THE YALE LAW JOURNAL

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The Continuum of Excludability and the Limits of Patents

ABSTRACT. In IP scholarship, patents are commonly understood as more efficient than other approaches to innovation policy. Their primary ostensible advantage is allocative: as a form of property rights, patents act as a conduit between market signals and potential innovators, ostensibly guiding investment toward inventions with the most social value. Existing accounts recognize that, in practice, signals of social value that patents facilitate may be attenuated because of, for example, transaction costs and limits on the scope and length of patent rights. We show here, however, a different problem with the conventional allocative account. The appropriability mechanism patents rely on, namely excludability, operates in asymmetrical ways for different kinds of information goods. While scholars have noted that patent systems fail to create goods whose value is difficult to appropriate in consumer markets, this fact has not been fully appreciated in the literature, nor have its implications for the standard justification for patents. Through detailed examples in the health context we show that some kinds of information goods will be much more difficult to exclude than others. Importantly, there is no reason to expect that the ease of exclusion will be correlated with social value. The analytic point that emerges is generalizable: patents themselves can have distortive effects, stemming from structural features of exclusion rights. Unlike the problem of attenuation, the problem of asymmetric nonexcludability cannot be resolved by increasing patent scope or length. Because excludability is variable along a continuum, property rights in information, even if formally perfected, and even assuming away conventional transaction costs, will create asymmetrical demand for different kinds of information goods. This argument provides an important new justification for alternatives to patents such as government funding and gives us new insights about how to allocate such funding. It also reinforces the need for a comparative institutional approach to innovation policy, and for incorporating into our debates currently unrecognized implications that patents may have for values such as privacy and free speech.

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ESSAY CONTENTS

INTRODUCTION

Each year, nearly 30,000 people in the United States die from infections resulting from central-line catheters used for monitoring in intensive-care units (ICUs) in hospitals.[1] These deaths are in part a result of the growing problem of antibiotic-resistant infections in hospitals.[2] The intellectual property (IP) literature is replete with proposals to address that problem by incentivizing the creation of new antibiotics—proposals that sometimes have price tags in the billions of dollars.[3] But in 2006, a different kind of breakthrough was reported in the *New England Journal of Medicine*—a new technology that reduced the number of these infections by about two-thirds.[4] The technology was a humble checklist, featuring important and well-known hygienic practices such as hand washing and the use of antiseptic.[5] Clinical trials have shown that the intervention works in a range of settings, including in otherwise poor-quality ICUs.[6] While the mechanism is still somewhat unclear, it seems to work by giving nurses the authority to enforce the listed practices with doctors and by improving communication in hospitals in other ways.[7]

The checklist intervention is a classic information good: it is immaterial and was much more expensive to create (or to validate, which is often the more pertinent issue with medical interventions, as we will explain) than it is to copy. By any measure of social welfare, it is also a great intervention. It is cheap, has no known side effects, and prevents infections up front rather than simply treating them after the fact. If widely implemented in the United States,

1. Peter Pronovost et al., *An Intervention To Decrease Catheter-Related Bloodstream Infections in the ICU*, 355 NEW ENG. J. MED. 2725, 2726 (2006).

2. Anne Elixhauser & Claudia Steiner, *Infections with Methicillin-Resistant Staphylococcus Aureus (MRSA) in U.S. Hospitals, 1993-2005*, AGENCY FOR HEALTHCARE RES. & QUALITY (July 2007), http://www.hcup-us.ahrq.gov/reports/statbriefs/sb35.pdf.

3. *See, e.g.*, Jorn Sonderholm, *Wild-Card Patent Extensions as a Means To Incentivize Research and Development of Antibiotics*, 37 J.L. MED. & ETHICS 240, 241 (2009).

4. Pronovost et al., *supra* note 1, at 2725.

5. *Id.* at 2726.

6. *Id.*; *see also* Allison Lipitz-Snyderman et al., *Impact of a Statewide Intensive Care Unit Quality Improvement Initiative on Hospital Mortality and Length of Stay: Retrospective Comparative Analysis*, 342 BRIT. MED. J. d219 (2011) (finding that statewide implementation of checklists in Michigan significantly decreased hospital mortality).

7. *See, e.g.*, Charles L. Bosk et al., *Reality Check for Checklists*, 374 LANCET 444, 445 (2009). Pronovost and his colleagues have gone to pains to point out that the checklist intervention requires not just deployment of a checklist, but other changes in feedback processes and work culture. Pronovost et al., *supra* note 1, at 2726-27.

it could save more than 15,000 lives and $1 billion in treatment costs each year.[8] These figures are particularly impressive when compared to the billion-dollar figures often attached to proposals for new drug treatments.

Yet the checklist approach is unlikely to be well rewarded by even a very expansive patent system. Even if we assume that patent law permits a strong and enforceable patent on the intervention, it would be difficult for the creator to use that patent to appropriate any significant proportion of the social value created by the intervention. He would have to track behavior that is routine and to some extent cloaked by privacy norms related to doctor-patient relationships. Thus, the state of technology and of norms place limits on the freedom of our hypothetical patentee to enforce his patent. Of course, we should not overstate the case. An institutional factor would work in the inventor's favor: the existence of hospitals as an organized intermediary. This setup reduces the number of potential infringers and increases the likelihood of tangible evidence of infringing conduct by creating a "paper trail" of written or oral records of established hospital protocols. On balance, though, the checklist will be much less excludable than a drug.

Recognizing this shortcoming of the patent system draws attention to what we call "the continuum of excludability." As we elaborate below, excludability is not a binary quality, either "on" or "off" depending on the availability or absence of property rights. Rather, it is highly variable across information goods, and is affected not only by formal legal entitlements, but also by existing technologies for detecting or tracing such uses (and their costs); existing social norms regarding "acceptable" or "reasonable" enforcement efforts (in light of concerns about privacy, freedom of thought and speech, and so forth); and the existing institutions—or social roles, relations, and organizational forms—within which the predominant uses of the good will be made. Once we recognize that excludability is a continuous and not binary variable, an impressive array of information goods that are difficult to exclude even in the presence of patents comes into view.[9] Our central aim in this Essay is to develop, with examples in public health, our analytic understanding of the continuum of excludability, and to elucidate its substantial implications for innovation theory and policy.

8. STAFF OF H. COMM. ON OVERSIGHT & GOV'T REFORM, 110TH CONG., SURVEY OF STATE HOSPITAL ASSOCIATIONS: PRACTICES TO PREVENT HOSPITAL-ASSOCIATED BLOODSTREAM INFECTIONS 2 (Comm. Print 2008) [hereinafter SURVEY OF STATE HOSPITAL ASSOCIATIONS].

9. Although our focus here is on highly nonexcludable information goods, our analysis of the limits of property rights may also be applicable in the context of other material or immaterial goods, a point we do not develop here. The analysis offered here may also provide us with a slightly different way to describe some of the problems with private provision of network goods and public goods, another issue that we leave for another time.

The central justification for patent rights in the United States is economic in nature and is premised on the incentives that they provide to innovators.[10] But patents are only one strategy for incentivizing information production. Many others exist, and two in particular are much discussed in the economics literature: public funding (where a government agency either directly carries out research or sponsors others through grants), and financial inducement through prizes (where financial rewards are established, typically by the government, in exchange for specified information goods).[11]

The most influential theoretical account of the advantages of patents over these other institutional approaches can be traced to the influential work of Harold Demsetz.[12] In a 1969 article, Demsetz suggested that patents are plausibly superior to more directly government-led strategies for generating innovations because markets utilize dispersed private information more effectively than government actors can.[13] Because they link the magnitude and direction of innovation incentives to market prices, in other words, patents may be a better mechanism than reliance on government funding for ensuring that all truly valuable information goods—and *only* truly valuable information goods—are generated. Demsetz thought that this allocative advantage of patents could outweigh their acknowledged drawbacks, most prominently the fact that patents inefficiently curb the use of protected information.[14] Today, this is the most common justification for patents in the legal literature,[15] which we will call the "allocative" account.

External or foundational critiques could be made of the basic logic of the allocative case for patents. For example, one might challenge welfarism as a value, question the relationship between market value and social value, or be skeptical of the positive assumptions of the underlying "homo economicus" model of innovator motivations. We set aside such foundational objections

10. *See, e.g.*, ROBERT P. MERGES, PETER S. MENELL & MARK A. LEMLEY, INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 14 (5th ed. 2010); William Fisher, *Theories of Intellectual Property*, *in* NEW ESSAYS IN THE LEGAL AND POLITICAL THEORY OF PROPERTY 168, 169 (Stephen R. Munzer ed., 2001); Peter S. Menell & Suzanne Scotchmer, *Intellectual Property Law*, *in* 2 HANDBOOK OF LAW AND ECONOMICS 1471, 1476-82 (A. Mitchell Polinsky & Steven Shavell eds., 2007).

11. For a well-known comparison of the merits of these three strategies, see Brian D. Wright, *The Economics of Invention Incentives: Patents, Prizes, and Research Contracts*, 73 AM. ECON. REV. 691 (1983).

12. *See infra* Part I.

13. Harold Demsetz, *Information and Efficiency: Another Viewpoint*, 12 J.L. & ECON. 1, 11-14 (1969).

14. For a more detailed discussion of this point, see *infra* Part I.

15. *See infra* note 39.

here, and, for the sake of argument, accept the basic premises invoked by the conventional account.[16]

The main internal criticism of the allocative account in the existing literature points out that patents will systematically underreward research because they yield less than full appropriability (for example, because patents have a limited term and can be designed around, and because transaction costs interfere with market signaling).[17] These concerns, however, are not so much a criticism of the allocative case for patents as a worry over obstacles to its full realization. Here we develop an account of a different problem with the allocative case for patents. The link that Demsetz drew between exclusion rights and revenues for creators assumed that exclusion rights do not themselves introduce distortions into the equation between production and social value. But this is not the case.

We offer a series of detailed examples to show that some kinds of information goods will be much more difficult to exclude (and thus to commodify) than others. Importantly, there is no reason to expect that the ease of exclusion will be correlated with social value. Thus, patents themselves can have distortive effects, stemming from structural features of exclusion rights. Importantly, the problem of nonexcludability cannot be resolved by increasing patent scope or length, and it is asymmetrical with respect to different types of information goods. The continuum of nonexcludability thus means that property rights, even if perfected, and even assuming away conventional transaction costs, will create asymmetrical demand for different kinds of information goods.[18]

Other scholars have pointed out that patent systems fail to create goods whose value is difficult to appropriate in consumer markets.[19] But the fact that

16. In Section III.C we will consider the implications of our arguments for moving beyond the internal critique.

17. *See infra* Part I.

18. By "conventional" transaction costs we mean the search, negotiation, and enforcement costs involved in making and upholding private bargains (as well as those involved in the definition and enforcement of any legal entitlements at issue). The contrasting set of "costs" or barriers that are the focus of our analysis stem from the existing state of technology, norms, and institutions, as specified *infra* Section I.B. Although many of these barriers may also be conceived in terms of "costs," not all are usefully understood in this manner, and in any case such "costs" (for instance, those involved in developing new technologies for surveillance or changing widespread privacy norms) are not plausibly subsumed under an analytically useful conception of transaction costs.

19. Brett Frischmann's work is perhaps the leading example in the IP literature. As he points out in his recent book, IP systems work

> in deliberate and unavoidable reliance on the market mechanism, which exhibits a predictable bias for intellectual goods that generate the most appropriable value in

excludability operates in asymmetrical ways for different kinds of information goods has not been fully appreciated, nor have its implications for the standard allocative case for patents. Part I illuminates our analytic arguments in more detail, while Part II illustrates the continuum of excludability and its importance with three examples: hospital checklists, negative information about drugs, and information and interventions regarding "lifestyle" risk factors. All three cases identify highly nonexcludable information goods—and position them opposite pharmaceutical products—to show that even though the less excludable innovations may plausibly outperform the pharmaceutical alternatives (in terms of net social benefit provided), a patent system will tend to promote the excludable pharmaceutical approaches over the less excludable alternatives.

> consumer markets. As a result, various socially desirable intellectual goods—basic research, drugs for diseases in small markets, well-reasoned political dialogue, and 'fair and balanced' news reporting, to name just a few—remain underproduced even with intellectual property regimes in place.

BRETT FRISCHMANN, INFRASTRUCTURE 109 (2012). Frischmann is primarily interested in the problem of externalities, and here he groups together problems related to nonexcludability—for example, basic research and well-reasoned dialogue—with other problems that disrupt the link between markets and social value. (For example, the undersupply of drugs for diseases with small markets is not primarily due to persistent nonexcludability, but rather to the fact that inability to pay dilutes the signal of social value perceived by innovators in a global market.) Carol Rose has called attention to similar dynamics in the environmental context, noting that

> rational economic decision-making favors investments in scientific investigation where there is some potential for private gains at the end of the road—that is, where the end-product can be turned into property. . . . [H]ence there is a gap between research whose results can be propertized relatively easily, and research whose results cannot be so easily propertized, even though the latter might much enhance our collective welfare.

Carol M. Rose, *Scientific Innovation and Environmental Protection: Some Ethical Considerations*, 32 ENVTL. L. 755, 764 (2002). Our contribution is to develop this general point into an analytically detailed conception of the continuum of excludability, and to draw out its important implications for the traditional allocative case for patents.

It is also worth noting the affinity between our argument and Richard Nelson's pioneering justification for government funding of basic research. As Nelson argued, the "yield" from foundational or basic scientific research, in terms of practical applications, is too uncertain and, more importantly, far off in the future to be adequately incentivized by private markets. Richard R. Nelson, *The Simple Economics of Basic Scientific Research*, 67 J. POL. ECON. 297, 304 (1959). Nelson's argument pertains to how patents track a suboptimality in the market (particularly regarding discount rates), while ours pertains to how patents suboptimally track market value. Despite this distinction, however, our argument shares with Nelson's the implication that there are certain kinds of information goods that cannot be adequately incentivized by property rights, regardless of how expansive such rights become.

In Part III, we draw out the central implications that emerge from our analysis. We begin by developing the point that patent rights have the potential to predictably and systematically distort private investment decisions over innovations by overstating the value of highly excludable information goods and understating the value of highly nonexcludable ones.[20] As a result, patents will fail to incentivize many significant innovations (even if we were to increase the length or scope of their protection), and indeed may promote the production of less valuable inventions over the production of more valuable ones. The possible first-order distortions that we identify can also become entrenched over time as institutions, training, and cultural habits incline individuals to look for excludable solutions. The continuum of excludability thus opens up new ways of understanding the forces that lie behind important phenomena in our existing institutional environment, such as the widely shared sense that our current healthcare system is "overmedicalized," or disproportionately focused on technological—and particularly pharmaceutical—interventions. Finally, we show here that our analysis, though illustrated in the context of health innovation, is not limited to that domain. The distortive potential of patents exists across different technological domains, although, for reasons we will describe, it may be easier to identify, and have more consequential effects, in some domains than others.

We move next to policy implications. Our analysis suggests a new justification for institutional approaches to innovation that do not rely on exclusionary mechanisms (including public funding, prizes, commons-based approaches, and regulatory approaches). Such alternatives can help promote important but highly nonexcludable innovations that would be neglected by the patent system, and also help to counter the distortionary pressures that may be generated by patents. Moreover, our argument gives new support to

20. Our argument here builds on earlier treatments. Arnold Plant noted long ago that patents may divert effort from inventive activity that is not patentable toward activity that is patentable. *See* Arnold Plant, *The Economic Theory Concerning Patents for Inventions*, 1 ECONOMICA 30, 42 (1934). Plant was referring not to inventive activity that *could not be patented*, but to activity that was left out of patent law at the time (for example, plant breeding). *Id.* at 45; *cf.* C. EDWIN BAKER, MEDIA, MARKETS AND DEMOCRACY 17 (2002) (pointing out that existing copyright law covers expression but not facts, and will therefore distort investment toward entertainment rather than news). This point is susceptible to the rejoinder that exclusive rights should be extended to the omitted domains. Our point is that exclusive rights themselves have limits, and will generate asymmetries that cannot be remedied through extensions of those exclusive rights. Along similar lines, Glynn Lunney has pointed out the possible distortionary effects of IP incentives on activities in other, unrelated sectors of the economy, as opposed to on innovation activities for which IP protection is unavailing. Glynn S. Lunney, Jr., *Reexamining Copyright's Incentives-Access Paradigm*, 49 VAND. L. REV. 483 (1996). For further discussion, see *infra* note 146 and accompanying text.

the traditional case for public funding of basic research. The conventional case is based on the long-term and uncertain character of the dividends of such research.[21] We add a further consideration—namely, the highly nonexcludable character of many outputs of basic research. At the same time, our argument suggests that the traditional case for publicly funded research is too narrow, because it focuses on "upstream" research. Where information goods are highly nonexcludable, markets will undersupply them, suggesting that governments should be involved in not just basic research, but a range of applied research targeting nonexcludable interventions.

Finally, we discuss a set of broader theoretical implications. First, our analysis highlights a previously unnoticed means by which patents and the pursuit of efficiency through patent law can generate conflict with non-welfarist values such as privacy and free speech. Recognizing this potential conflict has important implications, particularly for arguments about the proper scope of patent law. Second, our analysis suggests that reasoning about the most cost-effective way to produce information should be understood as a process of rough judgment rather than optimization. What is needed is a comparative institutional approach to information policy, one that incorporates an understanding of the continuum of excludability and, moreover, factors in both efficiency and non-efficiency values.

I. UNDERSTANDING THE CONTINUUM OF EXCLUDABILITY

A. Patents as a Solution to Information Goods' Appropriability Problem

Patents are intended to allow market-driven innovation by permitting inventors to exclude others from the results of their investment, and thereby to appropriate its returns.

Given our focus on excludability here, it makes sense to say a bit more about the relationship between exclusion and appropriation in the context of information goods. Conventional economic actors will only produce a good when they can appropriate sufficient returns to recoup the capitalized costs of providing the good. (We use the term "appropriate" here in its broadest sense, to simply mean obtain or secure.) One way to appropriate returns from producing information is by selling the information itself, or by selling an information-embedded good. This is a commodity strategy, and it typically requires exclusion of others from the information in question. (If no one is excluded from the information, then the first attempt at exchange may

21. Richard Nelson's work was foundational on this point. *See* Nelson, *supra* note 19.

undermine all others.) One way to exclude others from information is to use simple secrecy.[22] Such secrecy does not work when you are selling information itself (absent IP rights), since you must reveal it to sell it. But secrecy can work as an exclusionary strategy if the information is embedded in a good and is difficult to obtain from reverse engineering that good.[23] By contrast, secrecy is not an option if the valuable information may be easily obtained by reverse engineering.[24] The difficulty of the secrecy strategy in the context of information goods is one key component of the economic argument for intellectual property rights, which offer creators the possibility of exclusion without secrecy.

There are also many nonexclusionary ways to appropriate returns from information. Most importantly for our purposes, a creator can produce information in exchange for a government reward, such as a prize or a government grant. Here, the creator appropriates returns, but no one is excluded from the information produced. There are also market-based nonexclusion strategies to appropriate returns from information production. For example, first-mover advantages may be the basis for returns,[25] as may

22. Here we do not mean trade secrecy, which is a form of IP involving government enforcement, but rather the straightforward strategy of keeping something secret.

23. Famously, the family that made Stradivarius violins never revealed their techniques, which remain somewhat mysterious to this day, and are the continuing subject of intense, if inconclusive, investigations. *Compare* Graham Tibbets, *Secret of Stradivarius Violin's Superiority Uncovered*, TELEGRAPH (London), July 1, 2008, http://www.telegraph.co.uk/news/worldnews/europe/netherlands/2230123/Secret-of-Stradivarius-violins-superiority-uncovered.html (reporting findings of a study using a CT scanner, claiming that the violins' superiority lies in the density of the wood used), *with* Richard A. Lovett, *'Alchemy' Was the Secret to Making Stradivarius Violins, Study Says*, NAT'L GEOGRAPHIC NEWS, Nov. 29, 2006, http://news.nationalgeographic.com/news/2006/11/061129-violins-alchemy.html (reporting findings of a study using magnetic resonance and infrared spectroscopy, claiming that the secret lies in "chemical tricks" used by the makers, amounting to a "magic potion"), *and* Richard Gray, *The Secret Behind a Stradivarius—Imperfection*, TELEGRAPH (London), Dec. 2, 2012, http://www.telegraph.co.uk/science/science-news/9716271/The-secret-behind-a-Stradivarius-imperfection.html (reporting findings of a study using high-energy light beams from a particle accelerator, claiming that the secret lies in imperfections in the wood used).

