Systemic Bias in Patent Law

Alan Devlin

Follow this and additional works at: https://via.library.depaul.edu/law-review

Recommended Citation
Alan Devlin, Systemic Bias in Patent Law, 61 DePaul L. Rev. 57 (2011)
Available at: https://via.library.depaul.edu/law-review/vol61/iss1/3

This Article is brought to you for free and open access by the College of Law at Via Sapientiae. It has been accepted for inclusion in DePaul Law Review by an authorized editor of Via Sapientiae. For more information, please contact digitalservices@depaul.edu.
SYSTEMIC BIAS IN PATENT LAW

Alan Devlin*

INTRODUCTION

The ongoing patent debate displays all the hallmarks of interest-group theory, given the spectrum of diametrically opposed, self-interested positions that different industries advocate.1 Certain groups maintain that patents are choking cumulative innovation and commercialization, such that lawmakers should discard or radically restructure the system.2 Those cries have been met with equally vociferous protestations that the patent regime is the sine qua non of industrial research and development (R&D), such that any change in the law would have disastrous repercussions.3

The relevant arguments fall along divergent, but predictable, lines. Companies that find that the patent regime fetters their business models, such as firms operating in the information-technology (IT) field,
advance positions aimed at diluting patentees' right to exclude. Conversely, companies for which patents constitute the foundation of their innovation platforms, such as those in the pharmaceutical field, seek to fortify intellectual property (IP) rights both by broadening their scope and making them more difficult to challenge in court. Yet, even within the same industry, pioneer inventors' and subsequent improvers' views on an ideal patent system can diverge markedly. The controversy is problematic not because of its acerbic tone, but because of the lack of information necessary to resolve it and the absence of an objective framework within which to craft policy prescriptions. Unless one adopts a relativist position aimed at promoting the interests of a particular industry or industry segment—thus eschewing the notion that one can articulate economy-wide policies in a determinate manner—it is difficult to discern the optimal contours of the patent system.

This shortcoming is alarming, not least because those charged with administering the patent system are presently beset with conflicting calls for change. Critics have railed against what they perceive to be the courts' overcompensation of patentees. They single out the entire-market-value rule for particular disapproval. Detractors bemoan the ever-expansive nature of patentable subject matter; the scope of exclusivity associated with patent grants; the absence of effective claim construction rules that would both cabin monopoly rights and provide much-needed certainty; the indeterminacy of analysis under the doc-


trine of equivalents; the lack of an independent-invention defense; and the evidentiary rules that hinder defendants' attempts to invalidate asserted patents. The patent system creates problems in the computer-software, information-technology, and business-method fields, in particular, though patent-related issues also afflict certain innovators working in the semiconductor, biotechnology, and nanotechnology fields.

Yet, other inventors laud the cited grounds of criticism as indispensable elements of a desirable IP system. The pharmaceutical industry, in particular, staunchly defends the status quo and, indeed, urges ever-stronger patent rights. Given the vast investment required to research and develop commercially viable drugs, the absence of powerful exclusive rights would lead to a catastrophic decline in pharmaceutical innovation and output. Certain inventors in other capital-intensive industries, including semiconductors and biotechnology, also require some proprietary control in order to facilitate ongoing levels of innovation. Many such innovators seek stronger patent protection in the form of enhanced periods of exclusivity, automatic entitlement to injunctive relief upon established infringement, a reconstruction than district court judges and considering three possible explanations: "(1) trial judges... cannot master claim construction, especially without a technical background; (2) the Federal Circuit's claim construction case law is poorly articulated; or (3) claim construction is inherently indeterminate" (footnote omitted)).


13. See discussion infra Part III.B.2.a.

14. These industries, which the patent system can negatively affect, typically support any change in the law that would weaken patent rights. See, e.g., Brief of Google Inc. et al. as Amici Curiae in Support of Petitioner, Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238 (2011) (No. 10-290).

15. See supra note 5 and accompanying text.


duced role for the exhaustion doctrine, and greater contractual freedom to bolster the value of their IP rights. They also vigorously defend the presumption of patent validity, as well as the clear and convincing evidence standard that the Supreme Court has ascribed to it.

Like any ideologically driven controversy, the patent debate features arguments of varying nuance and scope. Some advocate the wholesale abolition of the patent system from the U.S. economy—a position that critics typically advance without a strong empirical foundation or a nuanced regard for the likely economic effect of such a monumental transformation in the law. Others counsel incremental adjustment in doctrine to effect change in a more responsible manner. Although the micro-adjustment approach is surely more reasonable, those propounding it still face the challenge of identifying the direction in which the law should move. Given the fact that different stakeholders invariably take conflicting, entrenched positions on any patent issue of note, how should policymakers identify optimal adjustments in the law and achieve the requisite level of consensus to facilitate their creation?

This is far from an academic problem. For several recent years, Congress repeatedly tried and failed to pass comprehensive patent reforms. Some had argued that those failures evidence the judiciary's superior institutional competence in tailoring patent doctrine more closely to the traits of individual industries. Of course, in September 2011, Congress passed comprehensive patent-reform legislation for the first time in almost sixty years, bringing such significant changes as a first-to-file system, post-grant review, qualified prior-user rights, and

22. See, e.g., Brief of Computer & Commc'ns Indus. Ass'n, supra note 4; Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238 (2011).
23. See supra note 2 and accompanying text.
27. See The Patent Crisis, supra note 17, at 95-108.
the elimination of tax-strategy patents and qui tam false-marking patent suits by noncompetitors.  

Although the Leahy-Smith America Invents Act (AIA) constitutes a significant step forward in resolving many difficult problems afflicting the patent system, many vexing features of the patent regime remain unresolved. The spectrum of conflicting perspectives accompanying these issues is vast, which in turn implies that consensus is likely to be elusive. If the courts must pick up the mantle from Congress to address issues left unresolved by the AIA, it would be helpful to provide them with some objective guidance.

While acknowledging the divergent incentive characteristics of the various industries subject to the patent regime, this Article identifies a lens through which one may analyze certain divisive issues that are of contemporary importance. Those scrutinizing the present system would benefit by at least partially reorienting their analysis of discrete issues in patent law away from the industry-specific analysis that is currently the norm. To the extent that the patent regime continues to apply rules and principles in horizontal fashion to industries displaying asymmetric incentive structures, tailoring a doctrine to effect superior rates of innovation in any particular industry is likely to solve one problem, only to create more. What is efficient in one setting may not be in another.

A partial solution to this quandary might be to view the patent system as a neutral framework within which legal actors endeavor to provide inventors with optimal rewards. In its “first-best” light, relevant actors would apply the various tenets of patent law with an error rate of zero. In such a hypothetical environment, the patent system would not produce many of the consequences that many currently perceive to be inefficient. Although no one seriously posits that the current system works in such an optimal manner, viewing it in such a light allows one to realize that the relevant rule under consideration is not necessarily undesirable. Instead, it is courts’ and examiners’ capacity to err that renders the relevant rule potentially problematic. The academic literature has missed this important insight. This Article argues that policymakers should scrutinize the patent system for features that are likely to upset the neutrality of the framework within

which judges, juries, and examiners strive correctly to apply the fundamental principles of patent law.

To undertake this analysis, one should first inquire into the effect of erroneous applications of the relevant rule under consideration. Interestingly, a rule or standard can be efficient even if courts are incapable of applying the same correctly in all cases. Courts are, of course, prone to err in making determinations of law and fact. An error in one direction may, however, eliminate the distortive effect of a separate error in the opposite direction. As a result, a court’s improper invalidation of a patent, refusal to award injunctive relief, or other mistaken ruling may not, as a theoretical matter, negatively affect initial incentives to invent. Even if courts routinely err in making such determinations, ex ante expected rewards from patent protection will remain at optimal levels if judges, juries, and examiners are as likely to err in the direction of overcompensation as they are in the direction of undercompensation and if inventors are risk neutral. In the long run, variations from the mean should cancel one another out, such that the expected return from innovation is equal to the level that would exist under a system in which judges, juries, and examiners operated accurately. Industry-specific considerations—relating in particular to those markets in which follow-on innovation is intimately dependent on the nature of the property right granted the initial inventor—complicate the analysis, but the principle potentially holds true in the long run.

Rules and doctrines of the preceding type are to be distinguished from those that are susceptible to biased application. If a particular rule leads judges, juries, and examiners to err systemically, then the mean outcome will be one of under- or overcompensation, depending on the direction of the bias. This, of course, is inefficient, though the extent of the inefficiency depends on the nature of the systemic error. To the extent that one can identify rules that lend themselves to systemically skewed outcomes, there is a strong a priori basis for revisit-


33. One might question the desirability of a system that reacts with indifference to incidences of under- and overreward as long as the mean reward is optimal on the ground of fairness. After all, erroneous application of law will deprive some deserving inventors of their due reward, while granting a windfall to those whose inventions were unworthy of patent protection. Given the U.S. patent system’s unqualified utilitarian foundation, however, such fairness-based objections carry little weight. The law’s sole focus should be on maintaining optimal incentives.

ing them. Importantly, the normative case for altering such rules applies across industries.

