe by performing the patented process, or those who actively induce or contribute to direct infringement.[199] For example, in the medical context, patent holders could sue patients, prescribing physicians, pharmacists who fill prescriptions, and competitors who encourage these actors to infringe patents covering new indications for old drugs. However, due to public relations and other pragmatic considerations, patentees generally are reluctant to pursue these avenues of enforcement.[200]

2. Constraints on Regulatory Incentives

Federal regulations create additional incentives for innovators to develop socially valuable information about new uses of known products. In performing its core role of protecting the public from "misbranded" products, the FDA induces manufacturers to generate safety and efficacy data.[201] Through this regime, the agency encourages firms to engage in R&D that they may otherwise lack sufficient motivation to perform. But statutory and constitutional constraints on the FDA's authority limit the extent to which developers are encouraged to invest costly resources into investigating the clinical effects of medical products.

If the FDA has never licensed a particular drug or device for any indication, the manufacturer must obtain the agency's permission before selling its product. This gatekeeping power enables the FDA to compel firms to generate data that meets applicable evidentiary requirements to support promotional claims.[202] However, once a

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generally do not offer sufficient incentives to incur the expense of developing and commercializing a new drug).

[198] *See, e.g.*, Allergan v. Alcon Labs., 324 F.3d 1322 (Fed. Cir. 2003).

[199] *See* 35 U.S.C. § 271(b) (establishing liability for active inducement); 35 U.S.C. § 271(c) (establishing liability for contributory infringement).

[200] Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, *supra* note 1, at 351.

[201] *See* Part IIA(1), *supra*.

[202] *See, e.g.*, Federal Food, Drug, and Cosmetic Act § 505(d) (providing that the Agency may refuse to approve a drug if the sponsor fails to include adequate tests showing whether or not it is safe, or if there is a

product has been approved for a single indication, physicians and patients may use it for any indication, irrespective of the existence of clinical data to support "off-label" use. This is because the FDA expressly acknowledges that its statutory authority extends only to regulating manufacturers, and it cannot regulate physicians' practice of medicine.[203]

Manufacturers can take advantage of this limitation on FDA authority to avoid performing risky, costly clinical studies of new indications for licensed products. Although the FDA rigorously polices the content of manufacturers' product labels, it is less able to control other forms of communication to physicians and patients regarding unapproved off-label uses. For example, a manufacturer might promote off-label uses of its products through distribution of reprints of scientific publications or through participation in continuing medical education programs. Over the past several years, the agency's attempts to restrict off-label promotion have been repeatedly challenged on First Amendment grounds.[204] A survey of recent cases shows an escalation in the intensity of the challenges to the FDA's speech-related policies.[205]

Information that meets criteria for patent protection sometimes is generated in the process of using licensed products for unapproved off-label uses. For example, preliminary clinical data may suggest new indications for known drugs that are patentable processes. Drug sponsors who submit evidence to the FDA to support promotion of a new use can attempt to capture the value of this regulatory property through acquisition of formal IP rights. However, because of the practical impediments to enforcing these types of proprietary rights, process patents may not sufficiently encourage efforts to gain regulatory approval to promote new uses for old products.[206]

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lack of "substantial evidence" that the drug will have the effect that it purports to have under the conditions of the proposed labeling).

[203] *See* 21 C.F.R. § 312.2(d) (2001) (explaining that the FDA's investigational new drug requirements "do[] not apply to the use in the practice of medicine for an unlabeled indication of [an approved] new drug."); 37 Fed. Reg. 16,503, 16,504 (1972) ("[I]t is clear that Congress did not intend the [FDA] to regulate or interfere with the practice of medicine….").

[204] *See* Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998); Washington Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000); Thompson v. Western States Med. Ctr., 535 U.S. 357 (2002); United States v. Caronia, 703 F.3d 149 (2nd Cir. 2012).

[205] Gerald Masoudi & Christopher Pruitt, *The Food and Drug Administration v. The First Amendment: A Survey of Recent FDA Enforcement*, 21 HEALTH MATRIX 111, 111 (2011) ("A survey of recent developments illustrates that the frequency and magnitude of such actions have grown more pronounced as the agency increases its enforcement activities.").

[206] *See* Part IIIB(1), *supra*.