24. Think here of the design of a mousetrap, or the composition of a pharmaceutical in the context of the modern regulatory state that requires disclosure of its chemical makeup. The ability to use secrecy can be enhanced technologically, as when a company releases a piece of software but encrypts it so that others cannot access the code. But encryption schemes can be cracked, meaning that encryption often requires legal reinforcement to act as a successful exclusion strategy. Anti-circumvention laws are to encryption what trade secrecy laws are to secrecy.

25. By this we mean factors such as consumer loyalty, establishing distribution networks, fixed-cost barriers to competitive entry, lead time in sales, or learning-curve advantages—

ancillary rights such as trademark.[26] Think here of the fashion industry, where designs are easily reverse engineered and no IP right directly covers fashion design, but where first-mover advantages and trademarks allow designers to appropriate some of the returns from their creations.[27] Creators can also profit by selling the customization of information goods as a service, but not excluding anyone from the information goods themselves, as the Linux-based firm Red Hat does when it customizes open-source software for clients, or as a lawyer might do when she writes a customized brief for a client.[28] Crowdsourcing strategies may also allow a creator to appropriate returns from an informational work without exercising exclusionary control over it.[29]

The conventional economic debate is primarily between a subset of these strategies–typically, IP rights, prizes, and ex ante public funding. That is because that debate is premised upon a set of assumptions, including that the information in question is relatively expensive to produce (so that first-mover advantages and trademark are an inadequate reward), and inexpensive to reproduce or difficult to keep secret (so that secrecy is not viable).[30] In the pages that follow, we work from these same assumptions in order to address the implications of patents in their most favorable context.

In the debate between patents, prizes, and public funding, the patent approach has some well-known drawbacks. Because information is nonrival, meaning that its use by one person does not detract from its simultaneous use by others, the grant of exclusion rights threatens to produce an inefficient underuse of said information. Due to transaction costs and other barriers to perfectly tailored price discrimination and licensing agreements, the price(s)

but not the time it takes someone to reverse engineer information from a good, since that process involves exclusion via secrecy.

26. Note that trademark does involve exclusive rights, but the trademark right covers the mark rather than the information itself. Think here of a company selling a branded generic drug, where the drug itself is not patented, but the trademark is protected as a source of information to consumers.

27. *See* Kal Raustiala & Christopher Sprigman, *The Piracy Paradox: Innovation and Intellectual Property in Fashion Design*, 92 VA. L. REV. 1687 (2006).

28. *See* YOCHAI BENKLER, THE WEALTH OF NETWORKS: HOW SOCIAL PRODUCTION TRANSFORMS MARKETS AND FREEDOM 43, 45-46 (2006).

29. Crowd-sourcing strategies that distribute information without restriction but ask for contributions are becoming quite common in the creative arts. See, for example, *Radiohead Reveal How Successful 'In Rainbows' Download Really Was*, NME (Oct. 15, 2008), http://www.nme.com/news/radiohead/40444; and SITA SINGS THE BLUES, http://www.sitasingstheblues.com (last visited Jan. 25, 2013).

30. The customization strategy is not typically discussed in conventional economic debates, perhaps because the information in question may be useful to only one or a limited number of clients, so does not exhibit public goods problems in the usual sense.

charged by the patentee will price out some consumers and follow-on innovators who are willing and able to pay the marginal cost of distributing the information good, but not the patentee's markup, resulting in what economists refer to as "deadweight loss."[31]

It was these drawbacks that long ago led Kenneth Arrow to argue that government funding was preferable to patents as a mode of innovation policy. He emphasized that government funding can provide the benefit of incentivizing information production without the static and dynamic costs from foregone uses of the information so generated.[32] Demsetz provided the canonical reply: while Arrow emphasized the benefits of marginal-cost pricing of information, Demsetz focused instead on "the production of knowledge at efficient rates."[33] A system of private market rights would, Demsetz suggested, be superior to government in one important allocative sense: it would produce superior "information on the desired directions of investment and on the quantities of resources that should be committed to invention."[34]

Demsetz's argument here owes much to Hayek's ideas about the informational advantages of disaggregated private actors over centralized government decisionmakers.[35] In this account, property rights are said to have a fundamental advantage in guiding the efficient production of information because they harness price signals to provide creators with information about how to direct and allocate the resources that they invest in producing information. The argument for patents is thus premised on a posited relationship between rights to exclude and the use of private information about

31. *See, e.g.*, Steven Shavell & Tanguy van Ypersele, *Rewards Versus Intellectual Property Rights*, 44 J.L. & ECON. 525, 529 (2001).

32. Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609 (Nat'l Bureau of Econ. Research ed., 1962).

33. Demsetz, *supra* note 13, at 13.

34. *Id*. at 12.

35. *See* F.A. Hayek, *The Use of Knowledge in Society*, 35 AM. ECON. REV. 519, 521 (1945). This argument can be further traced back to Mill, who advanced the link forged by patents between innovation incentives and market measures of social value as a key consideration in patents' favor over government rewards. *See* 2 JOHN STUART MILL, PRINCIPLES OF POLITICAL ECONOMY, bk. 5, ch. 10, § 4 (New York, D. Appleton & Co., 6th ed. 1864) (1848). Another important antecedent of Demsetz's position is, of course, Coase's comparative-institutional analysis of the respective advantages and drawbacks of government and market solutions to externality problems, an analysis that also bears the strong stamp of the Hayekian influence. *See* R.H. Coase, *The Problem of Social Cost*, 3 J.L. & ECON. 1 (1960).

the value of inventions.[36]

Though it was not the central point of Demsetz's article (which aimed primarily to promote a comparative institutional approach to economics),[37] his argument about the informational advantages of patents has become central to our contemporary understanding of the economics of patent rights. For example, leading accounts of the comparative institutional benefits of patents versus financial prizes and government funding emphasize that patents' key advantage as a method of stimulating innovation is their superior ability to make use of private information about the value of prospective inventions.[38] Similar invocations of the allocative case for IP rights resound throughout IP scholarship, reflecting the deep influence of Demsetz's argument.[39] Moreover, a

36. Patents also make use of private information about the comparative efficiency of different approaches to information production, but as Wright points out, prizes may do this as well. Wright, *supra* note 11, at 703.

37. Demsetz, *supra* note 13, at 1.

38. *See* Nancy Gallini & Suzanne Scotchmer, *Intellectual Property: When Is It the Best Incentive System?*, *in* 2 INNOVATION POLICY AND THE ECONOMY 51 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., 2002); Wright, *supra* note 11, at 703. There has been a resurgence of interest recently in comparative analysis of patents and innovation policy alternatives, particularly, but not exclusively, among economists. *See* Steve P. Calandrillo, *An Economic Analysis of Property Rights in Information: Justifications and Problems of Exclusive Rights, Incentives To Generate Information, and the Alternative of a Government-Run Reward System*, 9 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 301 (1998); Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q.J. ECON. 1137 (1998); Shavell & van Ypersele, *supra* note 31; Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115 (2003); Aidan Hollis, *An Efficient Reward System for Pharmaceutical Innovation*, WORLD HEALTH ORG. (Oct. 6, 2004), http://www.who.int/intellectualproperty/news/Submission-Hollis6-Oct.pdf; Stephen M. Maurer, *The Right Tool(s): Designing Cost-Effective Strategies for Neglected Disease Research*, WORLD HEALTH ORG. (Mar. 29, 2005), http://www.who.int/intellectualproperty/studies/S.Maurer.pdf; James Love & Tim Hubbard, *The Big Idea: Prizes To Stimulate R&D for New Medicines*, 82 CHI.-KENT L. REV. 1519 (2007); Aidan Hollis & Thomas Pogge, *The Health Impact Fund: Making New Medicines Accessible for All*, INCENTIVES FOR GLOBAL HEALTH (2008), http://healthimpactfund.com/publications; William W. Fisher & Talha Syed, *A Prize System as a Partial Solution to the Health Crisis in the Developing World*, *in* INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES 181 (Thomas Pogge et al. eds., 2010). For a discussion in the copyright context, see Neil Weinstock Netanel, *Impose a Noncommercial Use Levy To Allow Free Peer-to-Peer File Sharing*, 17 HARV. J.L. & TECH. 1 (2003); and WILLIAM W. FISHER III, PROMISES TO KEEP: TECHNOLOGY, LAW, AND THE FUTURE OF ENTERTAINMENT 199-258 (2004). Although this literature has adduced numerous other considerations regarding the comparative merits and drawbacks of IP rights and alternatives, the particular consideration we highlight here has not been among them.

39. *See, e.g.*, PAUL GOLDSTEIN, COPYRIGHT'S HIGHWAY: FROM GUTENBERG TO THE CELESTIAL JUKEBOX 146 (rev. ed. 2003) (stating that prices "have the salutary eff[ect] of signaling consumer preference and channeling private investment in the right directions"); WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY

subset of these IP scholars, whom we call "optimizers," have extended the conventional allocative case for *some* property rights in information into a more ambitious aim: the pursuit of a global optimum through the fine-tuned expansion of such rights, guided more by neoclassical conceptions of efficiency in general equilibrium than by the comparative-institutional orientation of Demsetz's original article.[40]

There are existing critiques of the economic logic of the allocative account. Perhaps the most influential of these points out that transaction costs will interfere with market signaling and, as a result, that patent-based approaches will systematically underrepresent true market demand.[41] For example, for

LAW 24 (2003) (arguing that government financing of information is inferior to IP because it "substitut[es] a governmental determination of the value of particular types of intellectual property for a market determination"); MERGES ET AL., *supra* note 10, at 18 ("[IP] rights have the advantage of limiting the government's role in allocating resources to a finite set of decentralized decisions: whether particular inventions are worthy of a fixed period of protection. The market then serves as the principle engine of progress."); Fisher, *supra* note 10, at 178-79 (describing the role in the IP literature of the argument that private markets can best guide investment decisions); Wendy J. Gordon, *Fair Use as Market Failure: A Structural and Economic Analysis of the* Betamax *Case and Its Predecessors*, 82 COLUM. L. REV. 1600, 1611-12 (1982) ("Though taxation and centralized purchasing might provide a satisfactory solution for some public goods problems . . . for works of expression, the public goods problem is addressed by another method. . . . [T]he law provides a means for excluding nonpurchasers. Copyright law therefore allows a market for intellectual property to function." (footnotes omitted)); Menell & Scotchmer, *supra* note 10, at 1499 ("In the context of stand-alone inventions or creations, intellectual property rewards reflect the social value of the contribution, since the profit is determined by demand.").

40. *See, e.g.*, GOLDSTEIN, *supra* note 39, at 178-79; Tom W. Bell, *Fair Use vs. Fared Use: The Impact of Automated Rights Management on Copyright's Fair Use Doctrine*, 76 N.C. L. REV. 557 (1998); Frank H. Easterbrook, *Who Decides the Extent of Rights in Intellectual Property?*, *in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 405 (Rochelle Cooper Dreyfuss et al. eds., 2001); Trotter Hardy, *Property (and Copyright) in Cyberspace*, 1996 U. CHI. LEGAL F. 217; F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697 (2001). The primary inspiration for this optimizing line of scholarship, it bears noting, is not Demsetz's 1969 essay on the comparative virtues of patents versus public funding, but rather his foundational 1967 essay outlining a general theory of property rights based on internalizing externalities. *See* Harold Demsetz, *Toward a Theory of Property Rights*, 57 AM. ECON. REV. 347 (1967); *see also* Neil Weinstock Netanel, *Copyright and a Democratic Civil Society*, 106 YALE L.J. 283, 312 n.117 (1996) ("The inclusion of copyright within the post-Coasean neoclassical umbrella began with Harold Demsetz's landmark essay setting forth the basic tenets of neoclassical property theory."). It should also be noted that Demsetz's 1967 argument differs to some extent from those of the scholars we cite here; Demsetz's claims sound primarily in a positive and explanatory register, while the arguments advanced by these later scholars building on his work are more clearly prescriptive.

41. *See* Brett M. Frischmann & Mark A. Lemley, *Spillovers*, 107 COLUM. L. REV. 257 (2007); Zvi Griliches, *The Search for R&D Spillovers*, 94 SCANDANAVIAN J. ECON. S29 (1992); Edwin

consumptive uses of the good, various obstacles to perfect price discrimination will mean that patentees will capture only a portion of the value from consumed uses (and, of course, no value from those potential uses that are priced out). A similar situation applies for follow-on innovative uses of the good, due to transaction costs and other barriers to striking perfectly tailored and complete licensing deals.[42] A related argument points out that patent law itself is limited, thus confining the potential returns for innovators. For example, patents are term-limited, restricting the time over which an innovator can appropriate the social value of the innovation.[43] Similarly, the current criteria for patentability may fail to cover information that, although valuable and expensive to generate, nevertheless does not meet existing patent requirements such as novelty and nonobviousness.[44] These concerns, however, do not advance criticisms of the allocative case for patents so much as worries regarding its full realization. And they have tended to result in the following responses: that patent rights should be strengthened, that transaction costs can or should be reduced, and that these concerns do not fundamentally undermine a preference for private property rights since property-based allocative signals, while attenuated, are still fundamentally aligned with social value.[45]

In this Essay, we focus on a different problem with the allocative account: its assumption that excludability is relatively unproblematic in the presence of

Mansfield et al., *Social and Private Rates of Return from Industrial Innovations*, 91 Q.J. ECON. 221 (1977).

42. *See, e.g.*, JEAN TIROLE, THE THEORY OF INDUSTRIAL ORGANIZATION 389-421 (1988); Kremer, *supra* note 38, at 1140-42; Shavell & van Ypersele, *supra* note 31, at 534.

43. *See* LANDES & POSNER, *supra* note 39, at 296; Michael Abramowicz, *The Uneasy Case for Patent Races over Auctions*, 60 STAN. L. REV. 803, 832-33 (2007) (describing how the twenty-year life of patents insufficiently stimulates innovation in industries with long time horizons for appropriation); Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 720-24 (2005); *see also* Eric E. Johnson, *Calibrating Patent Lifetimes*, 22 SANTA CLARA COMPUTER & HIGH TECH. L.J. 269, 297-99, 297 n.92 (2006) (reviewing the economic literature on optimal patent duration).

44. *See* Eisenberg, *supra* note 43, at 722; Benjamin N. Roin, *Unpatentable Drugs and the Standard of Patentability*, 87 TEX. L. REV. 503 (2009).

45. *See, e.g.*, GOLDSTEIN, *supra* note 39, at 178-79, 224; Bell, *supra* note 40, at 567-71, 580-92, 600; Easterbrook, *supra* note 40, at 411-13; Hardy, *supra* note 40, at 231, 234-58; Kieff, *supra* note 40, at 717-36; Mark Stefik, *Trusted Systems*, SCI. AM., Mar. 1997, at 78. For critical responses to this line of argument, see Julie E. Cohen, Lochner *in Cyberspace: The New Economic Orthodoxy of "Rights Management,"* 97 MICH. L. REV. 462 (1998); Brett M. Frischmann, *Evaluating the Demsetzian Trend in Copyright Law*, 3 REV. L. & ECON. 649 (2007); Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031 (2005); and Netanel, *supra* note 38. Roin suggests mimicking (rather than strengthening) patents via clinical-data-exclusivity requirements. *See* Roin, *supra* note 44, at 564-68.

property rights. This assumption is reflected in Demsetz's original argument, where he asserts: "Appropriability is largely a matter of legal arrangements and the enforcement of these arrangements by private or public means. The degree to which knowledge is privately appropriable can be increased by raising the penalties for patent violations and by increasing resources for policing patent violations."[46] Shortly following this formulation, Demsetz offers this somewhat more modest surmise:

> The truth of the matter is that I, at least, have no more than casual notions about the cost, per dollar value of knowledge, of establishing property rights in information. Given the appropriate legal apparatus and schedule of penalties it may be no more difficult to police property rights in many kinds of knowledge than it is to prevent the theft of automobiles and cash. And even if some kinds of information are more difficult to protect, I am not sure which institutions yield the better solution to the problem or what public policy deduction should be made.[47]

Where appropriability is a problem, it can generally be increased by legal arrangements, as Demsetz suggests. Patents will typically permit more appropriability than exists without patents, and ratcheting up patent law in various ways (for example, by increasing penalties for infringement), generally will increase appropriability for the covered information. But some kinds of information are more difficult to protect with patents than others, as we will show. Put in the language of cost, the same legal entitlement to a patent can have very different costs of deployment, depending on the kind of information that is covered by the patent.[48] In the presence of patent rights, information that is more readily excludable will yield greater private returns than equally socially valuable information that is less readily excludable. This tradeoff has significant consequences both for theory and policy.

To formalize and simplify the point, we conventionally want investors to invest when the expected value of a good is greater than the expected cost ($c < v$). It is well recognized that an innovator can expect to enjoy not a full share of the social value created by the good, but only some fraction of that value ($0 < \alpha < 1$). If this fraction—while not 1—is at least constant, then there

46. Demsetz, *supra* note 13, at 10.

47. *Id*. at 10-11.

48. Patents on different kinds of information goods are also not equally costly for the state to create or enforce. The state may bear such costs in different ways, such as providing resources for examination, adjudication, and enforcement (for example, at the national borders). This point is of some importance, but not the subject of our analysis here.

is no distortion introduced into the production function and investment will occur whenever $c < \alpha v$. If, however, α is variable, then its introduction into the production function will distort investment choices: excludability, rather than the ratio of social value to cost alone, will influence what is produced.[49]

B. The Key Determinants of Excludability

Analytically, the degree to which excludability works as a solution to the appropriability problem depends on how much of the good's social value can be privately internalized by exclusion. Appropriability in this context, then, is a function of how effectively (or cheaply) the exclusionary mechanism can be deployed. In the presence of a patent, effective exclusion requires monitoring and identification of possible infringers and subsequent deployment of legal entitlements. To better understand when and why excludability may or may not work for any one type of good, we need to understand the factors shaping the conditions for its success.

Three influences are of particular importance. The first is the state of *existing technology*. For some information goods, much of the valued use may simply involve absorbing the information into thought, which is at present technically impossible to monitor, much less prevent. An inventor who was able to obtain a patent on a basic scientific principle—or on the insight, for example, that quitting smoking reduces the risk of heart attack—would have a great deal of difficulty detecting unapproved uses of this information. Sometimes technologies will exist to detect an infringement—say, verbal communication of information from person to person—but will be expensive to deploy on a large scale. Invariably, the cost of enforcement will thus depend in part on the availability and cost of existing technologies to detect infringement.[50] And there is no reason to think that the cost and existence of

49. The result is akin to "Campbell's Law" in the context of education policy, which asserts that when we use intermediate indicators of a value as a stand-in for an ultimate value that is hard to measure (such as when we use test scores to measure educational attainment), we distort behavior toward the indicator and away from the value it is meant to measure. *See* Donald T. Campbell, *Assessing the Impact of Planned Social Change*, 2 EVALUATION & PROGRAM PLAN. 67, 85 (1979) ("The more any quantitative social indicator is used for social decision-making, the more subject it will be to corruption pressure and the more apt it will be to distort and corrupt the social processes it is intended to monitor."). In the educational context, relying on test scores ultimately encourages "teaching to the test." In information production, using patents as a measure of social value results in "inventing to the patent." We thank Yair Listokin for helping us see this parallel.

50. The same is true of technologies needed to threaten or initiate legal action, but these are not our focus here, in part because they may not introduce the same asymmetries across types of information.

such technology will vary in ways that are systematically correlated with the social value of the covered information.