This Article identifies a number of patent doctrines that may predispose courts to err systemically in one direction over another. These include the entire-market-value rule; the requirement that defendants prove an asserted patent's invalidity by clear and convincing evidence rather than by a preponderance of the evidence; the argument that the law should categorically exclude certain fields of innovation (most recently, medical-diagnostic tests based on biotechnology) from patent protection; and the judicial rule that patentees may enter into reverse-exclusionary payments in the pharmaceutical industry. All of these examples are serious candidates for revision, though for reasons based in part on decision theory, the last is the most vexing.

The Article proceeds in three Parts. Part II explores the disparate array of innovation characteristics that exist in the many industries subject to the patent system. It then explains why the heterogeneous quality of incentives in these contexts creates a major quandary for patent policy and articulates some reasons why these difficulties render conclusive policy recommendations elusive. Part III addresses a number of specific controversies that currently afflict, and that have recently afflicted, the patent system. This facilitates the Article's central discussion of systemic error in the patent regime and the various doctrines that induce it. A brief conclusion follows.

II. The Heterogeneity of Industrial Innovation

A. The Patent System's Professed Purpose

The patent regime's raison d'être is well known. Inventions and discoveries, the functional embodiments of which are the principal sub-

35. See discussion infra Part III.B.
38. See infra notes 41–185 and accompanying text.
39. See infra note 186 and accompanying text.
40. See infra notes 187–276 and accompanying text.
jects of patent protection, essentially constitute knowledge. Both common sense and economic theory suggest that one can acquire such previously unknown knowledge only by expending resources, through educating oneself in the relevant field and then conducting the experimentation required to advance the prior art. In order to induce prospective inventors to undertake this costly process, society must allow them to appropriate a sufficient amount of the social value of their discoveries. When one commercializes a product or process incorporating a novel technology, however, the sold item may be a "public good," which in the parlance of economics refers to items that are both "nonexcludable" and "nonrivalrous" in consumption. As it is difficult to maintain private control over information, many technological advancements are subject to reverse engineering and, hence, appropriation. Competitors therefore have an incentive to free ride off the innovative advances of their entrepreneurial rivals. Because competition induces positive externalities with respect to the invention and commercialization of technology, an unregulated market will underproduce socially desirable public goods.

This is the classic economic justification for the IP system. Unfortunately, this rationale has taken on a life independent of its intellectual mooring and so has become a mantra that many proclaim in uncritical fashion to defend the status quo in a multitude of industries. As the following discussion explains, the normative case for twenty-year exclusive rights over one’s claimed invention differs markedly depending on the relevant context. Inventors’ vulnerability to third-party appropriation varies enormously depending on the pertinent industry. The greater the inventors’ vulnerability to ex post free rid-

44. Cf. Stephen M. McJohn, A New Tool for Analyzing Intellectual Property, 5 NW. J. TECH. & INTELL. PROP. 101, 102 (2006) (“To take a current controversy, Google seeks to create a searchable database by scanning copyrighted books. Whether the benefits to scholars, students, and other readers outweigh the costs to authors and publishers cannot be balanced against each other arithmetically, rather only by value judgments.”).
ing, the greater the case for stronger patent rights, and vice versa. It bears emphasizing, however, that not all machines, manufactures, compositions of matter, and processes are vulnerable to easy appropriation. Where innovators can embody their discoveries in a marketable product or service while keeping the underlying technology from prying eyes, no public-goods problem emerges. Patent protection may be unnecessary—even costly—if granted in such cases.

Yet, barriers to successful reverse engineering do not in themselves suggest the absence of patent protection. Even in such cases, innovators may face a socially undesirable risk of ex post undercompensation. This will occur if the ratio of inventors’ R&D expenditures to their competitors’ reverse-engineering costs is sufficiently high. Conversely, even when reverse-engineering costs are trivial relative to innovators’ research investment, it does not follow that a public-goods dilemma will emerge. In certain industries, particularly those subject to powerful network effects or those in which reputational effects are strong, first-mover advantage may enable a breakthrough innovator to capture sufficient returns ex post to justify its ex ante expenditures on innovation.

The public-goods dilemma also fails to provide a comprehensive rationale for patent protection because, at least in its classic expression, it does not distinguish between pioneer innovations and incremental, follow-on improvements over existing technologies. In industries characterized by rapid cumulative innovation—comprised of a large number of continuous, albeit individually modest, marginal gains over the prior art—awarding any one inventor broad exclusive rights may hinder subsequent innovation. The phenomenon of “blocking pat-

49. See, e.g., Katherine J. Strandburg, What If There Were a Business Method Use Exemption to Patent Infringement?, 2008 MICH. ST. L. REV. 245, 264 (“Commentators have argued that patents are unnecessary to provide incentives to invent business methods . . . .”).

50. For the author’s broader discussion of this point, see Alan Devlin, Restricting Experimental Use, 32 HARV. J.L. & PUB. POL’Y 599, 626–28 (2009).

51. Some uncritically argue that it is important to grant patents over such inventions due to patent law’s so-called “incentive-to-disclose” rationale. See Alan Devlin, The Misunderstood Function of Disclosure in Patent Law, 23 HARV. J.L. & TECH. 401, 417 (2010) (observing and critiquing these arguments). As the author has explained elsewhere, rational inventors of non-self-disclosing technologies will rarely elect patent protection in lieu of trade-secret protection due to the ephemeral nature of exclusivity under the circumstances and the cost involved in meeting the enablement requirements of patentability. See id. at 420. To the extent they do so, it may be because they wish to raise rivals’ costs rather than protect themselves against reverse engineering. See id.

52. See THE PATENT CRISIS, supra note 17, at 42–44.

53. See id. at 43.

54. Granting holders of upstream technologies broad exclusive rights may induce anti-commons effects that frustrate the commercialization of valuable downstream products. See
ents'' may become problematic in such settings. Similarly, a particular invention may have depended on considerable investment in R&D and may be resistant to reverse engineering, yet be undermined by the subsequent development of cheaper functional substitutes.

It follows that innovation policy is a matter of some complexity. As a result, one can neither understand the dilemma currently afflicting the patent system nor appreciate the difficulty of molding a solution without possessing some familiarity with the disparate industrial settings in which patent law applies. Given the broad spectrum of innovation characteristics displayed by these industries, one might imagine that an optimal IP system would employ distinct rules and doctrines in different markets. Yet, the U.S. patent regime purports to apply a single body of rules in uniform fashion. As a result, fashioning a desirable body of law that applies in unvarying fashion to heterogeneous industries is far from straightforward. The following discussion explores the relevant characteristics of the major industries in which patent law, for better or worse, currently plays an important role.

B. The Pharmaceutical Industry

Pharmaceuticals epitomize the public-goods justification for a patent system. New drug development depends almost entirely on vast amounts of private investment. Yet, the precarious and costly nature of pharmaceutical innovation may repel crucial venture capital. Pioneer-drug researchers must first canvass potentially useful chemical compounds and identify the small subset that ought to proceed to generally Michael A. Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, SCIENCE, May 1, 1998, at 698, 698 (1998).

55. See id. at 700 ("When owners have conflicting goals and each can deploy its rights to block the strategies of the others, they may not be able to reach an agreement that leaves enough private value for downstream developers to bring products to the market.").


60. See Benjamin N. Roin, Unpatentable Drugs and the Standards of Patentability, 87 TEX. L. REV. 503, 504 (2009).
animal and preclinical laboratory testing.\textsuperscript{61} Through those tests, they must demarcate the relatively few compounds that are sufficiently promising to warrant Phase I trials on human subjects, which establish whether the compound is safe.\textsuperscript{62} They must then conduct Phase II trials in order to determine the compounds’ efficacy in treating a particular condition.\textsuperscript{63} If a candidate drug survives this scrutinizing process—the majority does not \textsuperscript{64}—large-scale clinical testing on thousands of patients begins.\textsuperscript{65} These Phase III trials seek to establish the effectiveness of the relevant drug and its side-effect profile, as well as relevant information for the drug-package label.\textsuperscript{66} Phase III trials constitute the single most expensive and protracted part of the innovative process; indeed, they often take years.\textsuperscript{67} The FDA will only approve about twenty percent of compounds that make it to human trials (and those compounds are but a tiny subset of those that are initially studied).\textsuperscript{68} Only 1 out of up to 10,000 compounds identified as “promising” will ultimately result in a commercialized product.\textsuperscript{69} Of the drugs that do go to market, the majority will not reap a sufficient return to cover the cost of development.\textsuperscript{70} The industry has to rely on a small number of “blockbuster drugs” to cross-subsidize loss-

\textsuperscript{61} See Sean B. Seymore, \emph{Rethinking Novelty in Patent Law}, 60 DUKE L.J. 919, 927 n.41 (2011) (‘A pharmaceutical company may screen hundreds of thousands of chemical compounds as likely candidates for development . . . ’).

\textsuperscript{62} David Magnus, \emph{Translating Stem Cell Research: Challenges at the Research Frontier}, 38 J.L. MED. \\ & ETHICS 267, 267 (2010).

\textsuperscript{63} Rahi Azizi, Comment, “Supplementing” the DSHEA: Congress Must Invest the FDA with Greater Regulatory Authority over Nutraceutical Manufacturers by Amending the Dietary Supplement Health and Education Act, 98 CALIF. L. REV. 439, 463 (2010).


\textsuperscript{65} \textit{E.g.}, Tara Arschin, Note, \emph{Battling Breast Cancer: New York’s Laws Are Not Enough}, 13 CARDOZO J.L. \\ & GENDER 579, 584 (2007).