As explained in Part IIB(3), *supra*, manufacturers who successfully obtain FDA approval to promote new uses for licensed products receive three years of data exclusivity. This reward offers additional enticement to manufacturers to carry out costly clinical trials. However, data exclusivity does not prevent competitors from selling previously approved products and marketing them for other previously approved uses. Moreover, the FDA cannot use data exclusivities to stop physicians from prescribing competitors' drugs for off-label uses that competitors have not gained approval to promote. These limitations significantly hamper manufacturers' ability to rely on FDA-administered data exclusivities to appropriate regulatory property created in the process of gaining approval to promote newly discovered uses for old products.[207]

IV. A Coordinated Approach To Intellectual and Regulatory Property

A. Shared Problems of Declining Average Costs

The various functional connections between the IP and regulatory regimes demonstrate the need for a coordinated approach to incenting the generation of socially valuable intangible property. IP is a good with declining average costs: its creation generally requires significant capital expenditures, but once produced the marginal cost of using it is virtually zero.[208] Typically, the *ex post* costs to develop and commercialize IP are lumped together with the *ex ante* costs to create it. However, when these capital expenditures are conceptually separated, regulatory property can be identified as a distinct downstream "declining average cost" good. For example, it costs hundreds of millions of dollars to gain FDA approval of a pharmaceutical, the bulk of which is spent to generate safety and efficacy data beyond that required under patent law.[209] Once such regulatory property is created, like other types of information, it is costless for others to use it.

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[207] *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, *supra* note 1, at 360-61.
[208] John F. Duffy, *The Marginal Cost Controversy in Intellectual Property*, 71 U. CHI. L. REV. 37, 40 (2004) (noting that describing a good as "non-rivalrous" is the same thing as saying that it is produced at zero marginal cost).
[209] Footnote _, *supra*.

Two important corollaries follow from the fact that both intellectual and regulatory property are goods with declining average costs. First, firms will not produce them absent some government mechanism that enables them to avoid or recover their fixed costs. Second, it is socially wasteful for more than one entity to produce identical pieces of either intellectual or regulatory property.[210] Just as inventing the same medical device would needlessly duplicate fixed costs, so too would performing two sets of clinical trials to test the safety and efficacy of identical devices. Hence any efforts to tailor incentives to develop intellectual and regulatory property should aim to concentrate production of each new information resource in a single organization.[211]

After such information goods are produced, government restrictions on price and access may be necessary to constrain strategic behavior and maximize social welfare.[212] Allowing information producers to enjoy monopoly power over intangible goods typically will produce deadweight losses.[213] On the other hand, unrestricted free riding on information resources also may be economically suboptimal.[214] When firms incur high fixed costs to produce information resources, legal structures governing their exclusive use must be calibrated to strike a desirable balance between static costs and dynamic benefits.[215]

Several alternatives to IP have been proposed to offset firms' capital expenditures to create new inventions, including both *ex ante* government subsidies such as grants and

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[210] *See* John F. Duffy, *The Marginal Cost Controversy in Intellectual Property*, *supra* note _, at 40-41 (making both points with respect to IP).

[211] This principle only applies to the wasteful duplication of identical, or closely equivalent, information goods. It may be socially beneficial to create incentives for multiple entities to develop similar, but non-equivalent, intellectual and regulatory property.

[212] *See* John F. Duffy, *Rethinking the Prospect Theory of Patents*, *supra* note _, at 509-10 (explaining that the analogy between the patent system and natural monopoly regulation is apt, and noting, "In both areas, the central policy question [is] how to constrain the behavior of the monopolist so as to maximize social welfare.").

[213] Robert C. Guell & Marvin Fischbaum, *Toward Allocative Efficiency in the Prescription Drug Industry*, 73 MILBANK Q., June 1995, at 216-17 (explaining that deadweight losses occur when monopolists set prices above the marginal cost to produce an additional unit, and as a result "consumers lose more from higher prices than producers gain.").

[214] *See* Michael Abramowicz & John F. Duffy, *Intellectual Property for Market Experimentation*, 83 N.Y.U. L. REV. 337, 342 (2008) ("Industrial organization scholars have long recognized that in many contexts, free entry will not lead to socially optimal entry.").