The second influence is *social norms*. For some information goods, technology will permit monitoring at an acceptable economic cost, but such monitoring will be normatively unacceptable. For example, it may be technically and economically feasible to monitor communications between doctors and patients, or between individuals in other therapeutic settings (for example, addiction support groups), but such surveillance would likely be too intrusive of privacy or burdensome on speech to be acceptable. Highly entrenched norms may also be reflected in law and will thus be particularly costly to override. The First Amendment, for example, codifies commitments to free speech that could extend to the patent context.[51] State sovereign immunity doctrines codify norms against extracting monetary compensation from state governments, which could also interfere with the ability to enforce patents on, say, legislative innovations.[52] Indeed, constitutional and private law restrictions on privacy invasion could be implicated in the patent context, and so forth. And, as with technology, there is little reason to believe any systematic correlation exists between the social value of information and the extent to which it can be effectively protected without running afoul of strongly held social norms.

The third influence is perhaps less intuitive than the first two, but no less important. The existence of a wide variety of *institutions* will influence the viability and effectiveness of exclusion rights over information—again in ways that do not systematically vary with the social value of the information.[53] We use "institutions" here in both its classical sociological sense of social roles, relations, and rules through which convergent expectations and patterns of conduct are congealed or stabilized (including, but not exclusively, through legal arrangements), as well as in a broader, looser sense that also encompasses "organizations" of various sorts—as "players" in a "game" structured by institutional rules.[54] For example, hospitals are organizations, and their

51. *See, e.g.*, Dan L. Burk, *Patenting Speech*, 79 TEX. L. REV. 99 (2000) (discussing tensions between patent law and the First Amendment in the context of software).

52. *See infra* note 123 and accompanying text.

53. There is a parallel between this notion and a point that some have made in the property law scholarship. As some scholars have pointed out, Demsetz's famous argument that property will emerge when resources become more valuable also takes institutions for granted, since it does not acknowledge the need for effective legal institutions to create and police property rights. *See, e.g.*, Daniel Fitzpatrick, *Evolution and Chaos in Property Rights Systems: The Third World Tragedy of Contested Access*, 115 YALE L.J. 996, 1007-08 (2006).

54. In the classical sociological sense of the term, "institutions" are often synonymous with "social structure." *See, e.g.*, ANTHONY GIDDENS, THE CONSTITUTION OF SOCIETY: OUTLINE

existence influences the excludability of a patent on checklists, as suggested above. Tort law can also be considered a kind of institution. That is, the fact that tort rules may operate to render hospitals or other medical providers liable for not using state-of-the-art techniques may lower the cost of enforcing patent rights across a range of medical technologies.

Though it is more difficult to see, the *absence* of certain institutional relations or organizational forms may also render information less excludable. For example, if no organization is needed to mediate or transmit the information that smoking causes heart attacks, it will be relatively more difficult to track and exclude people from that information. Consider a last example: in the pharmaceutical context, patents on "methods of use" are quite common. A patent of this sort might claim the information that, say, the compound imatinib mesylate is effective against a particular form of cancer.[55] Such a patent prevents not the use of imatinib mesylate itself, but only its use for the treatment of the specified form of cancer. The information covered is highly immaterial—it pertains not to the drug itself, but to a particular intended use of the drug, and as such we might think it would be very difficult to exclude others from exploiting this information. But institutions such as public and private insurance, medical licensing laws, and drug regulatory laws

OF THE THEORY OF STRUCTURATION 16-17, 24 (1984) (noting that "'structure' is usually understood . . . by the vast majority of social analysts—as some kind of 'patterning' of social relations or social phenomena" with "institutions" being those patterning "practices which have the greatest time-space extension" or which embody "the more enduring features of social life"); Kieran Healy, *Sociology*, *in* 1 A COMPANION TO CONTEMPORARY POLITICAL PHILOSOPHY 88 (Robert E. Goodin, Philip Pettit & Thomas Pogge eds., 2d ed. 2007) (tracing as a common theme among otherwise divergent sociological schools an emphasis on "social structure" and "social institutions" in conditioning individuals' preferences, capacities, and choices). A similar notion is deployed by economists taking an "institutionalist" turn. *See* SAMUEL BOWLES, MICROECONOMICS: BEHAVIOR, INSTITUTIONS, AND EVOLUTION 47-48, 368 (2004) ("Institutions . . . are the laws, informal rules, and conventions that give a durable structure to social interactions among the members of a population."); ROBIN HAHNEL & MICHAEL ALBERT, QUIET REVOLUTION IN WELFARE ECONOMICS 127-29 (1990) (defining institutions as "conglomerations of interrelated roles" or "commonly held expectations" about appropriate behavior patterns). Bowles also provides a useful discussion of the relation between this notion of "institutions" and that of "organizations," which tracks the meanings we give these terms in this Essay. BOWLES, *supra*, at 48-49. In the context of innovation theory, a similar development of the two concepts and the distinction between them is provided in Pavel Pelikan, *Can the Imperfect Innovation Systems of Capitalism Be Outperformed?*, *in* TECHNICAL CHANGE AND ECONOMIC THEORY 370 (Giovanni Dosi et al. eds., 1988).

55. *See* Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, PLOS ONE (Dec. 5, 2012), http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0049470.

all function to make these kinds of patents relatively excludable in practice.[56] This result is easy to see if we compare a patent on a particular use of imatinib mesylate to a patent on a particular use of aspirin. The discovery that aspirin reduces the risk of heart attacks and stroke for those who have already had them was an important advance in medical knowledge.[57] But aspirin is also an over-the-counter medication, and as such it interacts differently than imatinib mesylate with health insurance, the medical profession, and drug regulatory authorities. Aspirin's over-the-counter nature makes infringing uses of it much more difficult to detect than infringing uses of imatinib mesylate. As such, the same exact kind of patent—a patent on a method of a compound to be used to treat a particular disease—exhibits wildly different levels of excludability, for reasons that can best be described as features of the institutional context.

All three factors can, to some extent, also be expressed in the language of costs. That is, under a given state of technology, norms, and institutions, some information will be more or less costly to exclude others from. With enough resources, the state of existing technology can presumably be altered, at least to a significant extent. And likewise, perhaps, with existing norms and institutions. Thus, over time, the state of technology, norms, and institutions is likely, to some degree, endogenous to the design of patent law.[58] But there will be limits on the ability of innovators to change norms, institutions, and technologies (which to some degree can be expressed in terms of the ratio of

56. FDA rules, for example, require all drugs to be approved before being sold in interstate commerce. *See* 21 U.S.C. § 355(a) (2006). The need for FDA approval means that companies may gain effective control over all sales of a drug even when they have a patent only over certain uses, because no one else may sell the compound without submitting trial data to the FDA. If two companies were to have FDA approval for selling the same active ingredient for different uses, and patents on their different uses, regulatory and insurance rules might still help them enforce their patents. *See, e.g.*, Prescription Drug Advertising, 21 C.F.R. § 202.1(e)(4) (2012) (prohibiting manufacturers from directly marketing off-label uses for their approved drugs); Am. Soc'y of Clinical Oncology, *Reimbursement for Cancer Treatment: Coverage of Off-Label Drug Indications*, 24 J. CLINICAL ONCOLOGY 3206 (2006) (describing the refusal by private insurers and Medicare to reimburse many off-label uses for cancer drugs); Alexander T. Tabarrok, *Assessing the FDA via the Anomaly of Off-Label Drug Prescribing*, INDEP. REV., Summer 2000, at 25, 35-36 (describing insurance companies' resistance to reimbursing for off-label prescriptions and the responding movement to require reimbursement in certain cases).

57. *See, e.g.*, *Recommendations of Aspirin for Prevention of Cardiovascular Disease*, CENTER FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/heartdisease/aspirin.htm (last updated Sept. 12, 2011).

58. For example, if patent law is expanded in ways that make patents on thought more viable, we would expect patentees to exert pressure on norms, institutions, and technologies to facilitate the enforcement of such patents. This dynamic has important implications for the relationship between patents and nonefficiency values, as we discuss in Part III.

cost to return, and diminishing marginal returns). Even in the long run and allowing some endogeneity, then, we cannot expect social value and the cost of exclusion to be closely correlated.

As the following sections will describe in more detail, under existing conditions of technology, norms, and institutions, we can identify key characteristics of highly nonexcludable information. Most saliently, uses of information goods that manifest in relatively more immaterial fashion will be more difficult to exclude, because the state of technology makes monitoring intangible processes (like thoughts) more difficult than monitoring more tangible things. Here, norms buttress technology. Or perhaps it is the other way around: part of the reason more invasive surveillance technologies do not exist may be that they are deemed normatively unacceptable. Generally, the more immaterial the valuable uses of an information good—that is, the more that the good can be deployed without necessary connection to identifiable material goods—the less excludable it will be, under technological conditions that make activities like mind reading, or surveillance of processes as opposed to consumption or purchasing behavior, relatively difficult. To determine how relatively immaterial the use of an information good is, in turn, we can ask questions such as: Would infringement happen entirely inside someone's head? If so, the good is highly immaterial. Would infringing the patent require a nexus to a tangible good such as a pharmaceutical compound, a diagnostic test, or a service provider? If so, its uses are less comprehensively immaterial in the sense we mean here.[59] Numerosity will also matter. The fewer possible infringing parties there might be, the lower we would expect the cost of detection and enforcement of patents to be.

Once the influence of technology, norms, and institutions is brought into view, it becomes clear that patents do not and cannot, in a consistent or symmetrical way, translate social value into private appropriability through the mechanism of exclusion. Rather, all information goods will exist on an excludability continuum. Those on the highly nonexcludable end of the continuum represent a smaller ratio of social value that is privately appropriable through IP rights. Those on the highly excludable end of the continuum represent a correspondingly larger ratio of social value. We can represent points on this continuum numerically: perfectly excludable goods will exhibit a ratio of social value that is approaching one (assuming away, for the moment, other forms of transaction costs that will reduce appropriability). Perfectly nonexcludable information goods would exhibit a ratio approaching

59. In the classic economic sense, these information goods are all immaterial—what we mean to identify here is the nature of the nexus that exists between the deployment or use of the information, and materially controllable goods such as medicines, etc.

zero, and highly nonexcludable information goods would exhibit what we can call a "low" signaling ratio, i.e., where appropriability is a very small fraction of social value.[60]

II. ILLUSTRATING THE THREE INFLUENCES ON EXCLUDABILITY

In the literature related to IP and health, there is a notable focus on one particular kind of health intervention: pharmaceutical products (and, to a lesser degree, on related technological interventions such as vaccines, diagnostics, and medical devices). But many kinds of information goods are essential to health, including basic scientific information, epidemiological information, understanding of the so-called "social determinants" of health, information about effective medical techniques, and so forth.

One reason that the literature on health in the IP field may have focused so much attention on pharmaceuticals and similar interventions is that they neatly fit the exclusion-rights model of innovation.[61] Medicines are highly excludable under existing technological, normative, and institutional conditions. The point may be immediately obvious to some, but it is worth explaining further. Technically, the valued information good in the pharmaceutical context is not the drug itself (which is a material, and not immaterial good), but rather *information* about the drug—for example, its chemical structure and qualities,

60. We do not say that perfectly nonexcludable goods would necessarily exhibit a ratio of zero, but rather that their ratio would *approach*, or tend toward, zero. This distinction is in recognition of the point that excludability is not the only means for private appropriation of social value. As is well established in the innovation policy literature, there also exist nonexclusionary market mechanisms—such as lead time advantages, high entry barriers, branding, or bundled goods and services—that may often enable innovators to privately capture some share of the social value of their innovation even in the absence of patent rights or other exclusionary mechanisms. *See* sources cited *infra* note 61. Recognition of this point, however, does not alter the general thrust of our argument. Even if an innovator of a highly nonexcludable good is able to capture *some* share of its social value in the absence of excludability, that share will remain lower than for an otherwise equivalent innovation that may take advantage of both excludability *and* the alternative, nonexclusionary market mechanisms. Thus, the gap in signaling ratios would remain.

61. Indeed, pharmaceuticals are frequently cited as perhaps the domain where patents function best to induce information production. *See, e.g.*, Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 3 BROOKINGS PAPERS ON ECON. ACTIVITY 783, 817, 818 (1987); Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173 (1986); Edwin Mansfield, Mark Schwartz & Samuel Wagner, *Imitation Costs and Patents: An Empirical Study*, 91 ECON. J. 907 (1981); Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 2 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000), http://www.nber.org/papers/w7552.

its efficacy in treating particular diseases, and any side effects associated with its use. Clinical trials are required to demonstrate safety and efficacy, and these trials comprise the largest share—around sixty percent—of drug development costs.[62] The generation of clinically verified knowledge on the properties of drugs is, then, a preeminent component of the innovative activity enabled by patents in the context of pharmaceuticals.

But drug companies profit not by selling (intangible) information, but rather by selling (tangible) drugs. The link between tangible drugs and intangible pharmaceutical patents is a tight one, because without the drug in question, the intangible information is largely useless to patients. And drugs are sold in a highly regulated context, in which a combination of drug-regulatory laws, medical-licensing laws, customs enforcement, and health insurance schemes all facilitate the enforcement of drug patents. The close link between the intangible patented information and the tangible good of the drug, along with the broader institutional, technological, and normative context, facilitates the use of exclusion rights to commodify by proxy the critical health information generated in the pharmaceutical field.[63]

62. *See, e.g.*, Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 165, 180-83 (2003) (estimating a total R&D cost per drug of $802 million, and clinical trial costs of $467 million per drug). Although there remains considerable controversy regarding the average development costs of new drugs, with estimates varying from $250 million to $1.3 billion, common to most such estimates is that expenditures on clinical approval constitute around half of such costs. *See, e.g.*, OFFICE OF TECH. ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISKS, AND REWARDS 48-72 (1993), http://www.fas.org/ota/reports/9336.pdf; *PhRMA 2012 Industry Profile: Pharmaceutical Industry*, PHARMACEUTICAL RES. & MANUFACTURERS OF AM. 58 (2012), http://www.phrma.org/sites/default/files/159/phrma_industry_profile.pdf. The controversies circle instead around issues such as the datasets on which estimates are based (e.g., firms' self-reported figures versus audited data), the types of drug development projects included (e.g., entirely new molecular entities or improvements on existing products; entirely self-originated drugs or also those taken over from federal or university labs), and the appropriate assumptions to adopt for costs of capital and for risk. *See, e.g.*, Donald W. Light, *Misleading Congress About Drug Development*, 32 J. HEALTH POL. POL'Y & L. 895, 896-900 (2007) (criticizing DiMasi et al., *supra*); F.M. Scherer, *The Pharmaceutical Industry—Prices and Progress*, 351 NEW ENG. J. MED. 927, 928 (2004).

63. Notice, however, that there are normative constraints on patent enforcement in this context, generated by moral arguments against the commodification of goods that are essential to life. Pharmaceutical companies no longer enforce patents covering HIV/AIDS drugs as they sought to earlier on in the AIDS epidemic. *See, e.g.*, Barton Gellman, *A Conflict of Health and Profit; Gore at Center of Trade Policy Reversal on AIDS Drugs to S. Africa*, WASH. POST, May 21, 2000, at A1; *Untangling the Web of Antiretroviral Price Reductions*, MÉDECINS SANS FRONTIÈRES 11-12 (July 2012), http://www.msfaccess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/AIDS_report_UTW15_ENG_2012.pdf (detailing a range of voluntary

Many other important kinds of health information, however, are much more difficult to exclude. We highlight three here: negative information about new medicines, lifestyle information and behavioral and structural interventions to reduce cardiovascular disease (CVD), and basic techniques, such as the hygiene checklist, to improve healthcare systems and quality.

A. Negative Information About Drugs

Our first and second examples both relate to the problem of CVD, so we begin with a brief introduction to this major public health concern. CVD refers to a broad range of disorders affecting the blood vessels and heart, from coronary heart disease and cerebrovascular disease to congenital and rheumatic heart disease.[64] The consequences of these conditions are more familiar than their proper names: CVD results in heart attacks, strokes, and high blood pressure,[65] and is the leading cause of death worldwide.[66] It is also the leading cause of death in the United States, accounting for more than one-third of all deaths each year.[67]

A central concern in the fight against CVD is hypertension or high blood pressure (HBP), a condition afflicting almost one in three Americans.[68] Although typically not the direct cause of serious symptoms, HBP is the most important risk factor for the development of premature CVD.[69] Little wonder, then, that keeping hypertension under control is a high public health priority. Antihypertensive drugs play a large role in advancing this goal: over fifty-four

licensing schemes that characterize the global anti-HIV drug market, and the historical impact this has had on medicine prices).

64. *Fact Sheet No. 317: Cardiovascular Diseases (CVDs)*, WORLD HEALTH ORG. (Sept. 2012), http://www.who.int/mediacentre/factsheets/fs317/en/index.html.

65. WORLD HEALTH ORG., GLOBAL ATLAS ON CARDIOVASCULAR DISEASE PREVENTION AND CONTROL 2-3 (Shanthi Mendis, Pekka Puska & Bo Norrving eds., 2011), http://whqlibdoc.who.int/publications/2011/9789241564373_eng.pdf.

66. WORLD HEALTH ORG., THE GLOBAL BURDEN OF DISEASE: 2004 UPDATE 8 (2008), http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf. The relative ranking of CVD as a worldwide health concern is diminished if the measure used is "years of lost life," since CVD disproportionately affects older people. *Id.* at 21-22.

67. *Heart Disease and Stroke Prevention: Addressing the Nation's Leading Killers*, NAT'L CENTER FOR CHRONIC DISEASE PREVENTION & HEALTH PROMOTION 2 (2011), http://www.cdc.gov/chronicdisease/resources/publications/aag/pdf/2011/Heart-Disease-and-Stroke-AAG-2011.pdf.

68. Véronique L. Roger et al., *Heart Disease and Stroke Statistics—2011 Update: A Report from the American Heart Association*, 123 CIRCULATION 459, e18, e101 (2011).

69. Norman M. Kaplan, *Cardiovascular Risks of Hypertension*, UPTODATE, http://www.uptodate.com/contents/cardiovascular-risks-of-hypertension (last updated Nov. 12, 2012).

million Americans are taking some kind of antihypertensive medication.[70]

Of course, medicines do not only have good effects, but potentially bad (side) effects as well. Moreover, to show that a medicine is effective against a placebo is not to show that it is comparatively more effective than the leading alternatives. Two important classes of information goods about drugs, then, constitute what we call "negative" information: information that the drug is *not* safe or efficacious, and information that it is comparatively *less* safe or efficacious than other (particularly older and less expensive) alternatives.

Imagine that Jane develops a new antihypertensive medicine. To sell it, she must meet FDA requirements and show that it is safe and efficacious.[71] But what if she suspects that the drug is rather less effective than the existing (and generic, thus also less costly) BP-lowering medicine, or similarly effective but less safe? She has no financial incentive to produce this information, because she can only capitalize on her research investment by selling drugs, not by *not selling* them. Her competitors may gain something from producing negative information about her new drug, but the problem is a matter of degree. Jane has more to gain by producing positive information about her drug than her generic competitors have by producing negative information about her drug, given the drastic differences in the markups they are able to charge and the coordination difficulties that generic competitors face. Competitors with patented drugs stand to gain more,[72] but will still often have incentives that are weak compared to Jane's. If there are multiple patented rival treatments, then collective action problems exist as they do for generic competitors. If Jane has but one rival, that rival's incentives will be more closely aligned with her firm's. But that situation may be rare, and where it exists, there is still no guarantee that negative information about Jane's drug will directly increase sales of the competitor's drug. For example, if the two drugs are in the same class, negative information about one may reflect badly on both.

This example is drawn from reality: from the early- to mid-1980s, a new wave of antihypertensive drugs hit the market, and several quickly became top sellers, including Pfizer's calcium channel blocker Norvasc and leading angiotensin-converting enzyme (ACE) inhibitors from Merck and

70. Roger et al., *supra* note 68, at e2.

71. 21 U.S.C. § 355 (2006).

72. This is due to the fact that their rival products also enjoy a patent-enabled markup or "quasi-rent." This difference between patented and generic competitors in the asymmetry of their incentives to generate negative information is an important way in which patents exacerbate any existing market suboptimalities regarding the generation of negative information.