\textsuperscript{66} Azizi, supra note 63, at 463; Andrew S. Robertson, \emph{The Role of DNA Patents in Genetic Test Innovation and Access}, 9 NW. J. TECH. \\ & INTELL. PROP. 377, 393 (2011); Elissa Levy, Note, \emph{The HEALTH Act’s FDA Defense to Punitive Damages: A Gift to Drug Makers or to the Public?}, 74 FORDHAM L. REV. 2425, 2433–34 (2006).

\textsuperscript{67} Carolyn A. Castagna, Note, \emph{Therapeutic Monoclonal Antibodies: The Dilemma of Delivering Affordable Biologics to Patients While Continuing to Incentivize Innovation}, 82 TEMP. \\ L. REV. 1071, 1082 (2009).


\textsuperscript{69} Richard B. Silverman, \emph{THE ORGANIC CHEMISTRY OF DRUG DESIGN AND DRUG ACTION} 8 (2d ed. 2004).

\textsuperscript{70} CONG. BUDGET OFFICE, \emph{HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY,} at xv (1998), available at http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf (‘For most drugs, the returns from marketing do not exceed the average capitalized costs of development. As a result, for a company’s aver-
making drugs and the myriad research projects that do not bear fruit.\textsuperscript{71} The entire premarket-approval process for a successful drug typically takes about nine years.\textsuperscript{72}

Beyond its axiomatic complexity and risk, the foregoing process is fantastically expensive. Industry observers estimated in 2003 that the average cost of developing a candidate drug and bringing it to market was $802 million.\textsuperscript{73} Some high-end estimates have been to the tune of almost $2 billion \textit{per drug}.\textsuperscript{74} More skeptical, left-leaning observers have posited a lower, though still considerable, figure of $110 million.\textsuperscript{75} Given the attenuated odds of any one identified compound resulting in a marketable drug, as well as the vast capital investment required to fund R&D, ongoing innovation in the pharmaceutical industry is contingent on inventors being able to appropriate a sufficient degree of their marketed drugs’ social value.

Several characteristics of the pharmaceutical industry combine to create a classic public-goods dilemma. First, as outlined above, the New Drug Application (NDA) process for receiving regulatory approval for a new drug is protracted and requires private enterprise to devote an immense amount of financial resources.\textsuperscript{76} This time and expense leaves pharmaceutical innovators vulnerable to free riding.\textsuperscript{77} In this respect, the pharmaceutical industry bears witness to the freest of riders: generic-drug producers.\textsuperscript{78} These entities’ business model is to wait on the sidelines while brand-name drug manufacturers (1) explore the universe of promising pharmacological compounds; (2) devote the capital necessary to determine which compounds are viable candidates for commercialization; (3) spend immense sums subjecting the selected drugs to years of clinical trials; and (4) eventually produce age returns to exceed its average development costs, the company must discover and market a highly profitable drug from time to time.”\textsuperscript{79}


\textsuperscript{72} Allen Rostron, Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers, 60 DUKE L.J. 1123, 1130 & n.16 (2011).


\textsuperscript{74} See Masia, supra note 68, at 82.

\textsuperscript{75} See The Patent Crisis, supra note 17, at 39 (“Ralph Nader’s consumer group argues that the average cost is only $110 million per drug.”).


a marketable product. It is only at this final stage that generic-drug companies become involved in the industry. If they can convince the FDA that their proffered drug formulation is bioequivalent to the brand-name drug, generic-drug companies can bypass the regulatory approval process by filing an Abbreviated New Drug Application (ANDA). The ANDA process is faster, cheaper, and simpler than the original NDA procedure by an order of magnitude.

All this might not matter if inventors could maintain exclusive knowledge over the molecular formula of the compound underlying their developed drugs. Yet, pharmacological compounds are susceptible to reverse engineering. Generic-drug producers have proven adept at decoding the formulation parameters of pioneer-drug products. These companies have developed techniques for ascertaining drugs' quantitative composition, the solid-state characterization of the drugs' active pharmaceutical ingredients, and their manufacturing processes. Although commercialized drugs are not immediately self-disclosing, meaning that interested third parties cannot determine the nature of the relevant drug by casual inspection, the important points are (1) that reverse engineering is feasible, even if nominally expensive, and (2) the ratio of profitability from successful reverse engineering to the cost of achieving it is so great as to be a no-brainer from a profit-maximizing company's perspective.

In light of these characteristics, some significant reward is an indispensable prerequisite of innovation in the pharmaceutical industry. This reward need not necessarily take the form of patent rights. Indeed, many economists have urged the adoption of a government-funded prize system to replace, or more realistically to complement, the patent regime. Others tout FDA regulatory rules as a viable,
alternative incentive mechanism. Nevertheless, if one were to pick a single field of innovation with which to showcase the patent regime’s efficient operation, the research, development, and commercialization of pharmacological compounds would be it. The field is a paradigm for Edmund Kitch’s prospect theory of patentability, in which society grants an original inventor strong exclusive rights over the use and future path of a given discovery. That theory posits that an inventor will efficiently guide his breakthrough technology’s commercialization and future development, whether by undertaking the necessary steps himself, or by bargaining with third parties to the same effect à la Coase. Given pharmaceutical R&D’s susceptibility to free riding, the fact that patents covering the relevant compounds clearly demarcate the boundaries of claimed inventions and that, typically, only one patent covers a given commercialized drug, the patent system is a desirable, indeed essential, component of innovation policy in this field.

Were the patent regime to be abolished tomorrow, and if it were not replaced with an alternative reward system, there is no question that the pharmaceutical industry would bear witness to a catastrophic collapse in R&D. Given the immense social value associated with medical innovation, such an outcome would be unthinkable.

Of course, the fact that patent protection is an indispensable component of a responsible policy in the pharmaceutical field does not mean that current levels of protection are in fact optimal. Indeed, the industry claims that it requires greater protection than contemporary patent rights currently provide. Regulatory delays, which eat into pioneer-drug manufacturers’ twenty-year exclusive rights, result in companies typically enjoying less than twelve years of post-patent

---

87. See The Patent Crisis, supra note 17, at 81.
90. The Patent Crisis, supra note 17, at 53.
marketing protection. The industry further maintains that it requires patent rights of greater duration. Conversely, many observers criticize what they perceive to be the inordinate cost of drugs in the United States and bemoan the insufficient level of generic competition. As Part II explains below, this industry is a hotbed for some of the most controversial issues currently afflicting the patent system. For present purposes, however, it will suffice to note that the field epitomizes public-goods theory, thus suggesting the propriety of IP protection without necessarily dictating the optimal contours of those exclusive rights.

C. Chemicals

The chemical industry is of vast importance to the modern economy, producing innumerable substances from such raw materials as oil, water, natural gas, and metals. The industry's output takes myriad forms, ranging from rubber, plastic, hydrocarbons, synthetics, and fertilizers to more exotic chemicals. These outputs are themselves key inputs for countless other industries and thus ongoing innovation in the field is of self-evident importance. Novel chemicals have long been patent eligible—typically under § 101's "composition of matter" prong—and it is clear that such protection serves a crucial role in spurring R&D in the chemical industry.


96. For an account of the importance of the industry in older times, see United States v. Chem. Found., Inc., 5 F.2d 191, 199 (3d Cir. 1925).


99. See, e.g., Jonathan M. Barnett, Is Intellectual Property Trivial?, 157 U. Pa. L. Rev. 1691, 1702 (2009) ("[O]utside of the pharmaceutical and chemical industries, managers consistently rank patents among the least effective appropriation instruments and rarely respond affirmatively when asked if patent protection is a 'but for' condition for undertaking a research project."); Edwin Mansfield, Patents and Innovation: An Empirical Study, 32 Mgmt. Sci. 173, 180 (1986) (noting that the effects of the patent system in the chemical industry are "very substantial"); F. M. Scherer, Antitrust, Efficiency, and Progress, 62 N.Y.U. L. Rev. 998, 1013 (1987) ("Patent protection appears to be a crucial means of appropriating the benefits from innovation in only a few industries such as pharmaceuticals and specialty chemicals.").
Innovation in the chemical field bears many of the same hallmarks as the pharmaceutical sector. Given the eclectic output of the chemical industry, statistics describing average R&D costs are not as illuminative as they are with respect to pharmaceutical innovation. Nevertheless, it is clear that research in chemicals is capital intensive, requiring considerable sunk costs in order to achieve advances over the prior art. These technological gains are similarly susceptible to third-party appropriation ex post. Such a setting is, of course, a paradigm for the public-goods justification for the IP system and thus gives rise to a strong case for patent protection. Consistent with this, surveys have revealed that patents are of great importance to innovation in chemicals.

Of course, vulnerability to post-research reverse engineering is an insufficient basis to conclude that patents are an unequivocal social good. Overlapping patent rights, indeterminate contours of exclusivity, and the number of exclusive rights implicated by a typical product are important determinants of optimal patent protection. As in the pharmaceutical setting, however, a single patent in the chemical field is likely to be coterminous with a commercialized product, and those skilled in the art can readily discern the meaning of claims directed at chemical structures. Given these traits, in conjunction with the private capital required to fund ongoing research and the ease with which third parties can appropriate the fruits of invention, patents are important fundamental components of innovation policy in the chemical industry.