[215] *Id*. at 340 (noting that "market exclusivity imposes a static cost but that the dynamic benefit of encouraging information production and dissemination may make this cost worth bearing.").

tax credits, and *ex post* subsidies such as prizes and rewards.[216] These government interventions are designed to push down prices of commercial end products toward marginal costs. However, there are several long recognized problems with publicly financed marginal cost solutions.[217] These include "distortionary costs" from government taxes imposed to fund subsidies; misallocation of resources where the government lacks information about what consumer demand would be if the government did not intervene; potentially unfair wealth redistributions that occur when revenues needed to cover fixed costs are derived from general taxation; and lost opportunities for efficient price discrimination that reduces deadweight losses.[218]

Any government initiative that aims to substitute for IP as a means to encourage invention must address these potential pitfalls and make the case that the marginal cost solution has more desirable allocative and distributive effects than the IP scheme that it aims to replace. In an influential 1969 article, Harold Demsetz argued that patents are a theoretically superior means to direct government interventions to support innovation, because patents link the type and magnitude of incentives to market prices.[219] Assuming that market prices reasonably approximate social value, patents ensure allocative efficiency by capturing distributed private information about the relative merits of different inventions. Efficient market-based schemes can produce undesirable distributive effects where technology users have unequal wealth. However, distributive justice concerns can be ameliorated by *ex post* resource re-allocations in lieu of *ex ante* government interventions.

The calculus changes somewhat when we consider downstream marginal cost solutions to encourage the generation of regulatory property. In this case, the primary aim is not to create alternative incentives to invent, but rather to induce the production of data about the risks and benefits of particular embodiments. In some contexts, the social value

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[216] *See* Brian D. Wright, *The Economics of Invention Incentives: Patents, Prizes, and Research Contracts*, 73 AM. ECON. REV. 691 (1983) (comparing the merits of these strategies for incenting information production).
[217] Ronald Coase, *The Marginal Cost Controversy*, 13 ECONOMICA 169 (1946).
[218] John F. Duffy, *The Marginal Cost Controversy in Intellectual Property*, *supra* note _, at 42-46. A perfect price discriminator charges each customer the maximum that the customer is willing to pay. Perfect price discrimination ordinarily is not a practical possibility, because sellers cannot know the maximum price point for each customer.
[219] Harold Demsetz, *Information and Efficiency: Another Viewpoint*, 12 J. L. & ECON. 1, 11-14 (1969).

of such data may be fairly easy to estimate, but may not be fully incorporated into a market price. For example, it may be possible to approximate the social benefits of learning about the safety and effectiveness of a particular diabetes therapy. Hence a government-financed initiative to generate regulatory property might not produce as much resource misallocation as government subsidization of upstream research. However, undesirable allocative and distributive effects could result if such programs were supported through general taxation. Additionally, rules regarding exclusion and use of downstream regulatory property, whether privately or publicly financed, have secondary feedback effects on upstream invention incentives.

B. Calibrating The Internalization Of Externalities

Property rights are legal mechanisms that enable actors to internalize the positive and negative externalities that result from production and use of privately owned resources.[220] As Ronald Coase explained in discussing the famous case of *Sturges v. Bridgman*,[221] in which a doctor sued a neighboring confectionary to enjoin the noise and vibrations coming from the confectionary machines, a negative externality can always be reframed as a positive externality merely by changing baseline assumptions.[222] If one assumes quiet as the baseline, then noise is a negative externality that results from the confectioner's use of the machines; if one assumes noise as the baseline, then quiet becomes a positive externality that results when the confectioner refrains from using the machines.[223]

This basic principle applies to the creation and use of information resources. Both IP and FDA regulation govern the internalization of externalities, although the characterization of these externalities depends on one's assumed starting point. If the baseline is no creativity, then IP internalizes positive externalities by rewarding creative work; if the baseline is creativity, then IP internalizes negative externalities produced by

[220] Harold Demsetz, *Toward a Theory of Property Rights*, 57 AM. ECON. REV. 347, 350 (1967) (noting that "property rights develop to internalize externalities when the gains of internalization become larger than the cost of internalization.").
[221] 11 Ch. D. 852 (Eng. Ch. App. 1879).
[222] R.H. Coase, *The Federal Communications Commission*, 2 J. L. & ECON. 1 (1959).
[223] John F. Duffy, Intellectual Property Isolationism and the Average Cost Thesis, supra note _, at 1087.

laziness.[224] Similarly, if the baseline is no safety and efficacy data about embodiments of newly created technologies, then FDA regulation produces positive externalities; if the baseline is comprehensive safety and efficacy data, then its absence is a negative externality that FDA regulation prevents.[225] The fluid relationships between negative and positive externalities suggests that externalities can be internalized in a variety of different ways through coordinated calibration of intellectual and regulatory property rights.