AstraZeneca.[73] Meanwhile, an older hypertension treatment that had been around for decades, generic diuretic pills, saw its share of hypertension prescriptions fall substantially (from fifty-six percent in 1982 to twenty-seven percent in 1993).[74] The cost differential between the drugs was significant: in 2002, the generic diuretics could be purchased for around $40, while the newer, patented ACE inhibitors cost about $700.[75] Though the newer drugs rapidly began to displace the older ones, their comparative benefits were never established. Only in 1995 did someone—specifically, the federal National Heart, Lung, and Blood Institute (part of the National Institutes of Health)—study the issue with a head-to-head trial. Addressing these questions required a high degree of statistical power,[76] and accordingly the Institute's so-called ALLHAT (Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack) study was the largest clinical trial of its kind to date, spanning eight years and involving over 33,000 patients from 623 clinics.[77]

In 2002, the results of the ALLHAT study became clear. The newer medicines were not significantly better than the older ones, and in some respects they were worse.[78] The authors of the study thus concluded that generic diuretics "should be preferred for first-step antihypertensive therapy,"[79] being "unsurpassed in lowering [blood pressure], reducing clinical events, and

73. MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT 96-97 (2004); *see, e.g.*, Jun Ma, Ky-Van Lee & Randall S. Stafford, *Changes in Antihypertensive Prescribing During US Outpatient Visits for Uncomplicated Hypertension Between 1993 and 2004*, 48 HYPERTENSION 846, 848-49 (2006).

74. Teri A. Manolio et al., *Trends in Pharmacologic Management of Hypertension in the United States*, 155 ARCHIVES INTERNAL MED. 829, 829 (1995).

75. ANGELL, *supra* note 73, at 97.

76. Marvin Moser et al., *The ALLHAT Study Revisited: Do Newer Data from This Trial and Others Indicate Changes in Treatment Guidelines?*, 9 J. CLINICAL HYPERTENSION 372, 372 (2007).

77. ALLHAT Officers & Coordinators for the ALLHAT Collaborative Research Grp., *Major Outcomes in High-Risk Hypertensive Patients Randomized to Angiotensin-Converting Enzyme Inhibitor or Calcium Channel Blocker vs Diuretic*, 288 JAMA 2981, 2981, 2983 (2002) [hereinafter ALLHAT 2002]; *see also* Moser et al., *supra* note 76, at 372 (noting that ALLHAT was "a landmark study, the largest hypertension study to date"); Richard J. Rodeheffer, Editorial, *Hypertension and Heart Failure: The ALLHAT Imperative*, 124 CIRCULATION 1803, 1804 (2011) (stating that ALLHAT was "a landmark clinical trial in hypertension management").

78. *See* ALLHAT 2002, *supra* note 77, at 2987; Moser et al., *supra* note 76, at 373-75. With respect to certain outcomes, the diuretic outperformed the two leading newer drugs, resulting in an almost forty percent lower risk of heart failure than the calcium-channel blocker and in fewer strokes and heart failure events than the ACE inhibitor (although faring no better than the ACE inhibitor in terms of overall reduction of CVD events). ALLHAT 2002, *supra* note 77, at 2985-86; Moser et al., *supra* note 76, at 373.

79. ALLHAT 2002, *supra* note 77, at 2981.

tolerability,"[80] while also "superior in preventing 1 or more major forms of CVD despite being less expensive."[81] The ALLHAT results have been corroborated by smaller-scale trials undertaken in Europe, some comparing diuretics and calcium channel blockers head-to-head[82] and others in terms of their respective results as compared to placebos,[83] as well as in a 2011 ALLHAT follow-up study.[84]

What could explain this multi-billion-dollar information failure?[85] The concept of a continuum of excludability gives us critical purchase on the problem. In a world where patents are the leading mechanism used to produce information about drugs, there are asymmetrical incentives to provide positive and negative information about new drugs. Positive information is easier to render excludable than negative information, because of its closer nexus to a tangible, physical product. A company that sought to profit from a patent on negative information about a drug would need to track either thoughts or abstention from purchasing. Even if monitoring such intangibles across a large number of individuals were technically feasible, it is doubtful that such monitoring would be economically viable and, in any event, it would bump up against deeply entrenched privacy norms against invasive mental surveillance. A patentee might instead seek to use circumstantial evidence, for example, a switch between products or other uptake of alternative treatment strategies.

80. *Id.* at 2994.

81. *Id.* at 2981; *cf.* Ron Winslow & Scott Hensley, *Dose of Reality: Study Questions High-Cost Drugs for Hypertension*, WALL ST. J., Dec. 18, 2002, at A1 (quoting the Director of the National Heart, Lung, and Blood Institute as stating that "A[LLHAT] shows that diuretics are the best choice to treat hypertension, both medically and economically").

82. Morris J. Brown et al., *Morbidity and Mortality in Patients Randomised to Double-Blind Treatment with a Long-Acting Calcium-Channel Blocker or Diuretic in the International Nifedipine GITS Study: Intervention as a Goal in Hypertension Treatment (INSIGHT)*, 356 LANCET 366 (2000); Lennart Hansson et al., *Randomised Trial of Old and New Antihypertensive Drugs in Elderly Patients: Cardiovascular Mortality and Morbidity: The Swedish Trial in Old Patients with Hypertension-2 Study*, 354 LANCET 1751 (1999).

83. *See* SHEP Coop. Research Grp., *Prevention of Stroke by Antihypertensive Drug Treatment in Older Persons with Isolated Systolic Hypertension*, 265 JAMA 3255 (1991); Jan A. Staessen et al., *Randomised Double-Blind Comparison of Placebo and Active Treatment for Older Patients with Isolated Systolic Hypertension*, 350 LANCET 757 (1997).

84. Linda B. Piller et al., *Long-Term Follow-Up of Participants with Heart Failure in the Antihypertensive and Lipid-Lowering Treatment To Prevent Heart Attack Trial (ALLHAT)*, 124 CIRCULATION 1811 (2011).

85. The ALLHAT researchers estimated that "the health care system would have saved $3.1 billion in estimated cost of antihypertensive drugs" over the ten years between 1982 and 1992 if the switch to newer drugs had not been made. ALLHAT 2002, *supra* note 77, at 2994. Of course, this figure does not incorporate the additional financial implications of the lesser efficacy of newer antihypertensives.

But such information could not reliably prove patent infringement absent a new—and normatively unappealing—legal theory of infringement based on indirect evidence of changes in individual consumption patterns. And this strategy would also capture only a subset of foregone uses—those switching away from the product—missing the many potential consumers of the product who will not have been prior users. This mismatch illustrates one of the analytic points made in more condensed form in Part I: negative information about drugs is very difficult to directly exclude, for reasons that can be attributed to technology and norms.[86]

Our hypothetical patent holder might also be able to employ other indirect means of capitalizing on the negative information she has created, but all of these strategies can appropriate at best a small portion of the social value at stake. For example, one could imagine a "Consumer Reports" business model in which firms profit from the sale of negative information about drugs sold by others. But the link between financial returns (for example via magazine sales) and the social value of the information will be radically attenuated when compared to the profits directly available from the sales of a patented drug. Intermediaries such as insurance companies, for whom negative and comparative information should be as valuable as positive information, are subject to the classic constraints on information production in a competitive market, and face collective action problems similar to those confronting generic and patented drug competitors: without an effective, excludable patent, a company that invested millions of dollars in trials could expect to lose out to competitors who would gain the advantage of the information but not bear its cost of creation. Hospitals themselves might be able to recoup some of the benefits of infections averted in the ICU, for example if they were able to advertise their infection rates and attract new patients as a result. But because they operate in (at least somewhat) competitive markets, they are likely to face the same problems that insurance companies would.

Our argument, then, is not that absent a high degree of patent-related excludability there will be no alternative market strategies or mechanisms for private appropriation of some of the social value of an information good. Rather, it is that the returns from such indirect, alternative mechanisms will tend to be significantly lower than from direct, patent-based sales. Moreover, when comparatively nonexcludable information goods must solely rely on such indirect forms of appropriation or finance, they are further disadvantaged

86. Institutional factors may also potentially play a role here. It is conceivable that all consumption decisions would be made by one or a few highly visible organizations (such as government purchasers, hospitals, or a small number of private insurers), which may then be held to account more easily for the reasons underlying their shifting purchasing decisions.

vis-à-vis excludable information goods that can rely on both these alternatives *and* on patent-based revenues.

B. Lifestyle Interventions

Now consider a second example: the comparative implications of patents for the development of medicines versus "lifestyle" interventions to address CVD. The pharmaceutical approach to CVD risk reduction is a prominent one in the United States: "statin" drugs that reduce cholesterol are the top-selling class of therapeutic drug.[87] Some have raised concerns that statins are overprescribed.[88] A 2011 Cochrane Review (considered the gold standard in meta-studies in the medical field) concluded that "[w]idespread use of statins in people at low risk of cardiovascular events . . . is not supported by the existing evidence,"[89] while a recent update concluded instead that statins are

87. *Top Therapeutic Classes by Prescriptions*, IMS HEALTH (Apr. 7, 2011), http://www.imshealth.com/ims/Global/Content/Corporate/Press%20Room/Top-line%20Market%20Data/2010%20Top-line%20Market%20Data/2010_Top_Therapeutic_Classes_by_RX.pdf.

88. *See* J. Abramson & J.M. Wright, *Are Lipid-Lowering Guidelines Evidence-Based?*, 369 LANCET 168, 168 (2007) (arguing that there is no clinical basis for the recommendation of statins for primary prevention for women and people over sixty-five); Isabelle Savoiea & Arminée Kazanjian, *Utilization of Lipid-Lowering Drugs in Men and Women: A Reflection of the Research Evidence?*, 55 J. CLINICAL EPIDEMIOLOGY 95, 95 (2002) (arguing similarly that statins have not been shown to be beneficial for primary prevention in women and for the elderly, and arguing that statin therapy should be focused on men with coronary heart disease).

89. Fiona Taylor et al., *Statins for the Primary Prevention of Cardiovascular Disease (Review)*, COCHRANE DATABASE OF SYSTEMATIC REVS. (2011), http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004816.pub4/pdf. There are other meta-studies that come to the conclusion that statins are helpful for primary prevention. *See, e.g.*, C. Baigent et al., *Efficacy and Safety of Cholesterol-Lowering Treatment: Prospective Meta-Analysis of Data from 90,056 Participants in 14 Randomised Trials of Statins*, 366 LANCET 1267 (2005); J.J. Brugts et al., *The Benefits of Statins in People Without Established Cardiovascular Disease but with Cardiovascular Risk Factors: Meta-Analysis of Randomised Controlled Trials*, 338 BRIT. MED. J. b2376 (2009); Edward J. Mills et al., *Primary Prevention of Cardiovascular Mortality and Events with Statin Treatments: A Network Meta-Analysis Involving More Than 65,000 Patients*, 52 J. AM. C. CARDIOLOGY 1769 (2008). The Cochrane Review, however, expresses skepticism about these studies because they tended to include trials that had a relatively high proportion of people with established CVD, confounding their results. Taylor et al., *supra*, at 11. This raises a concern we mention elsewhere, about the problems with relying on patent-holding firms to fund studies to show that their drugs are ineffective for certain populations. As the Cochrane Review notes, their research was made difficult by the fact that most studies did not focus strictly on primary prevention; perhaps not coincidentally, including individuals with secondary prevention needs would help ensure that a positive result could be shown. The researchers were also unable to obtain data disaggregated in a way that would allow independent analysis of the results of statins for particular subsets of patients. *See id.* at 11.

likely beneficial in this population.[90]

Debate, however, continues, despite significant investment by patent-holding companies in studies to validate the use of statins for the vast population of people at relatively low risk. A good example is the recent JUPITER trial,[91] which targeted a relatively low-risk group and had the potential to boost sales of the AstraZeneca drug in question by $2 billion a year.[92] The trial did show some reduction in cardiovascular events and in all-cause mortality;[93] however, it also showed an increased risk of diabetes,[94] so that "for every person who didn't get a serious cardiovascular event, three-quarters of a person got diabetes."[95] The trial offers no evidence regarding efficacy or safety beyond two years; because people may take these drugs for decades, side-effects over longer time horizons remain a concern.[96] Moreover, the beneficial effects of the statin, while statistically significant, were modest, such that "treating 120 people for 1.9 years with rosuvastatin (at a cost of about $287,000) would prevent one cardiovascular event."[97] Concerns about side effects and the expense of statins thus persist, leading to continued debate about the benefits of statins for very low-risk individuals.

There are other approaches to reducing CVD risk, however. It is now well known that unhealthy diets, lack of physical activity, and smoking substantially influence the risk of cardiovascular disease.[98] Evidence suggests that up to one-third of all CVD deaths in the United States can be attributed to smoking.[99] Those who are physically inactive increase their risk of CVD in a

90. Fiona Taylor et al., *Statins for the Primary Prevention of Cardiovascular Disease (Review)*, COCHRANE DATABASE OF SYSTEMATIC REVS. (2013), http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004816.pub5/pdf.

91. *See* Paul M. Ridker et al., *Rosuvastatin To Prevent Vascular Events in Men and Women with Elevated C-Reactive Protein*, 359 NEW ENG. J. MED. 2195, 2196 (2008).

92. Merrill Goozner, *CRP—The Next Chapter in Medical Waste?*, GOOZNEWS (Nov. 10, 2008), http://gooznews.com/?p=1291.

93. Ridker et al., *supra* note 91, at 2202.

94. *Id*. at 2205.

95. Goozner, *supra* note 92.

96. Ridker et al., *supra* note 91, at 2205.

97. Martin Fenner, *What Are the Right Numbers for JUPITER?*, PLOS BLOGS: GOBBLEDYGOOK (Nov. 23, 2008), http://blogs.plos.org/mfenner/2008/11/23/what_are_the_right_numbers_for_jupiter.

98. *Fact Sheet No. 317: Cardiovascular Diseases (CVDs)*, *supra* note 64.

99. U.S. DEP'T OF HEALTH & HUMAN SERVS., HOW TOBACCO SMOKE CAUSES DISEASE: THE BIOLOGY AND BEHAVIORAL BASIS FOR SMOKING-ATTRIBUTABLE DISEASE, A REPORT OF THE SURGEON GENERAL 355 (2010), http://www.surgeongeneral.gov/library/reports/tobaccosmoke/full_report.pdf.

manner similar to those who smoke.[100] And numerous studies have found that fish consumption reduces the risk of stroke.[101]

Behavioral interventions seek to reduce risk by affecting these habits, typically through education and counseling. Structural interventions seek to reduce CVD risk not by prescribing behavior changes for individuals, but by altering the conditions in which individuals make choices about their behavior. While a common behavioral approach would educate people about the benefits of exercise, for example, a structural approach might instead redesign their workplace to make exercise more attractive or endemic to daily life, or to restrict their ability to smoke in public.[102]

Retrospective studies suggest that public health information and education campaigns have had significant impacts on factors such as smoking rates, and thus have reduced CVD, albeit indirectly.[103] One recent study concluded, for example, that "[s]moking rates have fallen by one-third since 1960, and fat intake has been reduced. These changes have occurred at least partly as a result

100. U.S. DEP'T OF HEALTH & HUMAN SERVS., PHYSICAL ACTIVITY AND HEALTH: A REPORT OF THE SURGEON GENERAL 7 (1996), http://profiles.nlm.nih.gov/ps/access/NNBBHB.pdf.

101. *See, e.g.*, Richard F. Gillum et al., *The Relationship Between Fish Consumption and Stroke Incidence: The NHANES I Epidemiologic Follow-Up Study*, 156 ARCHIVES INTERNAL MED. 537 (1996); Sirving O. Keli, Edith J.M. Feskens & Daan Kromhout, *Fish Consumption and Risk of Stroke: The Zutphen Study*, 25 STROKE 328 (1994). *But see, e.g.*, Martha Clare Morris et al., *Fish Consumption and Cardiovascular Disease in the Physicians' Health Study: A Prospective Study*, 142 AM. J. EPIDEMIOLOGY 166 (1995) (failing to find a relationship between fish consumption and incidence of stroke). There is reason to be suspicious of the Morris study: half of the patients in the study were taking aspirin, which could have attenuated the effects of eating fish. Hiroyasu Iso et al., *Intake of Fish and Omega-3 Fatty Acids and Risk of Stroke in Women*, 285 JAMA 304 (2001) (pointing out this flaw and finding an effect of fish intake when aspirin use was accounted for, particularly for women). Several recent meta-analyses have found a protective effect of fish consumption. *E.g.*, Rajiv Chowdhury et al., *Association Between Fish Consumption, Long Chain Omega 3 Fatty Acids, and Risk of Cerebrovascular Disease: Systematic Review and Meta-Analysis*, 345 BRIT. MED. J. e6698 (2012); Susanna C. Larsson & Nicola Orsini, *Fish Consumption and the Risk of Stroke: A Dose-Response Meta-Analysis*, 42 STROKE 3621 (2011).

102. *See* K.M. Blankenship et al., *Structural Interventions: Concepts, Challenges and Opportunities for Research*, 83 J. URB. HEALTH 59 (2006); Mary Jane Rotheram-Borus, Dallas Swendeman & Gary Chovnick, *The Past, Present, and Future of HIV Prevention: Integrating Behavioral, Biomedical, and Structural Intervention Strategies for the Next Generation of HIV Prevention*, 5 ANN. REV. CLINICAL PSYCHOL. 143 (2009).

103. *See, e.g.*, David M. Burns et al., *Cigarette Smoking Behavior in the United States*, *in* MONOGRAPH 8: CHANGES IN CIGARETTE-RELATED DISEASE RISKS AND THEIR IMPLICATIONS FOR PREVENTION AND CONTROL 13, 13 (David M. Burns, Lawrence Garfinkel & Jonathan M. Samet eds., 1996), http://cancercontrol.cancer.gov/tcrb/monographs/8/m8_2.pdf (showing sustained reductions in the per capita rates of cigarette smoking and tobacco consumption from the 1950s onward); *id.* at 18 (concluding that health information and public advertising likely caused some of the reduction in smoking rates).

of research findings relating them to health outcomes."[104] But while there is some evidence for the impact of such information, it remains clear that we need better information, and better strategies for capitalizing on that information, to reduce risks related to lifestyle factors. For example, much more data exists about the health implications of heavy smoking than about so-called "social smoking,"[105] and there remain enormous unknowns in the science related to dietary influences on health.[106]

This information gap relates to a broader problem: we often lack basic epidemiological information that would help us understand the contemporary incidence of disease. This issue is perhaps most easily illustrated in the context of environmental toxins. In recent years, researchers have begun to consider the possible role played by exposure to various "background" industrial and synthetic chemicals in our environment (such as pesticides, petrochemicals, industrial by-products, solvents, preservatives, plastics and heavy metals) in contributing to rising rates of various medical conditions. And for a broad range of diseases, they have found strong (albeit indirect) reasons to believe that the role played by such exposure is considerable. This is because a large proportion of current incidence rates for leading diseases remain unexplained once known risk factors such as genetic disposition and lifestyle traits are accounted for, leading researchers to focus on the potential contribution of toxic exposure. Conditions believed to be so affected include CVD,[107] breast

104. David M. Cutler & Srikanth Kadiyala, *The Return to Biomedical Research: Treatment and Behavioral Effects*, *in* MEASURING THE GAINS FROM MEDICAL RESEARCH: AN ECONOMIC APPROACH 110, 110 (Kevin M. Murphy & Robert H. Topel eds., 2010); *see also id.* at 112 (summarizing evidence that "both medical treatments and behavioral changes are important factors" in the two-thirds reduction in CVD between 1950 and 1994).

105. *See* Rebecca E. Schane, Pamela M. Ling & Stanton A. Glantz, *Health Effects of Light and Intermittent Smoking: A Review*, 121 CIRCULATION 1518, 1518, 1520 (noting that the available literature on the health effects of light and intermittent smoking is "not large" and that the published cohort studies "lack a specific focus on intermittent smoking").