Once more, however, the fact that some form of IP protection is appropriate in the chemical industry is distinct from the assertion that the contours of the contemporary patent system are optimal. As with other fields of invention subject to the patent regime, difficult policy questions remain. Part III articulates a framework within which one

100. See The Patent Crisis, supra note 17, at 81 (using the two interchangeably in a discussion regarding the importance of patent protection to the pharmaceutical industry).
104. See Badenoch & Akyuz, supra note 1, at 598.
105. See The Patent Crisis, supra note 17, at 58.
106. One should also note that trade-secret law plays an especially important role in the chemical industry. See Dan L. Burk & Mark A. Lemley, Policy Levers in Patent Law, 89 Va. L. Rev. 1575, 1584 (2003) [hereinafter Policy Levers].
can more objectively determine the desirability of a proposed element of the patent system.

D. Biotechnology

Biotechnology has emerged as an increasingly important, yet occasionally controversial, field. The industry has given rise to exciting new innovations, from genome mapping to genetic engineering. Such scientific advances have yielded a rich variety of real-life rewards, including new vaccines, gene therapy, allergens, and other medical treatments. An important biotechnological breakthrough involved a method for producing hybridomas, which facilitated the production of monoclonal antibodies that in turn allowed scientists to identify antigens in the human body.\(^{107}\) This process constituted the foundation of effective medical diagnostic tests. More recent technological advances have focused on gene splicing, which permits the transfer of genetic material from one organism to another.\(^{108}\) These advances allow scientists to create organisms with new commercial traits and, more importantly, to transfer genes for valuable proteins into organisms that can produce significant volumes of those proteins.\(^{109}\)

Advances in biotechnology have ushered in a wide variety of personalized, as opposed to standardized, medical treatments.\(^{110}\) Traditionally, physicians engaged in a “trial and error” process, treating patients suffering from common ailments using a variety of different drugs and dosages to determine which treatment works best for each different patient.\(^{111}\) Personalized medicine takes a targeted approach, by which doctors prescribe treatments based on individual patients’ distinct traits.\(^{112}\) These treatments hail from the discovery of biomarkers,\(^{113}\) which enable scientists to detect the presence of a particu-

---

107. The Patent Crisis, supra note 17, at 144-45.
108. Id. at 148.
109. Id.
lar condition, the development of a disease, and the efficacy of a given medication.\textsuperscript{114}

Like pharmaceutical research, innovation in biotechnology is both capital intensive and risky.\textsuperscript{115} It is famously difficult to predict the ultimate efficacy of a particular biologic being researched.\textsuperscript{116} The necessary molecular studies are heavily laboratory based, and, although significant portions of the innovation process are automated, the requisite equipment is expensive.\textsuperscript{117} Biotech companies wishing to market new technologies for use on patients must, of course, meet stringent FDA regulatory requirements, which cause further uncertainty and considerable delays.\textsuperscript{118} Due to the investment-intensive nature of innovation in the field, venture capital is paramount.\textsuperscript{119} Unlike pharmaceutical research, however, government funding plays a major role in biotech innovation.\textsuperscript{120} As a result, the interaction between public and private researchers is of importance.

Given the necessity for private investment, patent rights play a significant role in inducing the same.\textsuperscript{121} Indeed, empirical research has revealed that the "patent premium" in the biotech field is high, such that the availability of IP protection is an important driver of innovation.\textsuperscript{122}

Yet, private ownership rights rest awkwardly with both academic and public-sector research, particularly when state grants play such an important role in financing innovation. Furthermore, inventors' in-

\textsuperscript{114} Problems abound with respect to the clinical evaluation of biomarkers, the absence of an evidence base for conducting such evaluations, and insufficient incentives to commercialize diagnostic biomarkers. Biomarkers and Targeted Therapies, OECD, http://www.oecd.org/document/48/0,3746,en_2649_34537_39405168_1_1_1_1,00.html (last visited June 26, 2011). In this last respect, some have observed that companies are unwilling to invest the necessary capital unless the markers are associated with a particular drug. Id.


\textsuperscript{116} E.g., Steven A. Nash \& Rebecca Workman, A New Pathway for Follow-on Biologics, 20 Fed. Cir. B.J. 193, 199 (2010).


\textsuperscript{122} Kevin Outterson, Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets, 5 Yale J. Health Pol'y L. \& Ethics 193, 200 n.28 (2005).
Increased patenting of biotechnology has alarmed many observers. Researchers have patented some twenty percent of the human genome. DNA-related patents abound. Given the perception that the United States Patent Trademark Office (USPTO) improvidently grants many patents—due in part to excessively broad claims that may overlap to an inefficient degree—as well as the fact that the agency has issued a vast number of patents in this field, biotechnology has come to epitomize some academics’ concern of an “anticommoms.”

Such difficulties have led a number of commentators to call for a research exemption for gene-related patents, justifying the plea on the ground that genomic materials, by their nature, are not susceptible to invent around. Kenneth Neil Cukier illustrates the point by observing that, with respect to “genes detecting disease susceptibility or encoding therapeutic proteins, substitutes are by nature not possible.” Others contend that the courts or legislature should dilute patent protection in the biotech field so as to free research and downstream commercialization from the search, negotiation, and other transaction costs that currently fetter it.

The extent of the problem remains a matter of some controversy. Certain commentators decry the scale and scope of patent protection afforded biotech inventions, while others submit that generous property rights are the sine qua non of innovation in the field. The empirical evidence thus far suggests that those critics’ most dire predictions, such as preclusive anticommons effects, have not come to pass. Ironically, this would seem to be because researchers are sim-
ply ignoring patents, while many patentees choose not to undertake the expense of enforcing their rights in court. This has created an environment of voluntary nonenforcement in the industry, which some hail as evidence of the efficiency of private-order solutions. Conversely, others worry that the status quo is unstable and likely to be undone by enforcement actions taken by outsiders who acquire patents, as has occurred in the IT field.

Nevertheless, the biotech field bears witness to some of the most divisive questions currently afflicting the patent system. Representatively, in 2009, the American Civil Liberties Union and the Public Patent Foundation targeted two patented genes associated with breast and ovarian cancer, arguing that the IP rights stifled medical diagnostic techniques and research, as well as free speech rights, and submitted further that the human genome is not an invention, but instead a discovery that belongs to all. The patentee, Myriad Genetics, sold a test aimed at identifying mutations in the two patented genes in order to determine a woman’s risk profile for the two forms of cancer. The price was more than $3,000. Some characterize private companies’ obtaining proprietary rights over human genes as immoral. In 2010, the U.S. District Court for the Southern District of New York ruled that the gene patents categorically fell beyond the scope of patent protection. In late July 2011, a divided panel of the Federal Circuit reversed in part, finding that the isolated genes constituted patentable subject matter. If the district court’s holding had stood, it would have had significant repercussions for the role of patent protection in the biotech sphere. 


134. See Holman, supra note 132, at 299.
136. See The Patent Crisis, supra note 17, at 152.
138. See Ass’n for Molecular Pathology v. USPTO, 653 F.3d 1329, 1334–35 (Fed. Cir. 2011).
141. Ass’n for Molecular Pathology, 653 F.3d at 1334.
E. Information Technology

The "patent premium" is significant in certain fields of innovative activity, including mechanical devices, pharmaceuticals, chemicals, and biotechnology. With the exception of certain aspects of the biotech sector, the patent system generally enjoys legitimacy within these settings. Few question the general desirability of patents within these industries.

One cannot say the same for computer-software and the broader field of information technology. Innovators in these industries routinely denounce patents as a major impediment to their work. Some researchers have estimated that the patent premium in these areas may be insignificant—even negative. If true, this means that patents are encumbering, rather than spurring, R&D. If this is in fact the case, patents are operating in diametric opposition to the economic rationale that justifies their existence. How can this be? How can twenty-year proprietary rights over one's claimed invention carry such asymmetric results with respect to computer software vis-à-vis, for example, pharmaceuticals? To answer this question, one must appreciate the distinct features of innovation in the IT sector. The differences between that field and those in which innovators warmly receive the patent system are profound.

In the first place, IT innovation is extraordinarily rapid and characterized by continuous incremental improvements over the prior art. Although some advances are technological "leaps," most innovation is cumulative, achieving modest gains over earlier versions of software or adapting known programming techniques to achieve new functional operations. The sheer pace and scale of innovation in

143. The Patent Crisis, supra note 17, at 47, 65.
144. See, e.g., Symposium, Molecules vs. Information: Should Patents Protect Both?, 8 B.U. J. Sci. & TECH. L. 190, 191 (2002) ("In recent years, we have been seeing similar kinds of [opposition] focused on the practice of patenting DNA sequences, but nothing like that happened when people first started patenting genes in the early days of the biotechnology industry, some twenty years ago." (statement of Professor Rebecca Eisenberg)).
146. But see Boldrin & Levine, supra note 2, at 15.
149. E.g., id. at 65.
152. See Policy Levers, supra note 106, at 1620.
the field quickly renders even initially valuable contributions defunct. For that reason, computer-software patents enforced in court rarely cover what is then a cutting-edge technology.\textsuperscript{153} In short, the protracted R&D process in such areas as pharmaceuticals, chemicals, and biotechnology—which gives rise to significant inventions of enduring value—is completely unlike that present in the IT industry. Prospect theory may accurately encapsulate innovation in the former industries, but it does not in the IT industry.\textsuperscript{154} As follow-on innovation pervades the IT sector, providing initial inventors broad exclusive rights over the use and future improvement of their software (or other technology) is apt to create undesirable transaction costs that threaten to stymie cumulative invention. Enhancing the initial inventor's incentive to invent through the provision of a strong property right serves to reduce that incentive for future improvers. This tradeoff always exists,\textsuperscript{155} but with respect to computer software and IT, it is one biased toward improvers, who play a more important role than original inventors.