Construing intellectual and regulatory property as distinct, though overlapping, information goods offers a framework for developing more efficient innovation policy. In many cases, the entities that create nascent inventions differ from the entities that are most suited to generate and interpret information about the uses of particular embodiments, which may differ from the entities that are best able to devise business models for commercial end products. Recognizing separate rights in regulatory property would promote efficient division of specialized labor by facilitating the allocation of entitlements in valuable information that falls outside the scope of IP.[226] It also would underscore important differences between the contributions of those who merely invent new technologies, and those who both invent and bring new products to market.[227]

Moreover, policymakers seeking to further distributive justice goals may have more leeway to modulate regulatory property rights than they do to modulate IP rights. The allocation of regulatory property that does not meet the criteria for formal IP protection need not conform to the strictures of the federal IP laws and the Trade-Related

[224] *Id*. at 1088.
[225] *See* Lucas v. S.C. Coastal Council, 505 U.S. 1003, 1024 (1992) ("[The distinction between 'harm-preventing' and 'benefit-conferring' regulation is often in the eye of the beholder.").
[226] *See* Oren Bar-Gill & Gideon Parchomovsky, Essay, *A Marketplace for Ideas?*, *supra* note _, at 398-99 (noting, "From an economic standpoint,…there is a powerful case for separating the [conception and development stages of the inventive process]"); Michael Abramowicz, *Orphan Business Models: Toward a New Form of Intellectual Property*, 124 HARV. L. REV. 1362, 1365 (2011) ("[W]hat may be especially important for intellectual property to protect is not so much investments in developing ideas for new business methods but investments in commercializing and experimenting with untested business models.").
[227] *See* Michael Abramowicz & John F. Duffy, *Intellectual Property for Market Experimentation*, *supra* note _, at 343-44 (explaining the intuition behind concerns over patent trolls by noting, "The law should be more generous to firms that have both made technological disclosure in patent documents *and* risked assets in launching new businesses based on the technology.").

Aspects of Intellectual Property Rights (TRIPS) agreement.[228] Although rules governing regulatory property must adhere to provisions under TRIPS that prevent agencies from disclosing proprietary data, such provisions permit information resource management designed to further public interests.[229]

Like all policy decisions to allocate valuable resources, the calibration of regulatory property entails tradeoffs of static and dynamic costs and benefits. Normative judgments about the relative importance of utilitarian efficiency and distributive fairness are unavoidable. But a coherent approach to IP and regulation clarifies the choices between competing social concerns by highlighting the ways in which interrelated property rights operate to affect their balance. In addition, it helps to identify areas in which the current regimes may be reformed or supplemented in order to further innovation goals.

C. Strategic Alternatives To Promote Innovation

1. Incentives to Disclose Patent-Ineligible Inventions

Recognizing the FDA as an information intermediary, not simply a market gatekeeper, helps to clear a sensible path for regulation of medical technologies lacking distinct physical embodiments. In those areas in which patent availability is uncertain, the regulatory system could be employed to create alternative incentives for innovators to generate and reveal valuable information. Patent law's disclosure requirements are designed to ensure that the size of the patent award is commensurate with the patentee's

[228] TRIPS is an international agreement administered by the World Trade Organization that was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994. *See* Agreement on Trade Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments-Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994), *available at* http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm. Article 27 requires signatories to provide patent protection "without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

[229] Section 7, Article 39, Part 3 of the TRIPS agreement states that Members shall protect against the disclosure of data submitted as a condition of marketing new chemical entities, "except when necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.").