106. For example, there is significant debate and uncertainty about the relative benefits of, for example, low-fat diets, "Mediterranean" diets (which have characteristics such as being rich in vegetables, fish, and poultry), and low-carbohydrate diets. Reviews have suggested benefits of the Mediterranean diet, but a recent (and rare) randomized trial—which involved only 322 subjects and followed them for just two years—suggested that a low-carbohydrate diet may have the best effects for cholesterol, while the Mediterranean diet may be best for those with diabetes. *See* Iris Shai et al., *Weight Loss with a Low-Carbohydrate, Mediterranean, or Low-Fat Diet*, 359 NEW ENG. J. MED. 229, 229 (2008); *see also* Gina Kolata, *Experts Want More Studies of Diet's Role for the Heart*, N.Y. TIMES, Mar. 2, 2013, http://www.nytimes.com/2013/03/03/health/experts-want-more-studies-of-mediterranean-diets-role-for-the-heart.html (calling for more studies on alternative diets).

107. Timothy E. O'Toole, Daniel J. Conklin & Aruni Bhatnager, *Environmental Risk Factors for Heart Disease*, 23 REVS. ENVTL. HEALTH 167, 167 (2008) (reviewing the evidence "linking

cancer,[108] childhood cancer,[109] autism and other neurodevelopmental disorders,[110] type-2 diabetes,[111] and obesity.[112] In each instance, however, it is

environmental pollutants to cardiovascular disease (CVD)," finding that "[c]ollectively, the data support the notion that chronic environmental stress is an important determinant of CVD risk," and concluding that "[f]urther work is required to assess the magnitude of this risk fully and to delineate specific mechanisms by which environmental toxins affect CVD").

108. An estimated seventy to eighty percent of breast cancer cases have no known cause, Task Force on Cost-Effective Health Care Innovation, *Valuing Health Care: Improving Productivity and Quality*, EWING MARION KAUFFMAN FOUND. 19 (Apr. 2012), http://www.kauffman.org/uploadedfiles/valuing_health_care.pdf, while some estimate that a woman's lifetime risk of contracting the disease has gone up from one in twenty in the 1960s to one in eight today, *Breast Cancer and Environment*, BREAST CANCER ACTION, http://bcaction.org/our-take-on-breast-cancer/environment (last visited Jan. 29, 2013). From this, some infer a strong role for environmental toxins, although their contribution relative to diet and exercise as other non-genetic risk factors remains a subject of considerable contention. *Compare* Karuna Jaggar, *Mammograms, Diet & Exercise Will Not End the Epidemic*, THINK BEFORE YOU PINK (Sept. 13, 2011, 4:02 PM), http://thinkbeforeyoupink.org/?p=1597 ("One of the ugly truths of breast cancer is that more than half of all breast cancers have no known cause and scientific evidence suggests that many cases are linked to exposure to environmental toxins."), *and* Karuna Jaggar, *Why We'll Never Underestimate Environmental Toxins*, BREAST CANCER ACTION (Sept. 14, 2011), http://bcaction.org/2011/09/14/why-well-never-underestimate-environmental-toxins (asserting that notwithstanding "the known health benefits of diet and exercise on reducing one's risk for breast cancer," "downplaying of the connection between exposure to environmental toxins and increased risk of breast cancer" risks "only addressing a part of the picture" by "keeping to just the narrow actions of individuals"), *with* David Sampson, *Breast Cancer: Just the Facts*, AM. CANCER SOC'Y PRESSROOM BLOG (Sept. 14, 2011), http://acspressroom.wordpress.com/2011/09/14/breast-cancer-just-the-facts ("While it is true that most cases of breast cancer have no known cause, the implication that exposure to environmental toxins is more important than diet and exercise would be—at the very least—an exaggeration.").

109. Childhood cancers are the second leading cause of death among children age zero to fifteen, and rose by approximately one percent per year from 1975 to 1998. Genetic predisposition is estimated to account for as much as twenty percent of cases, leaving environmental factors such as toxic exposure to take up between five and nine percent, depending on the cancer. Tami Gouveia-Vigeant & Joel Tickner, *Toxic Chemicals and Childhood Cancer: A Review of the Evidence*, LOWELL CENTER FOR SUSTAINABLE PRODUCTION 1 (May 2003), http://www.sustainableproduction.org/downloads/Child%20Canc%20Exec%20Summary.pdf.

110. Philip J. Landrigan, Luca Lambertini & Linda S. Birnbaum, *A Research Strategy To Discover the Environmental Causes of Autism and Neurodevelopmental Disabilities*, 120 ENVTL. HEALTH PERSP. A258, A258 (2012) (noting the existence of "proof-of-principle" studies that "early [toxic] exposures can cause autism," but acknowledging that "[a] major unanswered question is whether there are still undiscovered environmental causes of autism or other [neurodevelopmental disabilities] among the thousands of chemicals currently in wide use in the United States").

111. Donald Sharp, *Environmental Toxins, A Potential Risk Factor for Diabetes Among Canadian Aboriginals*, 68 INT'L J. CIRCUMPOLAR HEALTH 316, 316 (2009) (concluding that since "[a]ccepted risk factors such as diet, lifestyle and genetics do not fully explain" a three hundred to five hundred percent discrepancy in diabetes prevalence between the general

also evident that although the contribution of environmental toxins to disease rates seems potentially quite significant, investigations on this front are at a very early stage, and substantially greater study is required before specific linkages can be confidently established. Producing good epidemiological information about such chemicals is an enormous and expensive task, especially in light of the number of chemicals involved and the fact that they need to be studied in combination rather than isolation.[113]

To return to the heart disease context, we also know little about how to design interventions that will reliably change behaviors in low-risk individuals. A recent Cochrane meta-study considered the impact of "healthy heart" programs designed to reduce CVD risk by improving lifestyle.[114] Although the selected trials did show beneficial effects on risk-factors (including blood pressure, smoking, and cholesterol), they did not show an effect on long-term mortality, perhaps because people without established CVD have difficulty maintaining behavior changes over the long term.[115]

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population and indigenous peoples in Canada, the role of "environmental toxins bioaccumulat[ing] in the food chain and . . . found in wild game and fish traditionally . . . consumed by Aboriginal peoples" merits further study).

112. *See, e.g.*, Juhee Kim et al., *Trends in Overweight from 1980 Through 2001 Among Preschool-Aged Children Enrolled in a Health Maintenance Organization*, 14 OBESITY 1107 (2006) (finding a roughly four percent increase in obesity among children of all ages, including under six months, from 1980 to 2001, perhaps raising the possibility of environmental factors including toxic agents); Leonardo Trasande et al., *Environment and Obesity in the National Children's Study*, 117 ENVTL. HEALTH PERSP. 159, 163 (2009) ("Because so few chemicals have been tested for their toxicity, the possibility exists that other chemicals besides DES influence somatic growth and obesity," but "[i]dentification of endocrine-disrupting chemicals has been limited by the lack of toxicity testing data available for many chemicals in widespread use.").

113. The following is a representative statement of the challenges in this area, from a review of the existing state of evidence regarding childhood cancers:

> It is difficult to determine the exact magnitude of the contribution of toxic chemicals to the overall burden of childhood cancer. Because the majority of chemicals in commerce—some of which are widely used in everyday products—have not been studied for their potential to cause cancer, we do not have a complete picture of the potential chemical causes of cancer in children. The links with childhood cancer have been adequately studied for only a few chemicals. Mixtures of chemicals mimicking the complex exposures that occur in everyday life have been studied even less.

Gouveia-Vigeant & Tickner, *supra* note 109, at 3.

114. Shah Ebrahim et al., *Multiple Risk Factor Interventions for Primary Prevention of Coronary Heart Disease (Review)*, COCHRANE DATABASE OF SYSTEMATIC REVS. (2011), http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001561.pub3/pdf.

115. *Id.* at 1-2; *see also* Lawrence J. Appel, *Lifestyle Modification: Is It Achievable and Durable?: The Argument For*, 6 J. CLINICAL HYPERTENSION 578, 578 (2004) (documenting the positive

It is possible that we simply need better ideas about how to operationalize the general knowledge that we have about the relationship of diet, exercise, and smoking to CVD risk. Might there be ways, for example, to make exercise more sustainable by integrating it more fully into people's everyday lives? Perhaps simply standing rather than sitting during meetings, or working at a standing desk, could have effects similar to regular exercise.[116] Or perhaps researchers could generate an exercise routine that could be done simply, at home for a few minutes a day, and still achieve substantial reductions in risk of CVD.

More promising, perhaps, are structural interventions to reduce CVD risk.[117] For example, stair climbing is an excellent form of exercise, and it is one that can be readily integrated into many people's daily lives.[118] Unfortunately, prevailing approaches to building design often make stairs unappealing. A different form of structural intervention whose beneficial effects have been more robustly documented are smoking bans. Many studies in the United States have now shown that comprehensive smoking bans are associated with a reduction in the incidence of heart attacks. For example, a recent study documented the effects of Arizona's statewide smoking ban on a range of

effects of sustained lifestyle modifications on risk factors). Part of the problem may be inadequate data. For example, of the fifty-five studies included in the Cochrane review, just four were large enough to have the power to show possible effects on mortality. Ebrahim et al., *supra* note 114, at 5. Another possibility is bias in the studies, which is difficult to eliminate here, at least according to the conventional gold standard of the randomized controlled trial; researchers cannot blind people to whether they are receiving "lifestyle" interventions. *Id.* at 2, 6. The nature of the interventions studied undoubtedly varied greatly, given the wide parameters for behavioral interventions that the review used. It is possible that existing techniques could show mortality effects, but have not been studied at a scale sufficient to prove this. Notably, researchers often express pessimism about the possibility of such studies. *See, e.g.*, Appel, *supra*, at 583 ("Outcome studies have not been done for nonpharmacological treatments [of high blood pressure], and probably never will be . . . .").

116. Recent studies have begun to explore the implications of prolonged sitting for health. *See, e.g.*, Marc T. Hamilton, Deborah G. Hamilton & Theodore W. Zderic, *Role of Low Energy Expenditure and Sitting in Obesity, Metabolic Syndrome, Type 2 Diabetes, and Cardiovascular Disease*, 56 DIABETES 2655 (2007). For a study suggesting the advantages of a standing desk attached to a treadmill, see James A. Levine & Jennifer M. Miller, *The Energy Expenditure of Using a "Walk-and-Work" Desk for Office Workers with Obesity*, 41 BRIT. J. SPORTS MED. 558 (2007).

117. The Cochrane "healthy heart" Review concluded that structural interventions are more promising than behavioral ones. *See* Ebrahim et al., *supra* note 114, at 15.

118. *See, e.g.*, Philippe Meyer, Bengt Kayser & François Mach, *Stair Use for Cardiovascular Disease Prevention*, 16 EUR. J. CARDIOVASCULAR PREVENTION & REHABILITATION S17 (Supp. 2 2009).

cardiovascular events.[119] The result: "[T]here was a statistically significant decrease in the number of acute myocardial infarction (AMI), angina, stroke, and asthma cases admitted to hospitals in counties with no previous smoking bans, compared with counties with prior bans, during the months following the implementation of the statewide comprehensive ban."[120] The reductions were impressive: the statewide ban in the no-earlier-ban counties led to 13% fewer heart attacks, 33% fewer angina cases, 14% fewer acute stroke cases, and 22% fewer acute asthma cases.[121] The researchers estimated the resulting reductions in hospitalization costs to be $16.8 million in the thirteen months after the ban.[122] Moreover, such interventions have few of what could be considered negative side effects, apart from the possible hedonic costs for those who have a taste for smoking in public.

To summarize the previous few pages of evidence about the existing state of the field of primary prevention for CVD: millions of people take statin drugs for primary prevention, but there is substantial debate about how well they work, and when their benefits are outweighed by their side effects and cost. We know that lifestyle changes, in contrast, could very substantially reduce the burden of CVD, and producing and disseminating this information has led to some significant health gains. But there is still much that we do not know about lifestyle factors and health, and about how we can best translate the knowledge we do have into sustained, widespread changes in diet, smoking, and exercise practices.

Notice that patents operate asymmetrically with respect to the different kinds of information goods that might help reduce CVD. Positive information about pharmaceuticals is on the highly excludable end of the continuum, for reasons discussed above. But behavioral and structural approaches, and the information that they draw upon, will typically be very difficult to exclude. Imagine that a scientist who mapped the basic relationships between, say, exercise and disease could obtain a patent on that costly information. Commodifying this information nonetheless would be very difficult, as it would require tracking of either the dissemination of the information itself, or people's internalization of that information, or their response to it, including everyday activities like walking, jogging, or joining a gym. Similarly, many interventions to help people adapt to a healthier lifestyle will also often be

119. Patricia M. Herman & Michele E. Walsh, *Hospital Admissions for Acute Myocardial Infarction, Angina, Stroke, and Asthma After Implementation of Arizona's Comprehensive Statewide Smoking Ban*, 101 AM. J. PUB. HEALTH 491 (2011).

120. *Id*. at 494.

121. *Id*. at 494 tbl.1.

122. *Id*. at 495 tbl.2.

difficult to exclude. Consider, for example, the obstacles you would face if you held a patent on a method of reducing one's risk of heart disease by standing at one's desk and walking during meetings. Enforcing a patent on a method of improving cardiovascular health by banning public smoking would present different problems. The patent holder would have to threaten lawsuits against states for adopting her novel legislative approach. Such lawsuits would have many impediments, including the constitutional question of states' sovereign immunity.[123] Such obstacles are illustrative of the kinds of normative and technical hurdles that a hypothetical inventor would face. Consequently, we should not be surprised if we see—as we have recently—significant private sector investment intended to increase the pool of people eligible for treatment with statins, but see very little private sector investment in efforts to understand basic epidemiological links between diet, smoking, exercise, and CVD, or to develop and prove the efficacy of new ways to make exercise endemic to the workplace.

Again, in both cases, inventors might find more indirect ways to profit from their inventions, short of patent enforcement. Exercise gurus can produce copyrighted books and DVDs, for example, but these would offer a far smaller possibility of recouping the social value produced by the invention (along with the far more expensive and critical evidence validating the extent to which the invention effectively works to reduce morbidity and mortality) than would an enforceable patent. Copyright law could be strengthened, but it could not be extended to protect facts or ideas—such as the functional aspects of the exercise regime itself or the fact that it reduced mortality—without dramatic revision in its structure.[124] Moreover, a hypothetical copyright holder seeking to enforce a copyright on not simply expressions but also ideas would run up against the same nonexcludability problems that our hypothetical patent holder would encounter.

The point is not that there could be *no* way to profit from research and validation activities associated with behavioral or structural interventions to reduce CVD risk. Instead, it is clear that the ability of the producers of this kind

123. *See* Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 645-48 (1999) (finding that the Patent Remedy Act was not a valid waiver of state sovereign immunity). Patent holders could sue to enjoin states from continuing to practice the patent, however. Pennington Seed, Inc. v. Produce Exch. No. 299, 457 F.3d 1334, 1341 (Fed. Cir. 2006) ("[C]ontinuing prospective violations of a federal patent right by state officials may be enjoined by federal courts under the *Ex parte Young* doctrine . . . .").

124. *See* 17 U.S.C. § 102(b) (2006) (denying protection to any "idea" or "procedure, process, system, [or] method of operation"); Harper & Row, Publishers, Inc. v. Nation Enters., 471 U.S. 539, 547 (1985) ("[N]o author may copyright facts or ideas."); Baker v. Selden, 101 U.S. 99 (1879) (articulating the idea-expression dichotomy).

of health information to recoup the social value that they create, even if entitled to a patent, is very limited. And it is certainly much more limited than the ability of, say, a company that develops and sells statins, for reasons that have to do ultimately with the influence of technology and norms on the ease and cost of exclusion.

C. Innovations in Healthcare Quality

We now turn to a third example of a difficult-to-exclude information good, one that helps to highlight the influence of institutional context on the continuum of excludability. As previewed in the Introduction, hospitals and other health care settings are frequent sites of dangerous infection.[125] These infections can be lethal, particularly when they are antibiotic resistant.[126] One way to address them is by investing hundreds of millions of dollars, or even billions of dollars, in new and improved antibiotics.[127] Another is to improve the quality of preventive care in the hospital.

The checklist technique described above is a quality innovation, one first developed and tested locally by a doctor specializing in critical care at Johns Hopkins, Peter Pronovost. Although it is a complex intervention, the checklist technique clearly qualifies as an information good, and it required a nontrivial investment of time and resources to develop and validate. As with drug development, much of the cost was in the validation. Although Pronovost documented very good results in initial implementation at Johns Hopkins, many were skeptical that the remarkable reduction in infection rates he achieved there could be replicated in less well-resourced, receptive environments.[128] A randomized controlled clinical trial was thus needed to demonstrate the applicability and efficacy of the technique. And it showed remarkable success: the technique reduced the median quarterly rate of central-line catheter infections by sixty-six percent.[129] This rate was sustained during sixteen to eighteen months of follow-up studies,[130] and was estimated to save more than 1,800 lives and $200 million over a three-year period in

125. R. Monina Klevens et al., *Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002*, 122 PUB. HEALTH REP. 160, 160 (2007).

126. Elixhauser & Steiner, *supra* note 2, at 1-2.

127. For one proposal in this direction, see Sonderholm, *supra* note 3, at 241-42 (proposing a reward for new antibiotics in the form of a tradable patent-term extension, at a cost of about $2 billion per new antibiotic).

128. ATUL GAWANDE, THE CHECKLIST MANIFESTO: HOW TO GET THINGS RIGHT 40-44 (2009).

129. Pronovost et al., *supra* note 1, at 2725.

130. *Id*. at 2731.

Michigan alone.[131] On a national scale, the savings could be up to 15,000 lives and $1 billion in treatment costs each year.[132]

As noted earlier, by any measure of social welfare, the checklist technique is a great intervention. And although it was not costless to develop, it was relatively inexpensive. The foundational research at Johns Hopkins and in Michigan was paid for by the Federal Agency for Healthcare Research and Quality, at a cost of just $1 million.[133] The intervention looks even better when we compare it to the estimated price of treating central-line catheter infections (an average cost as high as $45,000 per infection),[134] or developing new antibiotics to better treat these infections (in the hundreds of millions, if not billions of dollars).

As good as the intervention is in public health terms, however, it is relatively undervalued by a system that allocates research dollars according to appropriability. Assume, for a moment, that the checklist technique meets the standards of patentability—perhaps Pronovost could claim "a process for reducing central-line catheter infections in the ICU, comprised of the use of a [checklist, personnel management interventions, monitoring, etc.]."[135] With a

131. *Preventing Central Line-Associated Bloodstream Infections: A Global Challenge, A Global Perspective*, THE JOINT COMMISSION, at x (May 2012), http://www.jointcommission.org/assets/1/18/CLABSI_monograph.pdf.

132. SURVEY OF STATE HOSPITAL ASSOCIATIONS, *supra* note 8, at 2.

133. *Id.* at 9.

134. Pronovost et al., *supra* note 1, at 2726 (citing an average per patient cost of $45,000). There is a markedly wide range of estimated treatment costs, but reasonable estimates range from $10,000 to $50,000 depending upon how costs are measured, the patients involved, the hospital in question, and so forth. *See, e.g.*, Justin B. Dimick et al., *Increased Resource Use Associated with Catheter-Related Bloodstream Infection in the Surgical Intensive Care Unit*, 136 ARCHIVES SURGERY 229, 231-33 (2001) (calculating the total increase in hospital costs for each infection in critically ill patients at over $50,000); David K. Warren et al., *Attributable Cost of Catheter-Associated Bloodstream Infections Among Intensive Care Patients in a Nonteaching Hospital*, 34 CRITICAL CARE MED. 2084, 2084 (2006) (finding an attributable cost of $11,971 per infection).