Second, R&D in the IT field is far less capital intensive than that of pharmaceuticals, biotechnology, and chemistry.\textsuperscript{156} The requisite private investment to develop new software, for instance, is relatively modest.\textsuperscript{157} One need not pay for expensive laboratory equipment and clinical testing. Although nominally significant, such sums are paltry compared to the sunk costs involved in researching and developing a new drug. Furthermore, as Dan L. Burk and Mark A. Lemley point out, although debugging may be tiresome, it does not compare to negotiating the maze of FDA regulatory requirements.\textsuperscript{158}

Third, inventors in the IT field have multiple avenues through which to appropriate the value of their technological advances. Computer software, particularly when written in nonhuman-readable object code, is relatively difficult to reverse engineer.\textsuperscript{159} Given its non-self-disclosing nature, software is hardly a paradigm for the non-excludable quality typically associated with public goods. Further-

\begin{itemize}
  \item \textsuperscript{153} The Patent Crisis, supra note 17, at 57.
  \item \textsuperscript{155} See generally Merges & Nelson, supra note 9.
  \item \textsuperscript{156} See Fed. Trade Comm’n, supra note 71, at 2.
  \item \textsuperscript{158} The Patent Crisis, supra note 17, at 156–57.
  \item \textsuperscript{159} Peter S. Menell, Envisioning Copyright Law’s Digital Future, 46 N.Y.L. Sch. L. Rev. 63, 74 (2003).
\end{itemize}
more, copyright protects software developers against direct copying.\(^{160}\) In addition, the first-mover advantage, which is driven by the network effects present in the IT sector, rewards purveyors of new software and other information technologies with a direct pecuniary return.\(^{161}\) Given the ratio of original-inventor R&D investment to third-party reverse-engineering costs, IT innovators enjoy significant incentives to invent independent of the patent system.

Fourth, with respect to semiconductors, other forms of computer hardware, and the IT field generally, each instance of patent-eligible invention tends to cover a technology that is but a subset of the art required to commercialize a final product.\(^{162}\) Unlike drugs, each of which tends to be covered by a single patent, products in the IT and computer-hardware industries are invariably subject to "dozens, hundreds, or even thousands of patents."\(^{163}\) Due to a figurative explosion in the number of IT patents that the USPTO has issued since \textit{State Street Bank \& Trust Co. v. Signature Financial Group} in 1998,\(^{164}\) the law charges companies operating in the field with identifying and inventing around, or negotiating a license for, countless patents.\(^{165}\) To make matters worse, the written claims of IT patents are notoriously indeterminate, such that even those skilled in the art are often unable to make an informed judgment whether a particular patent encompasses a planned product or process.\(^{166}\)

As a result, large companies in the IT field have accumulated vast patent portfolios, which they largely maintain for purely defensive purposes.\(^{167}\) Various private-ordering solutions have emerged as companies enter into broad cross-licensing agreements and patent pools.\(^{168}\) Although these arrangements facilitate the commercialization of final products, some consider their efficacy to be limited.\(^{169}\)


\(^{163}\) See \textit{id}.

\(^{164}\) State St. Bank \& Trust Co. v. Signature Fin. Grp., 149 F.3d 1368 (Fed. Cir. 1998).


\(^{167}\) See \textit{The Patent Crisis}, supra note 17, at 55.


In particular, these arrangements do not solve the so-called “patent-troll” phenomenon, which broadly defined involves nonpracticing entities’ acquisition and enforcement of numerous patents that did not provide the basis for the commercialized products accused of infringement.170 Furthermore, existing private-ordering solutions grant large-scale competitors a significant advantage over their fringe rivals, which lack comparable portfolios and hence possess less bargaining power.171

Fifth and finally, many observers have criticized the poor quality of IT patents that the USPTO issues.172 Given the vast number and indeterminate scope of patents in the field, many companies instruct their researchers not to search the prior art.173 Deliberate ignorance of this kind permits companies to avoid willful-infringement liability.174 Yet, this phenomenon is perverse not only because it means that IT patents rarely contribute technological knowledge that facilitates ongoing innovation, but because it leads the USPTO to grant some patents that are invalid in light of the prior art. Applicants are under a duty to reveal prior art of which they are aware—the law does not require them to search for anticipatory references.175 The result is that examiners approve many nonnovel or obvious “inventions” in the IT field.176

The net consequence is that patents play a controversial role in the IT industry. Indeed, many observers contend that the law should abolish patents from the field entirely.177 Such commentators are not bereft of support, given anecdotal evidence in the form of vociferous
condemnation by management in the industry and empirical studies showing that such IP rights are rarely a but-for cause of innovation in IT.\\footnote{178}

Nevertheless, abolishing patents over computer software and other forms of IT is less straightforward than might initially appear. In the first place, no satisfactory definition of a computer-software patent has emerged.\\footnote{179} Countless inventions that would otherwise qualify as patent-eligible machines or processes entail the use of software. Surely, one would not wish to deny such technology patent protection on account of its use of software (be it tangential or central).

Furthermore, there may be a role for patents within the industry. Such rights surely induce at least some inventors to develop information technology that they otherwise would not. Unlike biotech or pharmaceutical innovations, which rivals can rarely invent around, any number of computer-program innovations can achieve the same result as another company's new software, even if the former programs perform that identical function in an entirely dissimilar way.\\footnote{180} For that reason, the fact that a software company's output is not readily susceptible to reverse engineering does not mean that the firm can necessarily appropriate a sufficient degree of the value of its innovation to warrant its ex ante R&D expenditures.\\footnote{181} One must recall that copyright provides a narrow band of protection, preventing third parties from directly copying a particular form of expression.\\footnote{182} It does not offer a copyright holder exclusivity over the functional characteristics of her innovation.\\footnote{183}

Consistent with this insight, some of the most influential commentators on the patent system do not advocate the wholesale abolition of those IP rights from the IT industry. Instead, they counsel a cabined role for patents in the field.\\footnote{184} Specifically, they contend that IT pat-
F. Summary

As the preceding discussion should make clear, the patent system's one-size-fits-all rules fit awkwardly with the heterogeneous quality of innovation that takes place in the industries subject to the patent regime. As the interests of any one industry may be in some tension with those of others, identifying the optimal contours of patent protection, as well as efficient doctrines within the law, is a vexing task. Since one's attempt to reform the patent system is apt simultaneously to attract enthusiastic praise from one corner and fierce opposition from another, it is difficult to achieve consensus. Consistent with these difficulties, Congress failed for several years to pass reform legislation, until it finally succeeded in doing so in September 2011, when it passed the AIA.\textsuperscript{186}

Given the context-specific nature of innovation, the myriad factors that weigh upon optimal rates of investment in R&D, and the complexity of devising efficient policies for inducing the same, IP policy faces a vexing dilemma. The following Part explores a subset of the major controversies that currently afflict the patent regime. That discussion, in conjunction with the preceding account of the heterogeneity of industrial innovation, explains why policymakers find themselves in a bind. Indeed, optimal patent rules are so elusive as a practical matter that one wishing to craft policy can achieve a modicum of certainty only by embracing a quasi-relativist perspective, which aims to promote the interests of particular industries over others. When judges, USPTO officials, and academics try to go further—advocating broad policy prescriptions for the patent system as a whole—they likely do so in an indeterminate, and hence error-prone, manner. The next Part suggests an approach that would enable policymakers to analyze at least some issues of contemporary importance in a more objective light.

III. Systemic Bias in Patent Law

A. Error-Free Application of the Patent Laws

There is an important distinction between the existence of a truth and the availability of means by which to demonstrate the same. Some questions have definite but unidentifiable answers. The nature

\textsuperscript{185} Id. at 158–60.

of an incentive mechanism that would spur the perfect level of innovation is such an example. The contours of an optimal IP regime do not possess a metaphysical quality, for one can be confident that there in fact exists a series of policies that best encompass the sometimes-conflicting issues of incentivizing invention, commercialization, and improvement on the part of myriad actors in the economy.\textsuperscript{187} In this abstract sense, one might characterize IP policy as possessing a determinative quality.

Even though one could model such a comprehensive body of rules within the parameters of economic theory, epistemological limitations and the cost of the legal system combine to foreclose society's identification and use of optimal patent rules. Given the information-deprived setting within which policymakers actually operate, as well as the heterogeneous qualities displayed by the various industries subject to the patent system, one may have to adopt a quasi-relativist perspective in order to pronounce reasonably determinate prescriptions. When one must articulate principles of horizontal application to such diverse fields as biotechnology, semiconductors, computer software, and chemicals, it is almost inevitable that the proposed rules will negatively impact innovation in some settings and promote it in others.\textsuperscript{188}

Those called upon to address contemporary issues in the patent system, including those introduced in the previous Part, face a quagmire. If one embraces the interests of the pharmaceutical, chemical, and biotechnology industries, there may be good ground for upholding the Federal Circuit's clear-and-convincing standard, the entire-market-value rule, and the legality of pay-for-delay agreements—three controversial tenets of patent law discussed below. If one instead promotes the interests of the computer-software, computer-hardware, and IT sectors, then precisely the opposite conclusion follows. What should policymakers do? One answer is that they should analyze a contested issue to determine its capacity to induce systemic error on the part of those who would apply it.