social contribution.[230] A similar approach may be taken to define proprietary rights in government-mediated regulatory property. Just as the patent system structures a quid pro quo between the public and the creators of new information resources, regulatory laws can be used to allocate intangible goods across proprietary and public domains. A carefully crafted regulatory scheme could avert potential common interest tragedies by encouraging and coordinating the production of patent-ineligible discoveries.[231]

This model might work particularly well to promote the development of information processing technologies, such as medical diagnostics and mobile health software. By conditioning licensing decisions on the generation and disclosure of socially valuable information, the FDA could assert its regulatory authority to foster knowledge production and dissemination. For instance, approval of diagnostic tests might be conditioned on deposit into a centralized public database of patient-level data used to support the test's clinical validity. In exchange for enhancing the research commons, product sponsors would gain the competitive advantages of a government license.

Tying FDA approval to dissemination of submitted information might raise issues of regulatory takings and unconstitutional conditions.[232] To counteract these concerns, FDA regulations could be crafted to bestow benefits upon firms in exchange for producing and disclosing clinical data. For example, the FDA could operate in tandem with the Centers for Medicare and Medicaid Services (CMS) to ensure insurance reimbursement for FDA approved products. In addition, firms that make data publicly accessible might enjoy streamlined market entry of licensed products and protections from tort liability for failure-to-warn of product risks. Essentially, in exchange for voluntarily placing information into the public domain, firms would avoid some of the costs associated with private ownership.

Inevitably, such an approach would have disparate effects on technology users. Future users likely would benefit from enhanced enrichment of the public domain

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[230] *See* Anna B. Laakmann, *An Explicit Policy Lever For Patent Scope*, 19 MICH. TELECOMM. TECH. L. REV. 43, 54-56 (2012) (explaining the ways in which the disclosure requirements, supplemented by the patentable subject matter doctrine, restrict the scope of patent claims).
[231] *See* Robert B. Ahdieh, *The Visible Hand: The Coordination Function of the Regulatory State*, 95 MINN. L. REV. 578, 602-03 (2010) (explaining that the key function of the regulatory state is to prevent collective action failures).
[232] *See* Part IIB(1), *supra*.

stemming from agency-mediated information production and dissemination. In the short term, however, current users would be required to pay for more costly, FDA-regulated products. While some consumers may prefer to purchase products whose clinical validity has been assessed by government regulators, others with different information preferences may be forced to pay for information goods that they personally do not value. A possible way to mitigate this concern would be to structure a two-tiered system comprising information-rich, FDA approved products and information-poor, unapproved products, analogous to the current dichotomy between drugs and dietary supplements.[233]

FDA approval would not perform the same certification function if simply tied to information production rather than a formal agency determination of safety and efficacy. Although some users may benefit from access to FDA approved technologies before comprehensive information about their risks and benefits has been developed, others could be exposed to harm from market approval coupled with limitations on manufacturers' failure-to-warn liability. Linking data generation and disclosure to reductions in tort liability disincentives necessarily would entail a public policy judgment that the overall social benefits from such a scheme outweigh potential costs for certain classes of consumers.[234]

2. Public Funding to Develop Regulatory Property

Alternatively, information about the safety and efficacy of medical products could be generated using public funds. Unlike proposals to replace IP through government financing of new inventions, a scheme could be devised that focuses on the development of regulatory property to enhance the social value of existing technologies. This model might work particularly well to promote the discovery of new uses for old products. As discussed in Part III, *supra*, typically neither the IP nor the regulatory system offers

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[233] *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, *supra* note 1, at 379-380 (explaining the different regulatory regimes for drugs and dietary supplements and noting, "A benefit of the current uneven regulatory regime is that consumers often have a choice between costly, information-rich pharmaceutical products and less expensive dietary supplements that may be sold without the burdens and benefits of costly clinical trials.").

[234] Dan R. Cahoy, *Medical Product Information and the Transparency Paradox*, *supra* note _, at 657 (noting that "[r]educing tort disincentives [to encourage knowledge production] involves…a public policy choice – one that places greater value on society's increased access to information over the benefits plaintiffs and their attorneys derive from litigation uncertainty.")

sufficient private incentives for developers to make costly investments to investigate the risks and benefits of novel indications for known technologies. Firms generally refrain from developing unpatentable inventions, and manufacturers often stand to gain little from performing risky, rigorous clinical trials to study off-label uses of licensed products.[235] Inherent limitations of relying on market-based proprietary rights to prevent free riding on this type of information make it an attractive area for government funding.