135. In fact, similar patents, some of which cite Pronovost's work, are not hard to find. *See, e.g.*, U.S. Patent No. 7,991,625 (filed May 31, 2006) (claiming a "[s]ystem for providing expert care to a basic care medical facility from a remote location"); U.S. Patent No. 7,433,827 (filed Feb. 18, 2005) (claiming a "[s]ystem and method for displaying a health status of hospitalized patients," wherein "[i]nformation concerning the latest care and practice standards for a given condition is provided to a decision support module," which "comprises decision support algorithms that reflect a standardize[d] guideline of practice for a particular medical condition"). The recent *Bilski* line of subject matter cases might complicate matters for patents such as these. *See* Bilski v. Kappos, 130 S. Ct. 3218 (2010) (affirming that "laws of nature, physical phenomena, and abstract ideas" are ineligible general categories for patent protection, and specifically holding that a mathematical formula for hedging risks, and its application to energy markets, are patent-ineligible

patent in hand, Pronovost would nonetheless have difficulties detecting infringers. These efforts would likely require substantial surveillance or investigation, in part because there is no tangible product in which the information is embodied from which hospitals can be excluded or, more importantly, from which hospital use of the underlying information good can be discerned. Norms disfavoring proprietary rights over medical techniques—evidenced by the statutory bar on the enforcement of patents on surgical techniques[136]—might also generate an additional "cost" of enforcement (reputational or other social sanctions, reluctance to cooperate with investigations, etc.). In this type of scenario, technology and norms work against the enforcement of any such patent in ways similar to the two other cases discussed above.

But Pronovost has one salient advantage when we compare his technique to the lifestyle interventions or negative information on existing drugs discussed above: there are a limited number of ICUs in the country, and they are sizable players who cannot easily hide.[137] They are also bureaucratized, in part because the surrounding legal and regulatory environments require a certain level of monitoring and oversight. That in turn creates the possibility of a paper trail, reducing the evidentiary costs of enforcement to Pronovost. Regulatory forces, such as tort law or medical licensing and review boards, might also intervene effectively to require or produce prima facie evidence that hospitals used Pronovost's approach once it becomes the standard of care, again diminishing evidentiary and surveillance costs.

We should not overstate the case. Although the institutional context would make this setting easier to surveil, some detective work would be required, making enforcement still more costly than it would be if there were a tangible commodity associated with the patent. A hospital threatened with an

"abstract ideas"); *see also* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012) (invalidating, under the "laws of nature" exclusion, patent claims that involved administering a drug, measuring the level of certain metabolites in a patient's blood, and deducing from this level whether the dosage was correct); Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124 (2006) (Breyer, J., dissenting from dismissal of certiorari as improvidently granted) (contending that the drawing of a correlation between elevated levels of an amino acid in the blood and vitamin deficiency is an unpatentable "mental process"). Pronovost could also face substantial challenges on the obviousness front, but we set these issues aside for the moment to consider the dilemmas Pronovost would face even in the presence of a patent.

136. 35 U.S.C. § 287(c) (2006).

137. There are between five and six thousand hospitals in the United States, and not all of these will have an ICU. *See Fast Facts on US Hospitals*, AM. HOSP. ASS'N, http://www.aha.org/research/rc/stat-studies/fast-facts.shtml (last updated Jan. 3, 2013) (citing close to six thousand registered hospitals in the United States).

infringement lawsuit would presumably discount the threat according to the difficulty or expense of discovery and burden of proof that Pronovost would face, the odds that it could escape liability on a theory of non-infringement, and so forth. Indeed, norms against enforcing patents in a surgical ward might lead them simply to ignore potential patent issues—as many universities reportedly continue to do even after the *Madey v. Duke University*[138] decision indicated that their internal, noncommercial uses of patented inventions were potentially infringing.[139] Even if Pronovost could extract a licensing fee by sending off a series of registered letters, that fee would be reduced according to the payers' perceptions of the strength of his legal claim and the costs to him of proving his case.

Although norms and technology make the checklist technique somewhat difficult to exclude, the institutional context improves the outlook for Pronovost and puts this intervention somewhere in the middle of our continuum of excludability. However, the fact that the checklist holds out a *comparatively* lower ratio of private appropriability may disadvantage it against more excludable, but less socially valuable, alternatives.

Of course, as with our other examples, here too Pronovost could seek to appropriate some of the value of his invention via means more indirect than a patent. He could create a certification mark, and offer hospitals a "quality seal of approval" for a fee, using trademark law and advertising to recoup some of his expenses. He might offer to serve as a consultant for hospitals, helping to tailor the intervention to local contexts. He could write and sell copyrighted manuals about how to implement the approach.

Similarly, one can also imagine that hospitals have some strategies of appropriation—direct cost savings or reputational gains, for example—that might sustain investment into quality-improving techniques. But the cost to the hospitals of such infections is a small part of their total cost. Indeed, because hospitals tend to charge on a fee-for-service model, they may have

138. 307 F.3d 1351 (Fed. Cir. 2002).

139. John P. Walsh, Wesley M. Cohen & Charlene Cho, *Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research*, 36 RES. POL'Y 1184, 1200 (2007) (reporting a 2004 survey finding that patents did not deter university researchers); *see also* John P. Walsh, Ashish Arora & Wesley M. Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 324-27 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) [hereinafter Walsh et al., *Effects*] (reporting that university researchers "routinely ignor[e] IP rights" and that infringement is "pervasive"); Cristina Weschler, Note, *The Informal Experimental Use Exception: University Research After* Madey v. Duke University, 79 N.Y.U. L. REV. 1536, 1552-63 (2004) (describing the norms that allow university researchers to infringe patents). Part of the reason that university scientists may ignore patent issues may be the apparent norm against filing suit against university researchers. *See* Walsh et al., *Effects*, *supra*, at 325-28.

perverse incentives. Healthcare professionals who are compensated for providing particular services are likely, all other things being equal, to provide too many of those services—too many tests and interventions, for example.[140] If healthcare providers were paid according to the number of infections averted, rather than the drugs they provided, they would have more rational incentives to avert infections. However, although the fee-for-service model likely exacerbates the difficulty, the problem of misaligned innovation incentives is not reducible to it. Assume that hospitals invariably earn much more from averting infections than from treating them. A hospital that wishes to develop an information good to help reduce infections still faces the conventional information good problem, and is situated similarly to the insurance companies discussed in the context of negative information on drugs. A hospital that invested significant sums in a highly nonexcludable solution might well be unable to recoup its costs if others could freely copy its invention. And it would have greater incentives to produce more excludable interventions to reduce infections (e.g., technological ones) than to produce less excludable interventions (e.g., checklists), because producing the former would provide them with more effective exclusion rights and thus greater returns on their initial investments.

Although our three public health examples vary along numerous dimensions—including the types of innovative activity that may lead to their generation and the reasons for their high nonexcludability—they all have in common three crucial characteristics: (1) they are "innovations" in the specific sense of being costly-to-generate information goods; (2) they potentially offer very large social benefits net of their costs of generation in the form of improved health outcomes and reduced health-related expenditures; and (3) they will remain highly nonexcludable even with the availability of patent entitlements, resulting in a comparatively low signaling ratio. As a result, a system that relies on private appropriation as an incentive will not prioritize their development, and, as we now explain, will actively work against them in certain respects.

140. *See, e.g.*, Mireille Kingma, *Can Financial Incentive Influence Medical Practice?*, 3 WORLD HEALTH ORG. HUM. RESOURCES DEV. J., no. 2, 2005, at 8, http://www.who.int/hrh/en/HRDJ_3_2_05.pdf (reviewing the literature and finding a "consensus" that "doctors in such [fee-for-service] systems tend to generate more work (e.g. consultations, prescription items, surgical interventions) than those in other payment structures"); Merrill Goozner, *Incentives Spike Fee-for-Service Health Costs*, FISCAL TIMES (Aug. 17, 2012), http://www.thefiscaltimes.com/Articles/2012/08/17/Incentives-Spike-Fee-for-Service-Health-Costs.aspx.

III. EXPLANATORY AND POLICY SIGNIFICANCE

What implications can we draw for innovation theory and policy from the continuum of excludability and from the existence of highly nonexcludable information goods of the sort just canvassed? Perhaps the most fundamental conclusion is that a patent system will predictably and systematically distort private investment decisions regarding innovation, overstating the value of highly excludable information goods and understating the value of highly nonexcludable ones. As a result of these distortionary effects, patents will fail to provide sufficient private returns to enable investment in certain information goods that clearly offer a net social benefit. Indeed, the valuable innovations neglected by patents will in some cases be comparatively *more* valuable than the ones patents do incent. Finally, increases in patent protection will tend to exacerbate these distortions by channeling ever more resources toward comparatively less valuable (but more excludable) innovations and away from an increasingly larger domain of highly valuable, less excludable ones.

Below we elaborate on these effects and draw out their implications for the conventional theory of patents, for patent and innovation policy, and for debates about information policy.

A. The Potential Distortions of Patents

An optimally efficient system of innovation incentives would provide signals to private parties regarding the expected returns from innovative activity that directly tracked the underlying social value of the activity. Patents, however, link the expected private returns not to social value simpliciter, but rather to the portion of social value that can be effectively (or cheaply) extracted through the exercise of exclusionary rights. But there is no reason to think that variations in the ease or costs of exclusion are correlated with the underlying social value of different information goods. Reasoning in ideal terms, patents will drive innovative effort and investments away from an optimally efficient allocation providing the greatest net social value and instead toward information goods that may provide lower net social value but higher private value owing to lower costs or barriers to effective excludability

There are two distinct kinds of ideal-type distortion at issue here. The first type reflects the fact that there are some highly nonexcludable goods whose development a patent system will fail to incentivize because the private returns appropriable using patents remain lower than the private costs of creation or

validation of the good.[141] To be sure, it is to some extent a familiar point that patents will only incentivize a subset of the universe of net-beneficial innovations. As others have observed, transaction costs and other barriers to perfect price discrimination and tailored licensing mean that a patent system will fail to produce some net-beneficial innovations because some of the social surplus from innovations will go uncaptured by the private innovator (with the innovator's share further reduced by the limited duration of patent protection, etc.).[142] This claim is an extension of the point recognized above—that patents do not yield perfect appropriability because of limits on their scope, duration, and so forth. And indeed an "optimizing" response has developed in the literature; that theory urges the creation of ever more expansive, fine-tuned property rights, so as to capture all net-beneficial innovations in pursuit of a global optimum.[143] Our point, however, is different in two respects.

A first difference lies in the divergent prescriptions that these two arguments recommend. For highly nonexcludable goods, the standard "optimizing" response to the transaction cost problem—namely, to increase the strength of patent protection or the ability of patentees to extract a greater share of the surplus from transactions—will be ineffectual in remedying the underlying skew between social value and private appropriability. In fact, this intervention will have the opposite effect: strengthening patent rights will further distort the signal that exclusion rights transmit to make relatively excludable goods still more appealing targets of investment in comparison to relatively less excludable goods (as discussed below). Importantly, the features that make patents ineffectual at inducing the creation of highly nonexcludable goods do not apply to other institutional approaches to innovation. That is, if the government funds the creation of an information good such as a checklist (as it in fact did in our example), the innovation can be distributed without exclusion and thus without the need to confront the normative, technological, and institutional barriers to the enforcement of exclusion rights.

A second, somewhat subtler, difference between the transaction-cost problem and our argument lies in the force of our claim not only for

141. This will be the case for goods that are very valuable in comparison with their cost, but where the fraction of social value that an innovator can recover (α) is very low. It will also be the case where the fraction is higher, but the goods are only somewhat more valuable than their cost. In other words, if $\alpha = 0.01$, a good that costs less than $1 million will not be created even if it generates social returns of $100 million. If $\alpha = 0.5$, a good that generates $10 million of value will be created if it costs $1 million, but not if it costs more than $5 million.

142. *See, e.g.*, Frischmann & Lemley, *supra* note 41; Griliches, *supra* note 41; Mansfield et al., *supra* note 41.

143. *See* sources cited *supra* note 45.

optimizing but also non-optimizing views. For non-optimizers, the fact that patents will fail to incentivize all net-beneficial innovations is less concerning so long as we can assume that the innovations we obtain from a patent system will tend, as a whole, to be more beneficial than the ones we forego. And that standard assumption is appropriate if patents operate symmetrically on all kinds of information goods (that is, if symmetric transaction costs are the main problem with recouping value); if that is so, then at any given level of patent protection, the innovations that are incentivized will be those with a higher ratio of (privately appropriable) social value to private costs.[144] But where the constraints on private appropriation are not symmetrical across categories or types of innovation—as is the case for highly nonexcludable information goods—then some innovations that go under-incented may hold out greater ratios of social value to cost. It is easy to imagine, for instance, that there may be unincentivized lifestyle interventions that are not only net beneficial, but more beneficial than an incentivized statin drug (because the intervention is cheaper or generates more social value, or both). For such cases, alternative or supplemental innovation approaches will not just increase the overall amount of valuable innovations that we are able to obtain as long as we are willing to devote more social resources to this sector; they also hold out the promise of improving the efficiency of expenditures even if we keep them at the existing level. Shifting some resources from the patent system to alternatives will provide a greater welfare "bang for our buck."

If we wish to realize the social benefit from these highly nonexcludable innovations that remain unprofitable even under a patent system, then we must pursue alternative innovation policies, such as prizes, public funding, or commons-based approaches. Critically, the problem of nonexcludability points to a domain of innovation that patents, whatever their scope, cannot adequately address. And this holds even if our focus is not on more upstream or basic research, but rather solely on downstream or directly implementable interventions. Even for the latter, we cannot conclude that the most efficient system of innovation could rely solely on exclusion rights. This necessity of supplementing patents with some alternative policies has a pointed implication for innovation policy analysis that bears emphasizing. Any policy, such as prizes or public funding, that would generate more valuable, highly nonexcludable innovations than patents would not merely supplement the patent system, but would, at least in this respect, *outperform* it. This particular superiority should then be added to our understanding of the virtues of nonexclusionary approaches to innovation. Of course, nonexclusionary

144. *See* Alan V. Deardorff, *Should Patent Protection Be Extended to All Developing Countries?*, 13 WORLD ECON. 497, 504-05 (1990).

approaches have many possible disadvantages, too. Nothing we say here, for example, contradicts the concern that governments may make wasteful investments or may be susceptible to inappropriate influences. When deciding on the proper mix of institutional approaches, these possible costs must be weighed against the possible benefits—benefits that now must be understood to include the ability to generate investment in highly nonexcludable goods.

Precisely this sort of comparative-institutional approach was what Demsetz advocated in his original articulation of the allocative case for patents, when he cautioned against the "nirvana fallacy" of evaluating the actual operation of one system against an ideal version of another.[145] Yet, the continuum of excludability reveals that the allocative case for patents is itself premised on a flawed idealization: that of a one-to-one relationship between property/exclusion rights and private appropriability of market value. Correcting for this flaw boosts the comparative case for alternatives to patents—or, more precisely, the case for a broad ecology of innovation policies that includes a significant, expanded role for other institutional approaches.

A second type of potential distortion is presented by the fact that patents may not only fail to incentivize some net-beneficial goods, but also affirmatively jeopardize the creation of such goods by diverting resources away from them.[146] Consider again a lifestyle intervention that is more net beneficial, but less excludable, than a statin drug. At some low level of patent protection, it may be the case that the lifestyle intervention holds out greater private returns than the less valuable drug, and the returns are sufficient to recoup the capitalized costs of developing and validating the intervention. However, as patent protection increases, the private appropriability from the drug may increase to a point that it becomes the more profitable project. And, assuming increasing costs of capital (i.e., an upward-sloping supply curve for investment dollars), it may crowd out the lifestyle intervention entirely.[147]

The point generalizes: each time we increase the level of patent protection

145. *See* Demsetz, *supra* note 13, at 3.

146. For related arguments, see Fisher, *supra* note 10, at 169; Lunney, *supra* note 20, 492-98; and Plant, *supra* note 20, at 38-43.

147. It bears emphasizing a difference between our argument for patents' distortionary, crowding-out effect and those of the predecessor scholars cited in note 146, *supra*. Our assumption of increasing capital costs is weaker than the premises upon which prior treatments have been based, such as patents providing "monopoly" returns, *see* Plant, *supra* note 20, at 51, or innovators having only imperfect access to capital markets, *see* Lunney, *supra* note 20, at 486. For further discussion of the significance of these differences for analysis of the interaction between intellectual property rights and market structure, see Oren Bracha & Talha Syed, Beyond the Incentive-Access Paradigm? Product Differentiation and Copyright Revisited (Feb. 25, 2013) (unpublished manuscript) (on file with author).

provided, we may correspondingly increase the risk that some additional, highly valuable innovations will be squeezed out. Valuable but nonexcludable innovations may become increasingly less comparatively profitable and thus sidelined for the sake of more profitable but less valuable projects involving more excludable outputs. We cannot be certain, then, that the creation of even a modest level of patent protection improves the allocation of resources for innovation—although it perhaps remains plausible. We can be rather less assured that enhanced levels of patent protection, contra the optimizing tradition, promise an ever greater approximation of allocative efficiency in the channeling of innovation resources (whatever its other drawbacks).

Taking stock, we see that patents will undersupply some very valuable innovations: those that are highly nonexcludable. Further, the innovations that patents neglect will sometimes be more valuable than the ones they incentivize. Finally, increasing patent protection can exacerbate these distortions, diverting greater amounts of resources toward comparatively less valuable (but more excludable) innovations at the expense of more valuable ones.

This problem of marginalizing nonexcludable innovations becomes still more acute once we recognize that this bias can become entrenched. Two mechanisms of entrenchment are possible. First, we can expect those who specialize in the use of exclusive rights to recoup their investment to exhibit competitive hostility to inventions that solve the same problem through nonexcludable means.[148] One form such conduct may take is familiar from the literature on rent seeking and capture:[149] those whose business models rely

148. One recent illustration of such competitive hostility comes from a case paralleling in some respects our diuretic example: it has long been understood that a low-dose regimen of (off-patent, cheap) aspirin is as or more effective than many more expensive patented treatments in reducing secondary incidence of heart attacks and strokes. Over the past decade, however, concerns have arisen that a significant segment of the population, estimated to be anywhere from five to forty percent, is resistant to such treatment. Yet a recent study by university-based researchers (partly publicly funded) concluded that when uncoated aspirin is used, not one incidence of "aspirin resistance" could be found among a sample size of four hundred patients. Tilo Grosser et al., *Drug Resistance and Pseudoresistance: An Unintended Consequence of Enteric Coating Aspirin*, 127 CIRCULATION 377 (2013). The rise of "aspirin resistance," despite its apparent dearth of evidential support, has been attributed by some, including "prominent doctors," to "the prevalence of the condition [being] exaggerated by companies and drug makers with a commercial interest in proving that aspirin – a relatively inexpensive, over-the-counter drug whose heart benefits have been known since the 1950s – does not always work." Katie Thomas, *Study Raises Questions on Coating of Aspirin*, N.Y. TIMES, Dec. 4, 2012, http://www.nytimes.com/2012/12/05/business/coating-on-buffered-aspirin-may-hide-its-heart-protective-effects.html.

149. *See, e.g.*, JAMES M. BUCHANAN & GORDON TULLOCK, THE CALCULUS OF CONSENT: LOGICAL FOUNDATIONS OF CONSTITUTIONAL DEMOCRACY (1962); Richard A. Posner, *The Social Costs of Monopoly and Regulation*, 83 J. POL. ECON. 807 (1975); George J. Stigler, *The Theory of*

heavily on exclusionary rights that generate rents will predictably spend resources devoted to obtaining favorable laws that maintain or expand these exclusionary rights. Additionally, investors in more excludable innovations can be expected to be directly hostile to alternative approaches, such as proposals to invest government funding in highly nonexcludable solutions. The greater the asymmetry in profitability from excludable goods as opposed to nonexcludable goods, the more an innovation system that includes property rights as a major component can be expected to tilt toward excludable solutions over time.

Second, if institutions and individuals exist in social and cultural contexts that shape their ideas about where solutions are likely to be located, as we think they do, then as nonexcludable approaches repeatedly lose out to excludable ones, the process can be expected to shape deeper understandings and orientations of actors in the field. The ideas of researchers, doctors, patients, advisory boards, policymakers, etc., regarding what sorts of problems are most salient or worth pursuing and what kinds of solutions or interventions are paradigmatically "viable" or available may all be subtly shaped over time. Moreover, not only may each choice of pro-excludability approaches provide a piecemeal nudge that further acculturates actors in that direction, but a successive series of such choices may "snowball" so as to accelerate the entrenchment of certain frames of reference, forging deep, path-dependent grooves.