To place the analysis in context, envision an error-free patent system. In this hypothetical environment, judges, juries, and examiners would accurately apply every tenet of the patent regime, free from bias and capacity to blunder. Why conduct this academic exercise?

\textsuperscript{187} Such efficient rights would, of course, have to be fluid and dynamic, being able to evolve costlessly and instantaneously in the face of changing industry conditions. Moreover, such a system would likely entail the use of complementary incentive mechanisms, such as prizes and regulatory policy, to achieve optimal levels of innovation at the lowest possible social cost.

To view any given policy question in this light is to free oneself from the charged presumptions that too often accompany any divisive issue of note. Such a perspective reveals the extent to which the problems associated with a controversial policy are inherent in the policy itself or instead stem from the tendency of those charged with applying the legal system to go astray. To illustrate this hypothetical inquiry, consider three contemporary policy issues: (1) the relevant evidentiary burden that one must satisfy in order to invalidate a patent in court; (2) whether a company can pay one who disputes the validity of its patent in a legal proceeding to settle the case and concede validity; and (3) whether it is appropriate to determine patent damages by reference to the profitability of the infringing product. Each of these questions has attracted considerable controversy.

First, in a flawlessly implemented patent system, the relevant evidentiary showing necessary in order to invalidate a patent would be irrelevant because the USPTO would only issue patents that meet the statutory requirements of the Patent Act. From this perspective, policymakers would be indifferent to clear-and-convincing and preponderance-of-the-evidence interpretations of the presumption of patent validity. If one were to relax the "no-error" assumption on the part of the USPTO only, however, there would appear to be no basis for a clear and convincing evidence standard for litigants attempting to establish asserted patents' invalidity. A preponderance of the evidence standard would yield accurate determinations in every case, as juries would invalidate patents not meeting the requirements of §§ 101–112, while upholding the validity of those patents that do. Conversely, the current standard would accurately, though inefficiently, affirm the validity of a patent in circumstances when the weight of the evidence marginally favored a finding of invalidity.

Second, again assuming no error on the part of both the USPTO and the courts, patentees would properly enjoy an absolute right to settle with alleged infringers on any terms they wanted, save for terms going beyond the scope of the relevant patent. In an error-free

---

189. The meaning of "patent scope" is fundamental to IP law, though the concept is surprisingly ill defined. At the most fundamental level, a patent's scope is coterminous with the proper construction of the relevant claims. A court's interpretation of the same pursuant to a Markman hearing establishes the patentee's "zone of exclusivity." See, e.g., John M. Golden, Construing Patent Claims According to Their "Interpretive Community": A Call for an Attorney-Plus-Artisan Perspective, 21 HARV. J.L. & TECH. 321, 322 & n.1 (2008).

One who operates within that field of lawful monopoly must do so with the permission of the patent holder. The probabilistic nature of patent rights, however, complicates the concept of scope. When one artificially bolsters the expected validity of one's patent by creating an impediment to challenging it in court, does that action carry with it anticompetitive effects going be-
world, patentees could pay generic-drug producers whatever they wished to refrain from entering the market. Of course, with an unquestionably valid patent—and assuming no dispute as to claim construction and ensuing reach of the patent—pioneer-drug manufacturers would be unlikely to pay anything.

If one were to again introduce error into the USPTO’s, but not the courts’, operations, litigants’ current right to enter into reverse-exclusionary agreements in the pharmaceutical industry—save where there is clear evidence of the asserted patents’ invalidity or noninfringement—may appear to be undesirable. Where the evidence available to the court shows that the patent is more than likely invalid or not infringed, allowing a pay-for-delay agreement permits the patentee to appropriate greater value from its IP than Congress granted it through the Patent Act. If one accepts the parameters of patentability set forth in §§ 101–112 to be coterminous with the socially desirable level of property protection in the pharmaceutical industry, pioneer-drug manufacturers’ reverse-exclusionary agreements allow them to artificially enhance the expected validity of their patent rights. This would necessarily result in patentee overcompensation.

Where agencies but not the courts err, the law would efficiently allow pharmaceutical companies to enter into these arrangements only when the evidence makes it more likely than not that the underlying patent is valid and infringed.

With respect to the entire-market-value rule, which requires fact finders to base their damage calculations for infringement on the profitability of the infringing product, a flawless patent system would yield accurate damage determinations. When the accused product involves myriad technologies, of which the asserted claims capture only a modest subset, juries would correctly discount the market value of the accused device by the patent’s percentage technological contribution. Juries would similarly calculate a reasonable royalty by reference to hypothetical negotiations that would have taken place ex ante, as opposed to ex post.

---

190. Compound and formulation pharmaceutical patents have well-established meanings to those skilled in the art, so disputes over claim construction in that industry are relatively rare.

191. Such a normative baseline is open to question, for reasons addressed below, though employing a different metric raises problems of legitimacy.

192. This result, however, follows only if one accepts that the optimal degree of patent protection is what follows from accurate application of the conditions of patentability enshrined in the Patent Act.
One might deride the preceding observations on account of their lack of realism. Yet, viewing a policy question in this first-best light, unfettered by the practical problems and imperfections that invariably accompany real-life issues, serves a valuable illuminative purpose. It reveals that a particular tenet of patent law may exist to remedy or contain courts’ capacity to err. Similarly, it may demonstrate that a rule’s controversial nature follows only from judges’, juries’, and examiners’ tendency to misapply it. This, too, is valuable information. If appeal to an error-free legal environment suggests that the relevant rule would have no inefficient repercussions, it enables interested observers to focus on the nature of the policy challenge, which is not necessarily the substantive rule being scrutinized, but the phenomenon of those responsible for failing to properly apply it.

Of course, contemporary criticism does not arise from challenged policies’ negative impact in a hypothetical world in which the legal system operates perfectly. Instead, critics rail against the clear and convincing evidence standard because they believe that it accentuates the tendency of courts to mistakenly uphold the validity of a patent that falls short of statutory conditions of patentability.\textsuperscript{193} It is the tendency of judges, juries, and examiners to misapprehend the nature of the claimed invention in light of the prior art that makes the evidentiary threshold for invalidating a patent pertinent at all. Given relevant actors’ inherent capacity to err—a tendency that is magnified in the patent realm vis-à-vis other settings on account of the former’s unique complexity—the clear and convincing evidence requirement arguably serves to accentuate that capacity.

Commentators likewise criticize pay-for-delay agreements, in part because the courts’ permitting many such arrangements aggravates the problem of the USPTO’s erroneously issuing “bad patents.”\textsuperscript{194} Not only may such arrangements allow patentees to derive value from patents that they should never have received, the courts’ limited capacity to make the pretrial determinations of validity and infringement that are necessary for upholding the validity of reverse-exclusionary payments also ensures that they are likely to commit a high proportion of Type II errors.\textsuperscript{195} Similarly, the current-market-value rule exacerbates jurors’ tendency to calculate damages incor-

\textsuperscript{193} See, e.g., Brief of Computer & Commc’n Indus. Ass’n as Amicus Curiae in Support of Petitioner, Microsoft Corp. v. i4i Ltd. P’ship, 131 S. Ct. 2238 (2011) (No. 10-290).


\textsuperscript{195} A Type I error refers to a false positive, while a Type II error refers to a false negative. See, e.g., Jason R. Bent, The Telltale Sign of Discrimination: Probabilities, Information Asymmetries, and the Systemic Disparate Treatment Theory, 44 U. Mich. J.L. REFORM 797, 823 (2011).
rectly, which magnifies the Type I error cost of a court’s mistaken determination of infringement.

The same analysis holds true for a host of divisive issues of patent law decided by the Supreme Court in recent years. Patentees’ automatic right to injunctive relief in the event of established infringement would not be problematic if the courts and the USPTO never erred, for courts would grant equitable relief only in actual cases of valid patents’ infringement. The Court’s ruling in MedImmune, which granted licensees standing to bring declaratory judgment actions of invalidity, would be unnecessary if the USPTO never issued bad patents. The alleged problem pre-MedImmune was that licensees were reluctant to cease royalty payments and thus risk liability for patent infringement, which was a prerequisite of standing to challenge the licensed patent’s validity or infringement.

Similarly, the Court’s rejection of the “teaching-suggestion-motivation” test as a rigid test of obviousness would have been meaningless absent judicial and institutional capacity to err. In an error-free world, examiners and judges would reject and find invalid, respectively, any purported invention that would have been obvious to one skilled in the art. These determinations would, in such an environment, be invariant to the technical test giving rise to them. Given the hypothetical, backward-looking nature of the obviousness inquiry, however, the real-life probability of courts and examiners reaching an erroneous conclusion is significant. The Court saw fit to alter the means by which those entities engage in the relevant analysis because it determined that the judiciary was committing a disproportionate number of Type II errors.