The existing literature contains a variety of proposals suggesting that the government could reduce undesirable static inefficiencies by paying patent holders to place their inventions in the public domain. These proposals posit schemes whereby private actors fund the creation of new inventions, and the government subsequently compensates them with a reward or buy-out.[236] Yet the converse scenario also is possible. That is, the government could fund the production of socially valuable information, and then offer to sell it to private entities in exchange for proprietary rights to commercialize it. Firms could purchase these rights in exchange for the competitive benefits that commercial use of these data provides. The government could calibrate the scope of exclusivity based on the social importance of ensuring widespread public access to the associated products. The price that firms that would be willing to pay for use of government-funded regulatory property would correspondingly vary with the strength of the proprietary rights that are offered for sale.

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[235] *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, *supra* note 1, at 376-77 (noting that the manufacturer of the hormone replacement therapy (HRT) Prempro enjoyed expanded sales from widespread off-label use of HRT to reduce the risk of heart disease in post-menopausal women, but that its sales were sharply reduced after the NIH, not the manufacturer, conducted a long-term study that found that HRT actually increased women's risk of heart disease).

[236] Michael Polanvyi proposed a prize system as a means of patent reform in the mid-20th century. *See* Michael Polanvyi, *Patent Reform*, 11 REV. ECON. STUD. 61, 67 (1944) (proposing "to supplement licences of right by government rewards to patentees on a level ample enough to give general satisfaction to inventors and their financial promoters."). More recently, several scholars have proposed government-financed prize systems as alternatives to IP. *See* Steven Shavell & Tanguy van Ypersele, *Rewards Versus Intellectual Property Rights*, 44 J. L. & ECON. 525, 537-39 (2001) (proposing a prize system that inventors could opt into in lieu of the patent system); Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q. J. ECON. 1137, 1147-48 (1998) (describing a system whereby patentees would agree to give up their patents in exchange for compensation that would be determined through an auction process); Robert C. Guell & Marvin Fischbaum, *Toward Allocative Efficiency in the Prescription Drug Industry*, *supra* note _, at 213, 221 (proposing a system for the pharmaceutical industry whereby "the government buy[s] prescription drug patents at a price equaling the net present value of the profit they would have generated.").

Any publicly financed scheme designed to subsidize the fixed costs of information production unavoidably risks leading to a misallocation of resources.[237] Mechanisms should be put in place to minimize these effects by harnessing government funding allocations to private valuations. Since it often takes several years of marketing efforts to successfully promote a product, adequate incentives for commercialization should be built into a government-financed regime.[238] A potential way to do this would be to establish a market in which firms do not incur upfront R&D costs, but bid on the right to develop and appropriate regulatory property with known private value. Commercial entities typically are best informed about the development path for nascent inventions and best able to devise business strategies for licensed products.[239] A system that enabled them to purchase rights in publicly funded clinical data would enable regulatory property to be exploited by the highest value developer.

A futures market could be established to allow firms to purchase call options to exercise rights in information to be generated using public funds. …

[Here I plan to discuss the literature on auction models to allocate rights in intangible goods.]

Third parties could be induced to perform research on new uses for old products through allocation of government-funded grants or rewards. Also, in lieu of performing their own clinical trials, medical products manufacturers could purchase the rights to rely on third party-generated data that supports FDA approval of new marketing claims for

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[237] *See* Part IVA, *supra*.

[238] *See, e.g.*, Henry Grabowski et al., *Returns of Research and Development for 1990s New Drug Introductions*, 20 PHARMACOGENOMICS 11, 17-18 (Supp. 3 2002) (noting that even the most successful drugs typically do not reach blockbuster status until four or five years after product launch).