This last point provides a partial response to skeptics who might argue that some of the examples we have chosen—for example, of the apparent overinvestment in medicines and concomitant underinvestment in lifestyle interventions—are more likely to reflect genuine preferences of individuals than to offer examples of systemic distortion. Our argument does not turn on the success of the particular examples we have chosen, but this skepticism usefully permits us to illustrate the problem of path dependence. It may be that individuals appear to "prefer," under existing conditions, to take a pill rather than adopt a new exercise regime, but this may be because they have preexisting ideas about the likely benefits and experience of pharmaceuticals over exercise that are shaped by an environment that over-promotes the former and under-innovates in the latter.

The dynamics of such a process would help to explain what many in the fields of medicine and public health have bemoaned for years: an excessive focus on technological fixes to our nation's healthcare challenges, often labeled

Economic Regulation, 2 BELL J. ECON. & MGMT. SCI. 3 (1971); Gordon Tullock, *Rent Seeking*, *in* 7 THE NEW PALGRAVE DICTIONARY OF ECONOMICS 95 (Steven N. Durlauf & Lawrence E. Blume eds., 2d ed. 2008). For applications of public choice analysis to legislative activity concerning intellectual property rights, see Jessica D. Litman, *Copyright, Compromise, and Legislative History*, 72 CORNELL L. REV. 857 (1987).

an "overmedicalization" of society.[150] By analyzing how the continuum of excludability interacts with an institutional ecology that heavily emphasizes the role of patents in biomedical research and development, we provide analytic grounding for a central theme in this literature: the increasing emphasis on, or even preoccupation with, technologically embodied, commodifiable approaches to health and well-being and the devaluing of lifestyle or structural interventions, as well as of the etiological role of social factors. We have already touched upon two of the most commonly identified aspects of this process: an increased reliance on the development and use of new drugs, even in the face of inconclusive or negative data on their comparative safety or efficacy, and a corresponding tendency to sideline nontechnological interventions, such as those targeting lifestyle factors like diet and exercise.

Our analysis also helps account for an additional, related theme, one central to the fields of public health and epidemiology over the last two to three decades. This is concern over the predominance of a "biomedical model" that foregrounds the role in illness and health of physiological and other individual-level factors, and does so at the expense of infrastructural and institutional factors focused on by a "social epidemiology" lens.[151] These factors, commonly grouped under the label "social determinants" of health, include socioeconomic status, gender roles and relations, racial stratification, workplace organization and hierarchies, public infrastructure and architectural design of living spaces, and, on some accounts, the effectiveness and reach of health delivery networks.[152] Examples of particularly striking interventions and research in this vein include the wide-reaching public sanitation programs and hygiene campaigns implemented in the United States in the early part of the twentieth century, to which the lion's share of the country's radically reduced mortality rate from infectious disease today can be attributed.[153] Another is the over-two-decades-long "Whitehall" studies in the U.K., finding a strong correlation between occupational "grade" and risk factors for coronary heart

150. *See* PETER CONRAD, THE MEDICALIZATION OF SOCIETY: ON THE TRANSFORMATION OF HUMAN CONDITIONS INTO TREATABLE DISORDERS (2007); VICENTE NAVARRO, CRISIS, HEALTH, AND MEDICINE: A SOCIAL CRITIQUE (1986); THOMAS SZASZ, THE MEDICALIZATION OF EVERYDAY LIFE: SELECTED ESSAYS (2007).

151. *See* Lisa F. Berkman & Ichiro Kawachi, *A Historical Framework for Social Epidemiology*, *in* SOCIAL EPIDEMIOLOGY 3 (Lisa F. Berkman & Ichiro Kawachi eds., 2000); Michael Marmot, *Multilevel Approaches to Understanding Social Determinants*, *in* SOCIAL EPIDEMIOLOGY, *supra*, at 349.

152. *See* THE SOCIAL DETERMINANTS OF HEALTH (Michael Marmot & Richard G. Wilkinson eds., 2d ed. 2006).

153. *See* David Cutler & Grant Miller, *The Role of Public Health Improvements in Health Advances: The Twentieth-Century United States*, 42 DEMOGRAPHY 1 (2005).

disease among British Civil Servants.[154] Research and interventions into social determinants will, as with lifestyle factors, tend to result in highly nonexcludable outputs and hence predictably be undersupplied by market forces.[155] Our analysis thus offers a possible explanation for the widely shared sense that our current healthcare system is overmedicalized. It also suggests that, as with behavioral and structural approaches to lifestyle factors, more research and, especially, more work on developing strategies for operationalizing the insights from such research into effective interventions, may be called for.[156]

Finally, while we have used the field of health innovation to illustrate the implications of the continuum of excludability, the points we develop here are generalizable. Consider the problem of climate change. Strategies to address it range from technologies such as biofuels, to attempts to change attitudes toward consumption or reorganize cities to emphasize walking, biking, and public transport. Exclusion rights will reward the former set of more excludable innovations more than the latter set of behavioral and structural interventions. Another possible measure is carbon sequestration, a strategy that includes measures as diverse as reforestation,[157] subterranean injection of carbon dioxide,[158] and chemical scrubbing.[159] Some of these approaches are

154. The studies found a three-fold greater risk of mortality from coronary heart disease for the lowest as compared to highest grade, of which only forty percent was traceable to standard identifiable factors (such as smoking, obesity, baseline illness, leisure time/physical activity, or height differentials). The remaining sixty percent was attributed to job-related stress and anxieties, stemming from differences in job security and control over, satisfaction from, and support in, one's daily work. *See* M.G. Marmot et al., *Health Inequalities Among British Civil Servants: The Whitehall II Study*, 337 LANCET 1387 (1991); M.G. Marmot, M.J. Shipley & Geoffrey Rose, *Inequalities in Death—Specific Explanations of a General Pattern?*, 323 LANCET 1003 (1984); Caroline T.M. van Rossum et al., *Employment Grade Differences in Cause Specific Mortality: A 25 Year Follow Up of Civil Servants from the First Whitehall Study*, 54 J. EPIDEMIOLOGY & COMMUNITY HEALTH 178 (2000).

155. Not all interventions aimed at social determinants will involve information goods—some are more classically "infrastructural" goods. Nevertheless, research into the role of the determinants targeted by such interventions will generate information goods, as will studies of the potential efficacy even of noninformational interventions.

156. Precisely this assessment was offered by the World Health Organization's Commission on Social Determinants in its 2008 Final Report: "The evidence base on health inequity, the social determinants of health, and what works to improve them needs further strengthening." Comm'n on Soc. Determinations of Health, *Closing the Gap in a Generation: Health Equity Through Action on the Social Determinants of Health*, WORLD HEALTH ORG. 20 (2008), http://whqlibdoc.who.int/publications/2008/9789241563703_eng.pdf.

157. *Carbon Sequestration Through Reforestation: A Local Solution with Global Implications*, EPA (Mar. 2012), http://www.epa.gov/aml/revital/cseqfact.pdf.

158. *Geologic Sequestration of Carbon Dioxide*, EPA, http://water.epa.gov/type/groundwater/uic/wells_sequestration.cfm (last updated July 30, 2012).

likely more excludable than others.[160] The problem of nonexcludability may, however, be muted in the environmental context by an institutional factor: because climate change is responsive to endemic externalities, structural solutions may be especially likely to be mediated by government action, rendering enforcement of exclusion rights even on immaterial solutions easier. For example, a patent on a reforestation strategy might be quite excludable if governments rather than individuals were the primary users of the knowledge.

Is there a continuum of excludability in more mundane contexts—for example, those related to conventional consumer goods? Theoretically, the answer is yes: some means of meeting consumer needs and wants are likely to be more excludable than others, and those will be better rewarded by a patent system. Imagine that we want to reduce household drudgery. An innovator might address the problem of ineffective dishwashers by designing a more technologically sophisticated dishwasher (stronger jets, different settings), or by testing and validating nontechnological solutions (using less soap, adding vinegar). The continuum of excludability is, then, in principle universal. Nevertheless, the implications of asymmetrical excludability may be more difficult to see or less consequential in certain domains, such as where the cost of research on the whole is relatively low. Famously, patents are thought to be relatively unimportant outside of the resource-intensive, easy-to-copy context of pharmaceuticals and the chemical arts.[161] If the cost of research into the nonexcludable solutions is low enough, for example, then the problem of nonexcludability will have less significance.

B. Specific Policy Prescriptions

A first, foundational policy implication of our analysis has already been

159. *Scrubbing the Skies*, ECONOMIST, Mar. 5, 2009, http://www.economist.com/node/13174375.

160. Technology-focused solutions like chemical scrubbing, which relies on patented inventions to absorb carbon dioxide from the air, would be particularly amenable to exclusion. Assume that a carbon tax created a private market for the reduction of carbon intensity. Inventors could profit by selling the scrubbers both the government and the private sector. *See, e.g.*, *Pulling Profits Out of Carbon Capture: An Interview*, BUS. PUNDIT, May 20, 2010, http://www.businesspundit.com/pulling-profits-out-of-carbon-capture-an-interview (describing patented technology that would absorb carbon dioxide to produce marketable chemicals). By comparison, grassland management techniques for sequestering carbon dioxide—such as the use of cover crops, reduced tillage, and even the introduction of earthworms—would be difficult to exclude others from copying and not readily amenable to sale. *See* Richard T. Conant, Keith Paustian & Edward T. Elliott, *Grassland Management and Conversion into Grassland: Effects on Soil Carbon*, 11 ECOLOGICAL APPLICATIONS 343 (2001) (reviewing the literature on these techniques).

161. *See* Cohen et al., *supra* note 61, at 1; Levin et al., *supra* note 61, at 796.

underlined: we provide a new justification for a significant role in our innovation system for institutional approaches, such as direct public funding, prize schemes, and commons-based approaches that do not rely on exclusionary mechanisms to enable the generation of expensive information goods. That role is justified on two related grounds: these approaches fill in a gap left by patents' failure to incent valuable but highly nonexcludable innovations, and they counter the tendency of patents to exacerbate the problem by drawing resources away from such innovations.

Our analysis, then, bolsters the already strong case for public funding of basic research. Traditionally, that case has been based on some combination of the following factors: basic research is too "upstream" to be funded by the private sector, meaning that its practical dividends are too uncertain and far off in time to be adequately supported by market incentives;[162] basic research's strongly "cumulative" aspects favor a financing model that keeps it free from proprietary encumbrances;[163] and finally, the motivations and ethos of "open science" have proved durable institutional supports for such research, and these are better sustained in public sector settings such as universities than for-profit firms.[164] To these we add a further consideration: a large share of the most valuable uses of basic research will take highly abstract, intangible forms, rendering the output of such research highly nonexcludable and hence particularly ill suited to be generated by markets and patents.

Nonexcludability does not, however, simply add to the traditional case for public funding of basic research; it also transforms that case by expanding it beyond its traditional ambit. The scope of public funding should not be restricted to basic research, but rather should extend into other domains that also involve valuable but highly nonexcludable information goods. The government already carries out or sponsors some research that is far from the "basic" variety supported by the literature. The head-to-head drug trials mentioned earlier are a good example.[165] The checklist research is another.

162. *See* Nelson, *supra* note 19, at 304.

163. *See* LANDES & POSNER, *supra* note 39, at 306-08; STEVEN SHAVELL, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW 148-49 (2004). For the pioneering treatment of patent barriers in cumulative innovation contexts, see Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990).

164. *See* Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987); John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101 (2001); Robert P. Merges, *Property Rights Theory and the Commons: The Case of Scientific Research*, 13 SOC. PHIL. & POL'Y 145, 145-46, 157 (1996); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77 (1999).

165. ALLHAT 2002, *supra* note 77, at 2994.

Why, given the proximity of this research to practical applications, is it being undertaken by a public agency? The continuum of nonexcludability supplies an answer. Public agencies ought forthrightly to recognize nonexcludability as an additional reason for their mandate to support innovation, one that extends that mandate to projects more "downstream" than basic or even applied research. And in fulfilling this mandate, agencies should more systematically and saliently identify the criteria relevant to evaluating potential projects falling under this purview.

This mandate might be operationalized in a variety of ways. Government agencies might offer dedicated funding for categories of highly nonexcludable research, as was recently done for comparative effectiveness research.[166] Or peer review systems might be adjusted to promote nonexcludable research. For example, peer reviewers evaluating applications for National Institutes of Health (NIH) grants might be asked to score research proposals according to their propensity to produce highly nonexcludable outputs.[167] To do this well, agencies would first have to systematically elaborate different categories of highly nonexcludable research, building upon the initial list enumerated here (i.e., negative information and comparative-effectiveness information for drugs, basic epidemiological information, information about behavioral and structural interventions in lifestyle, and innovations in health care quality).

Notably, government agencies may be affected by their own dynamics of cultural entrenchment and path dependence, dynamics that would pose barriers to the reorientation we suggest here. A recent comment in *Nature* argues, in this vein, that there is an institutional bias within the NIH in favor

166. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6301, 124 Stat. 119, 727-47 (2010) (establishing the Patent-Centered Outcomes Research Institute to conduct comparative clinical effectiveness research); *see also Comparative Effectiveness Research*, HEALTH AFF., http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=27 (rev. Oct. 8, 2010) (describing the provisions of the Affordable Care Act aimed at improving comparative effectiveness research).

167. Peer review at the National Institutes of Health (NIH) involves five scored review criteria (significance, investigator, innovation, approach, and environment), which contribute loosely to an overall impact score. *Peer Review Process*, NAT'L INSTS. OF HEALTH, http://grants.nih.gov/grants/peer_review_process.htm (last visited Nov. 10, 2012). To implement our recommendation, the NIH could adopt a sixth review criterion to reflect the proposal's potential to produce nonexcludable innovations. Such an approach has some precedent: in 1997, the NIH included "innovation" as a review criterion, over the objections of some researchers, to further the goal of producing unconventional ideas. *See* Robert Finn, *Researchers Get Ready for NIH Reforms*, SCIENTIST, Aug. 18, 1997, http://www.the-scientist.com/?articles.view/articleNo/18552/title/Researchers-Get-Ready-For-NIH-Reforms. A perhaps more conservative alternative would be to modify the language of one of the existing review criteria to reflect the importance of encouraging nonexcludable, public health-oriented discoveries.

of biomedical approaches to health and against behavioral, sociological, and environmental approaches.[168] The author notes, for example, that

> [b]etween 80% and 90% of lung cancers have been linked to smoking tobacco. Yet of the $2.45 billion that the NIH has spent on trying to find a cure during the past decade, most has been directed towards the discovery of molecular and genetic causes and treatments rather than on establishing how to modify people's behaviour.[169]

To translate this into the terms of our Essay, this critique suggests that the NIH focuses on one kind of nonexcludable research (basic science that may lead to therapeutics) to the exclusion of others (behavioral interventions, basic epidemiology, or the understanding of social and environmental factors that generate disease). This argument reminds us that the public, as well as private, sector may be subject to dynamics of cultural entrenchment and path dependence. Moreover, we might expect that a private sector oriented toward highly excludable interventions would pressure the government to allocate its funding toward precursors to those excludable interventions—for example, toward biomarkers or the basic biology of disease, rather than toward nonexcludable solutions such as environmental or behavioral changes that would compete with therapeutic interventions.[170]

Progress on this front is already being made. The Affordable Care Act included several measures that respond to these criticisms, including allocation not only toward cost-effectiveness research, but also toward broad research into prevention for health.[171] These provisions reflect the fact that government funding can target a wide range of nonexcludable goods, even if existing

168. Michael M. Crow, *Time To Rethink the NIH*, 471 NATURE 569, 571 (2011) (advocating a "transdisciplinary" approach to research that reflects the "convergence" culture in today's life sciences).

169. *Id*. at 570-71.

170. The Bayh-Dole Act, which sought to induce more commercialization of public sector research by permitting federal grantees to obtain patents more easily, may have brought the problems of nonexcludability more directly into the public sector. Pub. L. No. 96-517, 94 Stat. 3019 (1980) (codified as amended at 35 U.S.C. §§ 200-211 (2006)).

171. Patient Protection and Affordable Care Act § 4001 (creating the National Prevention, Health Promotion, and Public Health Council to "develop a national prevention, health promotion, public health, and integrative health care strategy"); *id.* § 4002 (creating and providing funding for the Prevention and Public Health Fund). *But see* Betsy McKay, *What Obama's Budget Proposal Means for Disease Prevention*, WALL ST. J. HEALTH BLOG (Feb. 14, 2012, 4:45 PM), http://blogs.wsj.com/health/2012/02/14/what-obamas-budget-proposal-means-for-disease-prevention (describing how President Obama's 2013 budget would reduce funding for the Prevention and Public Health Fund and how existing funds are being used to compensate for cuts elsewhere).

allocations are shaped by social, political, and historical factors, as well as by scientific judgment. The existing allocation of government research shows at the same time that government can and does fund a variety of nonexcludable research, and that the concept of nonexcludability, if developed and articulated in relation to existing funding programs, could yield important changes in the allocation of the more than thirty billion dollars that the federal government spends on health research each year.

Another avenue by which government might foster the supply of valuable nonexcludable information is the use of prizes. Indeed, prize mechanisms are the alternative innovation policy that has received the most attention in recent years, not only from legal and economic scholars,[172] but also in broader public policy debates.[173] Perhaps the key attraction of prize systems is their potential to finance innovation without the distortions of patent pricing (something they share with public funding), while simultaneously harnessing (like patents), the decentralized information of market actors regarding the most promising lines of attack for whatever innovation targets are specified. It is in the specification of the targets, however, where the greatest promise and peril of prizes may lie. On the one hand, by severing the direct link between innovator returns and market sales that exists under patents, prize systems raise concerns regarding the incentives and information of those setting the criteria and amounts for prizes. That is, will prize administrators have either the competence or, when exposed to lobbying and fiscal pressures, the willingness to set rewards accurately to reflect the social value of innovations? On the other hand, advocates of prizes point to ways in which such systems may actually improve upon patent signals of social value. These include, principally, augmenting returns to factor in the positive externalities (or spillover effects) of innovations on follow-on research,[174] and amplifying the value of those innovations that predominantly serve poorer markets (and thus where demand signals would significantly understate social value).[175]

Against this background, nonexcludability considerations shed interesting new light on the comparative virtues of prizes vis-à-vis the alternatives. At first blush, prizes would seem akin to government funding in their ability to

172. *See* sources cited *supra* note 38.

173. *See, e.g.*, Medical Innovation Prize Act, S. 1137, 112th Cong. (2012); Prize Fund for HIV/AIDS Act, S. 1138, 112th Cong. (2012); *The High Cost of High Prices for HIV/AIDS Drugs and the Prize Fund Alternative: Hearing on S. 1138 Before the S. Subcomm. on Primary Health and Aging of the Comm. on Health, Educ., Labor, & Pensions*, 112th Cong. (2012).

174. Kremer, *supra* note 38, at 1141-44; Shavell & van Ypersele, *supra* note 31, at 543-45.

175. *See, e.g.*, Fisher & Syed, *supra* note 38, at 181-86; Hollis & Pogge, *supra* note 38, at 18; Love & Hubbard, *supra* note 38, at 1532-34.

improve upon patents in this respect: just as we might operationalize a concern for nonexcludable innovations by supplementing in various ways the traditional criteria for allocating government grants, so too we might explicitly take into account nonexcludability factors when determining the criteria for prizes. There remains, however, a significant difference between the two strategies. Although the criteria for prizes may be configured to incentivize a broader set of innovations than under patent, some of the most promising recent models of prizes will be constrained by an important limitation. In order to help measure the size of the prize, many recent prize mechanisms operate by using the sales of some discrete good as their substrate measure of social value (which then may be adjusted upward or downward).[176] Being tethered to a commodified measure of output serves to retain a comparative advantage of prizes (shared with patents) vis-à-vis public funding, namely proximity of the metric of social value to quantifiable market measures. But to the extent that prizes retain this proximity, nonexcludability analysis presents an Achilles heel for prizes that is similar to the one it presents for patents. Many nonexcludable innovations—such as behavioral or structural interventions inducing changes in eating habits or exercise or other lifestyle behavior—will not be linked to any commodifiable good or otherwise easily traceable uses. Consequently, to incentivize such innovations, prize systems will need to implement valuation mechanisms that travel some distance away from a tight link to patent-like tracking schemes, and closer to the sorts of decisions involved in public funding.