Interestingly, those who wish to restrict patent-eligible subject matter necessarily presuppose critical levels of examiner and judicial error. Many advocate the scaling back or wholesale elimination of patent protection for entire fields of innovation, especially business methods, but also computer software and IT. Some urge lawmakers to deny protection to gene sequences and medical-diagnostic tests founded on biotechnology. Such a large-scale retraction of patent protection would be imprecise, inevitably entailing

196. This assertion must be qualified on the basis that it assumes optimal scope and duration, as well as obviousness and disclosure requirements.
200. See, e.g., id.
Type I and II errors in application. One could defend such a policy by pointing to judges', juries', and examiners' more frequent and severe misapplication of the novelty, nonobviousness, utility, and disclosure conditions of patentability. Correct application of these conditions would effectively foreclose negative effects of the kind that critics could proffer in support of restricted subject matter. One might read *Bilski* as vindicating the view that the system is not as heavily error prone as some commentators suggest.\(^{201}\)

It follows that most criticized features of the contemporary patent system are controversial due to the many imperfections inherent in the judiciary's and the USPTO's operations. This fact raises the question whether judges', juries', and examiners' inaccurate application of patent rules may in itself give rise to a mode of critical analysis within which one could explore the optimal contours of any given doctrine.

**B. Analyzing Patent Policy Through the Lens of Systemic Bias**

Courts, examiners, and academics operate in the real world and are thus subject to the full panoply of limitations and constraints that bind us all. As the preceding discussion explained, hostility to a particular rule invariably emanates from that rule's misapplication, rather than from the consequences of its accurate enforcement. This might seem to be an academic observation, but it necessarily raises an important question. If courts regularly misapply tenets of patent law, what is the social harm?

1. *Departures from the Mean May Cancel Each Other out over Time*

   The answer to the posed query might appear self-evident, but it is not. Many of us are accustomed to framing questions of justice in case-specific terms, such that we are not indifferent to two erroneous decisions if their respective consequential effects cancel one another out.\(^ {202}\) Within the utilitarian framework of patent jurisprudence, however, policy would properly subsume case-specific determinations of optimal property protection within the larger question whether the ex ante expected value of innovation aligns with the social optimum. Counterintuitively, it is possible that courts could misapply a rule in

---

\(^{201}\) *Bilski* v. Kappos, 130 S. Ct. 3218, 3226–27 (2010) (holding that the machine-or-transformation test is not the exclusive test of patentability for process claims).

\(^{202}\) For instance, many people would object to a situation in which a court mistakenly acquitted a person of a criminal offense and then later erroneously finds him guilty of a distinct, though similarly serious, offense.
every case, and yet impart efficient incentives to invent. To be clear, it is unlikely that any one misapplication of law, or determination of fact, would give rise to an optimal expected reward ex ante. Nevertheless, across many parties, over time, and with a sufficient number of cases, the average of all outcomes may approach the optimal reward.

One could illustrate this possibility in many ways. Take the example of damages. Assume that a court has correctly found an asserted patent valid and infringed, such that the sole remaining issue concerns the patentee’s proper compensation. Suppose that the particular defendant had been a prospective licensee of the patented technology but, after negotiations, had elected to eschew a license. The defendant (a prospective licensee) mistakenly believed that it could invent around the patent by designing its product to avoid the scope of the claims. Due to the parties’ noncredible assertions as to their respective reservation prices, the jurors would lack conclusive means to identify the price to which the parties would have agreed absent the infringement. If that royalty term were $2 million per year and the jury returns a damage award of only $1.5 million, the judicial system would have undercompensated the patentee.

What if the preceding defendant were just one of several infringing companies? Offensive nonmutual issue preclusion would not apply to the first jury’s damage award unless the facts relevant to the calculation were identical to subsequent cases. If it were to apply, however, it would perpetuate the mistake over all cases initiated by the same plaintiff over the same patent. Assuming the nonapplication of collateral estoppel, though, subsequent cases would likely yield a range of damage determinations around the $2 million mark. This would hold true if the plaintiff brings suit against each of these infringing entities, the parties do not settle, each jury is privy to the same information that the first one enjoyed in returning a $1.5 million verdict, and no judge in any case makes mistaken evidentiary rulings that bias the expected outcome.

There are far too many variables to expect a given patentee’s compensation to be optimal over a limited number of lawsuits. Nevertheless, if one were to expand consideration to include all patentees

---

within the relevant field of innovation, other things being equal, one would expect the mean reward to approximate the correct one.

Case-specific departures from optimal compensation can and do occur in countless ways. Juries may seriously err in unfathomable cases involving financial harm of indeterminate magnitude. Such instances might involve the profit that would have flowed from sales that never took place or a license that would have opened up larger business opportunities. A court may grant injunctive relief in circumstances when a correct application of the four-factor test in equity would have directed the opposite result. Patentee overreward may occur when the courts (or the USPTO) fail to invalidate (or reject) an obvious, nonnovel, nonuseful, or nonenabled claimed invention, or when courts give claims a broader construction than comports with the patentees' actual invention.

Yet, each instance of overcompensation may in itself be irrelevant, depending on the relative incidence and magnitude of cases of undercompensation. The tendency of the courts and the USPTO to err stems from the amorphous, and hence probabilistic, nature of the many questions they are called upon to address. Contested factual issues, complex legal questions (such as claim construction), and myriad other imponderables that weigh upon determinations of scope, validity, infringement, and damages require decisionmakers to rule in circumstances of incomplete information. Each individual case is unlikely to yield patentee reward precisely commensurate with the social optimum. Instead, outcomes in patent-infringement suits are likely to occupy a spectrum—most will depart from the objectively correct result, some toward overcompensation, others toward undercompensation. Over the long run, though, deviations from the mean should cancel one another out. If judges, juries, and examiners strive to reach the correct outcome, given the information at hand, then their case-specific departures from the right result are as likely to be in one direction as they are in the other.

The fact of ex post error—even if it is pervasive—may therefore be irrelevant to ex ante incentives. Inventors spurred by the patent system to innovate do so on a forward-looking basis. It is the expected value of R&D that drives such risk-neutral entities to engage in the costly process of invention. By the time a court erroneously invalidates a pharmaceutical patent, for instance, which protected hundreds

205. See supra note 32 and accompanying text.
206. Large-scale inventors are likely to be risk neutral as they are apt to hold a diversified portfolio of ongoing research projects, the risk profiles of which do not correlate with one another. Start-up companies, however, are more likely to be risk averse, such that pervasive inci-
of millions of dollars' worth of R&D costs, the relevant company's innovation is already a completed act. To the extent such a mistaken ruling has pernicious consequences, they are largely limited to innovation processes that companies have yet to undertake.\textsuperscript{207} Such suppressive effects on dynamic efficiency are serious, of course. Yet, erroneous rulings of this sort need not distort incentives. To continue the example in the context of pharmaceuticals, if a court upholds the validity of a patent in circumstances where it should not, that ostensible windfall in fact combines with instances of erroneous deprivation to render the expected value of innovation equal to the social optimum. Of course, this does not mean that the law achieves horizontal equity or that each individual patentee actually receives the socially desirable level of compensation. Nevertheless, such a patent system would impart desirable incentives ex ante on risk-neutral inventors. In this respect—if the mean compensation bestowed by the patent system is equal to the optimal level—the quality of the patent system may be invariant to the standard deviation of the return granted patentees within a population of patent-infringement decisions.

Of course, the larger question of that system's efficiency would be rather more complicated. Although companies that have a diversified portfolio of investments are likely to be risk neutral, some innovators—particularly individuals or start-up companies, which depend on the success of a limited number of projects for their survival—may be risk averse. A patent system that facilitates patentee reward of high variance around the (optimal) mean would undercompensate such inventors.

Furthermore, it may not be the case that even optimal ex ante incentives translate into an efficient patent regime. Incentives to commercialize are also important, particularly with respect to capital-intensive or risk-filled industries that require considerable post-patent-grant investment to market the technology-bearing product.\textsuperscript{208} Erroneous deprivation in such settings may impose uncontained costs that a separate mistaken recognition of a patent would not eliminate. Similarly, incorrect recognition of patent rights in settings of rapid cumulative innovation stymies the efforts of third-party improvers, thus disrupting scientific progress in a serious way. Erroneous application
dences of under- and overreward will provide insufficient incentives to invent if the mean expected reward is equal to the optimal level.

\textsuperscript{207} An important exception is erroneous validations occurring pre-commercialization in circumstances where marketing entails considerable investment and is vulnerable to free riding by third-party competitors.

of the patent laws may therefore carry inefficiency-inducing externalities, even if the expected reward under those laws equals the optimal level.

Despite these complications, it remains true that case-specific departures from optimal patentee compensation need not skew ex ante incentives to invent, which remain the primary concern of the patent system. This Article is concerned, however, with circumstances in which the mean compensation for patentees departs significantly from the optimal level. To the extent particular features of the patent system give rise to such systemic bias, they are undesirable. The following discussion explores the possibility that certain tenets of patent law invite consistent under- or overreward on the part of patentees.