[239] *See* Malcolm MacCoss & Thomas A. Baillie, *Organic Chemistry in Drug Discovery,* 303 SCIENCE 1810, 1812-13 (2004) (asserting that academic and government laboratories are not capable of performing the work necessary to transform hits or leads into viable new medicines); John S. Lazo, *Roadmap or Roadkill: A Pharmacologist's Analysis of the NIH Molecular Libraries Initiative,* 6 MOLECULAR INTERVENTIONS 240, 241 (2006) (arguing that most academic medical centers lack the medicinal-chemistry expertise to develop a drug that is ready for clinical trials); Michael Privitera, *Large Clinical Trials in Epilepsy: Funding by the NIH Versus Pharmaceutical Industry*, 68 REVIEWS/EPILEPSY RES. 52, 56 (2006) (noting the pharmaceutical industry's superior ability to inform physicians about the results of clinical trials); JERRY AVORN, POWERFUL MEDICINES: THE BENEFITS, RISKS, AND COSTS OF PRESCRIPTION DRUGS 292-312 (2004) (discussing the effectiveness of pharmaceutical marketing strategies).

existing products. Additional legal wrinkles would arise where firms hold product patents, but lack sufficient incentives to invest in clinical research to develop information about the safety and efficacy of new uses. A scheme could be devised to grant non-patentees rights to investigate new indications for patented products, taking advantage of a statutory exemption from patent infringement liability for research related to submitting information to the FDA. This statutory safe harbor was created by a provision in the Hatch-Waxman Act that supplements a narrow common law experimental use privilege for purely non-commercial research.[240] Although the statutory language suggests a narrow exemption for generic drug manufacturers seeking to develop information to support ANDA applications prior to patent expiration, the courts have liberally interpreted this provision to cover a wide range of biomedical research designed to generate regulatory property for submission to the FDA.

[I plan to talk more here about the possibility of relying on the statutory safe harbor to create incentives to generate regulatory property covering new uses.]

Of course, any proposed program that involves government funding of clinical research would run up against strong political headwinds. Tight budgets for federally funded research have been a source of perennial angst, and Congress has given no indication that spending will significantly increase any time soon.[241] However, a limited program that garnered the support of both industry and patient advocacy organizations might be viable. If the interests of diverse stakeholders with strong lobbying support were sufficiently aligned, it is possible that a narrowly targeted pilot project could be successfully launched.

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[240] *See* 35 U.S.C. § 271(e)(1) ("[I]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States a patented invention . . .solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products.").

[241] See, e.g., Sam Stein, *A Scientist Laments the NIH Budget: I'm 'Bitter and Cynical' About the World 'I Wanted to Help'*, HUFFINGTON POST, January 16, 2014, http://www.huffingtonpost.com/2014/01/16/scientist-nih-budget_n_4604716.html; Jennifer Couzin, *Tight Budget Takes a Toll on U.S.-Funded Clinical Trials*, 315 SCIENCE 1202, 1202-03 (2007); Mike Mitka, *Scientists Warn NIH Funding Squeeze Hampering Biomedical Research*, 297 JAMA 1867, 1867 (2007).

3. Mechanisms To Support Collaboration

The IP and regulatory systems also could be coordinated to encourage the collaborative production of information resources.

[I plan to talk here about the ways that firms pool proprietary resources to develop nascent discoveries, and how regulation could be employed to support these collaborative arrangements.]

Conclusion

It is an exciting time for those who study and shape innovation policy. A diverse array of participants is engaged in wide-ranging efforts to advance technology's leading edge. It is also a daunting time for policymakers, as varied and perpetually evolving innovation environments put relentless pressure on the legal system to evolve. When considering difficult policy issues, it is tempting to narrowly focus on one substantive legal area at a time. But such temptations should be resisted, because the various legal regimes that interoperate to drive innovation policy can only be fully understood when considered in concert with one another.

This Article adds to the burgeoning literature on legal structures that encourage innovation beyond IP by showing how ostensibly conflicting IP and regulatory systems actually perform overlapping, complementary functions as parts of a composite legal scheme to govern technological knowledge production. It delineates conceptual distinctions between intellectual and regulatory property by examining the interplay between patents, secrecy, and FDA regulation in the creation and development of medical technology. The Article lays the groundwork for more holistic biomedical innovation policy by exploring the ways in which IP and regulatory laws may be coordinated and calibrated to improve their interoperability and to further social goals. More broadly, it suggests that drawing distinctions between intellectual and regulatory property can aid in developing coherent governance frameworks for all potentially beneficial, risky technologies.