But configuring prize mechanisms in this way will be no simple task. Public funding schemes require directly making rough assessments of the likely social value of various projects and then, accordingly, allocating grants up-front. The rewards held out by prize systems, however, are typically determined ex post, by tracking in some way a proxy or actual measure of the impact of the eligible innovation over some specified period of time and space. To be sure, the most ambitious prize proposals in this respect contemplate the use of quite intricate methods for assessing impact, which may ultimately sever their measure of social value from any reliance on indirect proxies such as sales data, and look instead directly at observed outcomes in terms of specific indicators, e.g., reduced disease incidence or improved health in a target population after the introduction of an innovation.[177] And such methods, if reliably established, would indeed be suitable for evaluating highly nonexcludable interventions.

176. *See, e.g.*, Love & Hubbard, *supra* note 38, at 1528-29; Shavell & van Ypersele, *supra* note 31, at 526; *see also* Kremer, *supra* note 38, at 1138-40 (proposing an auction system that requires that the inventions up for bid have a market value).

177. *See, e.g.*, Fisher & Syed, *supra* note 38, at 181-86; Hollis & Pogge, *supra* note 38, at 29-31.

However, they are not yet at the proof-of-concept stage and the complexity and costs in establishing them may ultimately prove insurmountably high, due in part to the presence of confounding variables (e.g., how much of the reduced heart disease in a target population should be attributed to a structural intervention aimed at increasing exercise at the office versus various other possible contributors?). Should that be the case, then for some subset of highly nonexcludable innovations public funding may be superior not only to patents but also to prizes.

Finally, on top of the financial incentives held out by alternative innovation schemes, another arrow in the governmental quiver is the imposition of regulatory requirements. FDA regulations are one example; they require firms to validate the safety and efficacy of their candidate drugs through clinical trials before receiving marketing approval.[178] These requirements create incentives for firms to generate and disclose valuable information about their drug products that they might otherwise not provide. Indeed, addressing this market failure in information production is a standard economic justification for FDA regulation (and related systems such as tort liability).[179] And so, as with direct funding and prizes, we might imagine broadening the regulatory ambit to take into account nonexcludability considerations. For example, rather than funding or rewarding comparative effectiveness research, government might instead extend FDA requirements beyond ensuring the safety and efficacy of drugs against placebos to also include the need to generate comparator data.[180] Of course, regulatory strategies will also be limited in a variety of ways. For example, while we might reconfigure FDA requirements to generate more reliable comparative or negative information on drugs, there is

178. *See* 21 U.S.C. § 355(b) (2006).

179. *See, e.g.*, HENRY G. GRABOWSKI & JOHN M. VERNON, THE REGULATION OF PHARMACEUTICALS: BALANCING THE BENEFITS AND RISKS 7-8 (1983); Ariel Katz, *Pharmaceutical Lemons: Innovation and Regulation in the Drug Industry*, 14 MICH. TELECOMM. & TECH. L. REV. 1, 7-8, 12-14 (2007); Richard A. Posner, *Strict Liability: A Comment*, 2 J. LEGAL STUD. 205, 211 (1973).

180. Existing FDA rules do, in limited cases, require comparative evidence—for instance, where it is deemed unethical to deny patients access to existing treatments in a trial for a new candidate drug. In such cases, the candidate treatment need not be shown to be superior to a placebo; rather, it need only be shown to be not inferior to the existing treatment—i.e., the purpose of the trials is to rule out a treatment difference of an unacceptable size between the new drug and the active control (the new drug, that is, must preserve a "reasonable fraction" of the beneficial effect of the existing treatment). The trials are not taken to establish the comparative effectiveness of the new treatment against the active control, and moreover, the comparator baseline itself is quite limited, typically comprised of only one existing treatment rather than, as is preferable, multiple treatments within one or more therapeutic classes. *See* Robert Temple, *A Regulator's View of Comparative Effectiveness Research*, 9 CLINICAL TRIALS 56, 56-57 (2012).

no corollary regulatory barrier that could be tweaked to help *produce* nonexcludable information about lifestyle and health or health quality research.[181] Moreover, even with respect to the evidence on risks or safety that falls within the existing regulatory purview, to the extent that such regulation is somewhat leaky—as plausibly suggested by a growing body of critical literature on the FDA[182]—then again the nonexcludability of such evidence threatens its undersupply.

C. Broader Theoretical Implications

The existence of a continuum of nonexcludability, we have argued, has substantial implications for innovation theory and policy as viewed from inside the frame of standard economic analysis. Our argument may also, however, bear some implications for the uses and limits of such economic analysis

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181. Information on environmental toxins lies somewhere in between. On the one hand, much of the relevant information may in principle be generated and disclosed by the firms whose industrial products and processes release such toxins into the environment. And thus significant gains may be made by improving the regulatory requirements aimed at securing adequate information disclosure at the individual-firm level, as is frequently advocated in the environmental law and policy literature. *See* John S. Applegate, *Bridging the Data Gap: Balancing the Supply and Demand for Chemical Information*, 86 TEX. L. REV. 1365, 1385-95 (2008); Wendy E. Wagner, *Commons Ignorance: The Failure of Environmental Law To Produce Needed Information on Health and the Environment*, 53 DUKE L.J. 1619 (2004). However, as we note above, *supra* note 113 and accompanying text, much of the information may not lend itself to firm-specific strategies, pertaining instead to combinations of chemicals from many sources and over long periods of time. In this case, more direct strategies of information generation will likely be needed. *See also* Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws To Produce and Use Data*, 87 MICH. L. REV. 1795, 1812, 1835-41 (1989) (noting that "epidemiological data suffer from many confounding factors, including multiple exposures, undetermined exposures, . . . poor record-keeping [and] latency periods of . . . twenty years or more," and advocating the creation of a publicly mandated "super study" research program on environmental toxins).

182. The critical concerns center on the strong financial incentives of drug companies—which are, by and large, unchecked by any countervailing incentives on the part of others owing to nonexcludability—to favorably shape the research undertaken to establish the safety and efficacy of their products, through, inter alia, faulty design protocols, conflicts of interest in evaluating results, suppression of negative findings, and skewed reporting of positive results. *See generally* JOHN ABRAMSON, OVERDO$ED AMERICA: THE BROKEN PROMISE OF AMERICAN MEDICINE (2004) (examining how major drug companies have commercialized medical knowledge); ANGELL, *supra* note 73 (same); JERRY AVORN, POWERFUL MEDICINES: THE BENEFITS, RISKS, AND COSTS OF PRESCRIPTION DRUGS (2005) (analyzing the role of market factors in the tradeoff between safety and effectiveness in medicine); JEROME P. KASSIRER, ON THE TAKE: HOW AMERICA'S COMPLICITY WITH BIG BUSINESS CAN ENDANGER YOUR HEALTH (2005) (arguing that the financial enticements that drug companies offer physicians degrade the quality of treatment).

itself.[183] Principally, it suggests two things.

First, our argument highlights a previously unnoticed means by which patents—and the pursuit of efficiency through patent law—can generate conflict with values such as privacy and free speech. Using property rights to generate information goods creates incentives to undermine norms that interfere with the ability to profit through exclusion, such as norms of privacy, free expression, and open communication. At the limit, the pursuit of maximal allocative efficiency through a fully rationalized regime of property rights, in which excludability directly tracked social value, would require the eradication of such norms in connection to the protected information. In other words, attempts to achieve efficiency will have implications for our ability to protect values such as privacy, free speech, and so forth. Because nonproperty approaches to information production, such as public funding, will have different implications for these values, debates about the choice of innovation regime (or mix of regimes) should be conducted with values other than efficiency in mind.[184]

Concerns about the possibility that IP rights will create incentives to undermine privacy are recognized, even if implicitly, in two existing literatures. In a line of judicial decisions regarding patentable subject matter, courts have forbidden and expressed discomfort with patents on purely "mental processes" or mere "mental steps," or patents that would prevent others from simply

183. We thank Seana Shiffrin for urging us to develop more fully this aspect of our argument, as well as for very stimulating suggestions in this regard.

184. A possible response would be that values such as privacy and free speech can be reduced to a common denominator of efficiency by accounting for how much people prize such values in dollar terms. But the difficulties with this are considerable. For one, it is very difficult to price or otherwise quantify individual preferences with respect to goods that are not commonly traded in markets. At the very least, a welfarist approach must develop procedures for pricing or otherwise weighing these values. Additionally, as discussed *supra* Section III.A, people's preferences may to some extent be endogenous to the choice of institutional mechanism. This underscores, at a minimum, the need for great care in deciding how much to weigh such values (using whatever procedure is selected), given the potentially far-reaching, path-shaping effects of such decisions. Even this may be inadequate, however, where people also have "preferences about their preferences"—that is, they care about the extent to which they will continue to hold their commitments to certain norms or values. In that event, a welfarist would also need to consult and duly factor in these second-order preferences. *See, e.g.*, JON ELSTER, ULYSSES AND THE SIRENS: STUDIES IN RATIONALITY AND IRRATIONALITY (1984); William W. Fisher III, *Reconstructing the Fair Use Doctrine*, 101 HARV. L. REV. 1659 (1988). Such calculations are at best daunting, and in fact may lead to an infinite regress, as our attempts to discern higher-order preferences reach ever further back, to third-, fourth-, etc.-order views. Ultimately, then, some more direct way of reasoning about such values seems necessary.

"thinking" about certain processes or correlations.[185] The patent applicants in question presumably thought that the challenged claims were excludable enough, despite any social-norm or technical barriers, to make the application privately cost effective. The fact that courts disallow these claims as a whole may be explained by an implicit judgment that the social costs of such enforcement efforts would be too high and that, as a result, such efforts should not be given judicial imprimatur or encouragement.[186] Similarly, a growing number of observers have pointed to the fact that IP rights holders, seeking to make their legal entitlements more practically excludable, have deployed digital rights management (DRM) technologies in ways that clash with the interests of consumers in privacy and online anonymity.[187]

Recognizing the impact of intellectual property rights on privacy, free speech, and related norms also helps us see more acutely some of the possible consequences of the commodification of information. There are familiar lines of critique of commodification, which suggest that it adversely affects the social meaning of certain goods or relations, violates certain rights, or corrodes solidaristic norms.[188] Here, we show something different: norms place limits

185. *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 136-38 (2006) (Breyer, J., dissenting from dismissal of certiorari as improvidently granted) (arguing that a patent claim that covered a correlation between blood test results and vitamin deficiency, in conjunction with the administration of a blood test, should be invalidated, because it covered an unpatented test and the act of simply "think[ing] about" its results); Gottschalk v. Benson, 409 U.S. 63, 67 (1972) (noting that "mental processes" are unpatentable subject matter); *In re* Prater, 415 F.2d 1378, 1386 (C.C.P.A. 1968) (rejecting claims for identifying equations for spectrographic analysis as impermissible patenting of "mental steps"). It is tangential to our focus here whether such statements should be taken to mark out a distinct category of ineligible subject matter ("mental processes") or merely to identify one element often present in another of the recognized categories (such as "fundamental principles" or "abstract ideas").

186. Of course, if we assume that in at least some of these cases a patent would have provided an important incentive to innovate, these decisions remain somewhat incomplete. They only inform us that patents are not an option where they bump against certain deeply held values, but they still leave open the question of what alternative options we should pursue.

187. *See, e.g.*, Julie E. Cohen, *DRM and Privacy*, 18 BERKELEY TECH. L.J. 575 (2003); Ian Kerr & Jane Bailey, *The Implications of Digital Rights Management for Privacy and Freedom of Expression*, 2 INFO. COMM. & ETHICS SOC'Y 87 (2004); Christopher May, *Digital Rights Management and the Breakdown of Social Norms*, 8 FIRST MONDAY 11, 37-39 (2003), http://firstmonday.org/htbin/cgiwrap/bin/ojs/index.php/fm/article/view/1097/1017.

188. *See, e.g.*, ELIZABETH ANDERSON, VALUE IN ETHICS AND ECONOMICS (1993); MARGARET JANE RADIN, CONTESTED COMMODITIES (2011); MICHAEL J. SANDEL, WHAT MONEY CAN'T BUY: THE MORAL LIMITS OF MARKETS (2012); DEBRA SATZ, WHY SOME THINGS SHOULD NOT BE FOR SALE: THE MORAL LIMITS OF MARKETS (2010); Yochai Benkler, *Law, Policy, and Cooperation*, *in* GOVERNMENT AND MARKETS: TOWARD A NEW THEORY OF REGULATION 299

on our *ability* to commodify, and when we seek to commodify in the face of these norms, we may inadvertently weaken the norms in question. This is not because (as the conventional critiques of commodification might suggest) we are sending a corrosive message that markets are a valid way to value the goods at stake, but because, more broadly, we are encouraging people to weaken norms that interfere with their ability to profit from commodification (here, via exclusion). The norms themselves may be that some things should not be commodified, but they may also include norms not directly related to the issue of commodification, such as privacy.

This brings us to a second implication of our account: when we reason about the consequences of innovation policy using economic tools, we should adopt a comparative-institutional approach, one that emphasizes a diversity of policy tools and, as importantly, recognizes that any judgment on the right mix will inevitably take the form of pursuing local improvements rather than a global optimum. An optimizing view tends to focus primarily on one mechanism, property rights, and sees that as a means to directly transmit signals of social value to those making allocative decisions. But as we have argued, property rights may send distorted signals, overemphasizing the value of solutions that lie on the more excludable end of the continuum. To be sure, it has long been recognized that property rights must be fine-tuned in ways that are difficult to square with the optimizing view. (For example, policymakers must establish the extent of exclusionary protection, whether and how property rights apply to different kinds of information, when a given level of protection will be worth its potential costs of barriers to access and rent dissipation, and so forth.) However, once we recognize that no amount of fine-tuning will capture all valuable information goods and, moreover, that each expansion of property rights threatens an inefficient diversion of resources away from some such goods, we can see that even finely tuned property rights cannot lead to a global optimum.

Reasoning about the most efficient mode to produce information should be understood as a process of making rough judgments about which mix of institutional mechanisms are likely to achieve a better overall balance of different hazards and benefits in a given context. By referring to the need for "judgment," we mean to highlight and resist any attempt to avoid judgment by simply deferring to the market, since doing so will simply involve its own, now implicit, judgment. If, as we have shown, property rights in information are themselves potentially distorting, then even if our sole aim is to achieve efficiency, we cannot assign decisions about allocation solely to the market.

(Edward J. Balleisen & David A. Moss eds., 2010); Samuel Bowles, *Is Liberal Society a Parasite on Tradition?*, 39 PHIL. & PUB. AFF. 46 (2011).

The judgments that people make, moreover, should be recognized as inevitably "rough" because of the broad range of contingent and contextual factors that influence the choices that we face. Recall that the effectiveness of property rights and, correspondingly, the need for alternative institutional approaches are a function of the state of technology, norms, and institutions, as well as the factors of materiality and numerosity. These factors themselves will be context specific and evolving. It will therefore sometimes be difficult to say precisely where a given set of information goods will fall along the continuum of excludability, and thus to determine how extensive our reliance on nonproperty approaches should be.[189] Moreover, technologies, norms, and institutions will, as we noted earlier, be affected by the existence (and magnitude) of such rights since the rights will incentivize their holders to shape the development of these factors in a manner conducive to increasing the reach of their entitlements. This observation adds an element of recursivity to the picture, and the highly uncertain character of the resulting calculations is fairly clear.

To a considerable extent, our call for rough institutional judgment is in line with Demsetz's own original article, which is itself within a Hayekian tradition of making comparative judgments about which policies are better suited to achieve more or less efficient outcomes starting from local baselines.[190] Demsetz, however, implicitly conceptualizes our choice as one *between* systems.

189. The problem is somewhat akin to that of determining public expenditures on basic research: once we recognize that sole reliance on property rights and markets will be both inadequate and distortionary, we then need somehow to make judgments regarding not only the likely value of various lines of research or areas of innovative activity, but also the extent to which the resulting outputs will possess characteristics (e.g., distant time horizons, high degree of nonexcludability) that necessitate nonexclusionary forms of innovation support.

190. By "Hayekian" here we mean to refer to both of Hayek's information-based or "epistemic" economic arguments. One is the argument that Demsetz explicitly relies on, which we review *supra* note 35 and accompanying text, namely, the information-based argument in favor of markets as against government decisionmaking. *See* Hayek, *supra* note 35. Roughly contemporaneous to that, however, Hayek advanced another argument, now an information-based critique of neoclassical economic reasoning, asserting that the search for equilibria that are in some sense globally optimal is misguided in the face of the severe epistemic hurdles facing any such approach. *See* F.A. von Hayek, *Economics and Knowledge*, 4 ECONOMICA 33 (1937). This raises, of course, the interesting question of the connection between these two arguments, and in particular the issue of what criteria, if not those of neoclassical efficiency, are to be used in assessing Hayek's claim of the economic superiority of markets to planning. The "Hayekian" answer, we believe, is along the lines of what we set out here, namely, a comparative-institutional approach that is more modest in its consequentialist evaluative criteria, both in terms of starting from local baselines rather than looking for global optima and in terms of realistically choosing among various imperfect or "second-best" institutional options rather than thinking in "nirvana" terms about institutional choices in their idealized forms.

A comparative-institutional perspective suggests instead an investigation of which systems might be best in a given context, and suggests that a *mix* of approaches may well be superior to a single approach.

Moreover, as we contemplate the appropriate mix of approaches, we must also consider the ways that different institutional approaches *interact* with one another. That is, we cannot assume that different approaches do not interfere with each other. As we have shown, there is reason to think that the property approach poses a threat to other approaches, with its distortions of the investment environment away from nonexcludable strategies and its possible entrenchment through forms of competitive hostility and cumulative acculturation effects. Other institutional approaches also have potential biases, but these are better known: for example, there is a risk that decisions about the allocation of government research funding will be influenced by repeat players who drive research toward their own domains, rather than more productive alternatives pursued by upstart competitors. We need, then, to conceptualize our innovation ecosystem *as* an ecosystem in the deep sense of the word, which is to say, as subject to complex and mutually constitutive interactions between component parts—interactions that should be an important part of our study of that system.

Finally, in evaluating different institutional alternatives and their interactions, we should not restrict our criteria to considerations of efficiency and the impact on values such as privacy and free speech. Rather, our argument offers two reasons for looking to a broader set of considerations. One is that the indeterminacy afflicting economic analysis we have underlined simply necessitates judgments that rely, at least implicitly, on other considerations as well. Moreover, when such judgments pertain not just to the existence and scope of property rights but also to the role of alternative institutional arrangements, then the possibility that such alternatives may perform better on certain nonefficiency criteria (such as distributive considerations) mandates giving such criteria careful consideration.

CONCLUSION

A proper appreciation of the continuum of excludability, we have argued, has significant implications for innovation theory and policy. Patents, as property rights, do not act simply as transparent conduits for market signals, but rather may introduce their own allocative distortions. While others have recognized before that appropriability is limited even where patents exist, many of these arguments suggest that more extensive patent protection can remedy the problem, leaving intact the allocative case for reliance on patents. In contrast, the continuum of excludability shows that market-based

approaches to innovation have a comparative disadvantage with respect to allocations toward highly nonexcludable goods, making it clear that patents do not act as a neutral conduit for information about social welfare. We have not, of course, established the superiority of any particular type or mix of alternatives, but we have provided an additional set of what we believe to be powerful arguments for the necessity of, and in certain areas comparative superiority of, alternative institutional approaches to innovation. Finally, to properly examine and evaluate these alternatives—as well as the interactive effects of their possible coexistence—will often require us to deploy (indeed, to further develop) a broader set of analytical tools, and attend to their unavoidable implications for a wider range of values beyond efficiency.