2. Systemic Bias in Patent Law

There are a variety of reasons to believe that courts and the USPTO display a bias in certain cases. That is, despite their sincere efforts, they may render determinations that consistently result in under- or overcompensation, depending on the context. To the extent it exists, such systemic bias leads to long-run departures from the efficient level of compensation and hence skews incentives to invent and commercialize. Yet, more must be said about the phenomenon of systemic bias and the manner in which it materializes. The concept is in some respects a perplexing one, as one would normally expect that competent actors who endeavor to reach the correct result would succeed in doing so on average—that is, in many cases over time. Bias in this context arises from frame of reference. It is well known in the behavioral literature, for example, that one can significantly influence survey outcomes by phrasing the same substantive question in different terms. Framing may have a particularly powerful impact in conditions of uncertainty, such as those of incomplete information, factual complexity, or other environments where determinative conclusions are elusive. Patent cases, of course, invariably display such traits. It is well established that people, acting in situations of


211. See, e.g., On Amir & Orly Lobel, Stumble, Predict, Nudge: How Behavioral Economics Informs Law and Policy, 108 Colum. L. Rev. 2098, 2112 (2008) (noting the well-established bias of reference dependence; namely, "the tendency to judge things not in absolute value, but rather in relative terms as compared to some focal level (the reference point)").

great complexity or uncertainty, resort to heuristics to inform their decision making. Those heuristics, in turn, are themselves vulnerable to systemic bias.

Given the imprecise nature of proof, the metaphysical quality of claim-term meaning with respect to certain arts (particularly IT), the speculative process of determining damages using counterfactual frames of reference, and the byzantine nature of some technologies that confounds layperson understanding, the questions that the patent system puts to judges and juries are fraught with uncertainty. In such an environment, the law should endeavor to present legal and factual issues to the relevant decision maker in a neutral manner designed to facilitate unbiased determinations. This is a principle of uniform application, the normative legitimacy of which transcends any one industry. It may indeed be the case that industry-specific analysis can guide courts toward a superior patent system, but screening for systemic bias is an independently desirable goal.

To present a sustained analysis of bias in the patent system, this Article considers certain areas of contemporary discord within the patent field. This discussion begins by examining the Federal Circuit’s clear and convincing evidence standard, proceeds by exploring the nature of the entire-market-value rule and the courts’ reception of pay-for-delay agreements, and then scrutinizes a number of policy issues that have recently been the subject of Supreme Court rulings. The Article concludes by questioning certain aspects of the patent system’s one-size-fits-all constitution in light of the disparate industry settings to which it applies.

a. Clear and Convincing Evidence as an Impediment to Patent Invalidation

The Patent Act bestows every issued patent with a presumption of validity. Congress left it to the courts to specify the legal effect of this presumption. The Federal Circuit has long required, and the Supreme Court recently confirmed, that the party wishing to invalidate a patent prove its invalidity by clear and convincing evidence. Such a


215. See Microsoft Corp. v. i4i Ltd. P’ship, 131 S. Ct. 2238, 2242 (2011).
showing obviously surpasses the typical evidentiary burden one faces in civil proceedings, which is a preponderance of the evidence.\textsuperscript{216}

Whence cometh the presumption? Its rationale is hardly esoteric. The USPTO is an expert agency, comprised of examiners who work on applications involving technologies with which they are familiar.\textsuperscript{217} The USPTO grants an allowance only after the pertinent examiner, who is skilled in the art, scrutinizes the claimed invention, engages in the relevant to-and-fro with the applicant, and rejects any claims that he or she perceives to be inconsistent with the requirements of the Patent Act.\textsuperscript{218} As the sphere of patentable subject matter encompasses an eclectic range of byzantine—indeed, occasionally exotic—technologies, an expert agency's determination of patentability is surely entitled to deference.\textsuperscript{219}

Courts, by contrast, are comprised of lay judges, juries, and law clerks, none of whom (save by chance) is fluent in the relevant technological underpinnings of the patents with which they are presented. Indeed, patented claims are sufficiently complex that a number of observers have questioned the courts' institutional competence to make informed determinations of claim construction, validity, and infringement.\textsuperscript{220} Given the asymmetric scientific expertise possessed by the USPTO and the courts, it is only natural that the latter would defer in some way to the former's conclusions.

Nevertheless, the clear and convincing evidence standard has been a lightning rod for criticism.\textsuperscript{221} Experience has revealed that the USPTO's substantive expertise is, in certain important respects, illusory. Although the agency assigns examiners to applications based on
their familiarity with the relevant art, a variety of factors undermine the reliability of the USPTO's conclusions. The reason is simple: the sheer volume of applications that the USPTO receives overwhelms the agency. Although it increased the number of allowances from 189,120 in 2009 to 240,438 in 2010, in the latter year there were 726,331 utility, plant, reissue, and design applications pending before the USPTO. Due to the backlog, the average current pendency is almost three years. Despite the amount of time applications remain before the USPTO, examiners spend only, on average, eighteen hours on each one. The applicant, who is presumably more closely acquainted with the field, is under no duty to conduct a search of the prior art. She must merely reveal that of which she is aware. Third parties, who may also be knowledgeable, traditionally played no role in the prosecution process, though this will change to some degree on account of the AIA.

Further problems exist. Examiners are compensated under a count system, which only credits the first action (the examiner's initial determination of patentability) and the disposal (when the USPTO issues a patent or the applicant abandons the application or files a request for continued examination [RCE]). This system gives examiners a pecuniary incentive to spend less than the optimal number of hours on complex applications. Furthermore, anecdotal reports recount a culture of permissibility at the USPTO, such that the agency tends to resolve borderline questions in the applicant's favor. Finally, and oddly, the continuation procedure means that an examiner can never dispose, once and for all, of an undeserving application. She may issue what is misleadingly known as a "final rejection," but an applicant

---

223. Id. at 12.
226. See USPTO, supra note 218, § 1.56.
228. Cf. USPTO, supra note 222, at 18 ("One significant change was the count system which gave examiners more time to examine each application as a clear sign that quality is [the USPTO's] first priority.").
is free to file an RCE and restart the prosecution process.\footnote{Mark A. Lemley \& Kimberley A. Moore, Ending Abuse of Patent Continuations, 84 B.U. L. Rev. 63, 67–68 (2004).} Thus, the only way an examiner can get rid of a recalcitrant applicant is to allow the application.\footnote{See id. at 68.}


This is perhaps the paradigmatic example of systemic bias. Under the preponderance of the evidence standard, a court is "correct" to find a patent valid if the weight of the evidence establishes that it is marginally more likely than not to be invalid. The Federal Circuit's interpretation of the presumption of validity thus shifts the relevant metric from whether the patent is more probably valid than not to whether the evidence makes such invalidity clear. Assuming that judges and juries endeavor to reach the result prescribed by law, under the clear and convincing evidence standard they will accurately, yet perversely, render decisions that systemically overcompensates patentees. Thus, if one credits the view that the Patent Act establishes a neutral framework for applying innovation-maximizing principles of patentability to a wide variety of inventions, then one should oppose an evidentiary burden that consistently skews the outcome of the judiciary's analysis.

Yet, as is invariably the case with respect to any issue of contemporary importance to the patent system, controversy exists. The legitimacy of the clear-and-convincing standard is bitterly contested. Given the broad spectrum of characteristics displayed by the many different industries under the patent regime's charge, it should be unsurprising that a proposed measure that would dilute patents' prophylactic effect would be welcomed by some and reviled by others. Predictably, the pharmaceutical industry fiercely opposes any weakening in the presumption. Conversely, companies practicing in the IT sector welcome
the prospect of being able to invalidate a patent by no greater a showing than a balance of probabilities.233

Who is right? The answer might depend on whose interests one wishes to promote. Given pharmaceutical and certain biotechnological companies' vulnerability to third-party appropriation—and hence greater reliance on patent protection—it is certainly conceivable that bolstering IP protection through the imposition of a demanding evidentiary burden to invalidate patents would lead to greater levels of innovation.

Yet, such a defense of the clear-and-convincing rule encounters two major problems. The first is founded on legitimacy. If one applauds a court's upholding an improvidently granted patent, one's normative baseline is necessarily distinct from the constituent elements of patentability laid down by congressional mandate. This need not be fatal, for those charged with running the patent system should not be blind to the consequences of their actions with respect to innovation incentives. Nevertheless, the issue of legitimacy fatally combines with the larger problem of trans-industry effect to undermine the clear-and-convincing rule. Even if one believes that courts should uphold marginally invalid patents in capital-intensive research industries such as pharmaceuticals and chemicals, this does not translate into an equivalent policy prescription for other industries.234 As noted above, the divergent innovation characteristics of different markets suggest that an effective policy in one setting may have negative repercussions in others. As society lacks the means to weigh the depressive effects of a rule on innovation in one industry against that rule's desirable impact in others, the author argues that the issue of legitimacy should control.235 Thus, if policymakers can agree that a rule that leads to systemic departures from compliance with the statutorily required tenets of patentability, they should proscribe that particular rule.

The Article therefore concludes that Congress should jettison the clear and convincing evidence rule, which serves to induce systemic departures from judicial determinations of optimal compensation.


234. Indeed, given the plethora of business-method, computer-software, and other IT patents, many of which are of dubious validity, such an artificial impediment to invalidation is most unlikely to be efficient. See generally Mark A. Lemley, Rational Ignorance at the Patent Office, 95 Nw. U. L. REV. 1495 (2001). This conclusion is bolstered by the negative effects of the patent system in these fields, as explored in Part I.

235. As noted below, reverse-exclusionary payments are distinct because their impact is limited to a single industrial setting: biopharmaceuticals.
Unfortunately, on June 9, 2011, the Supreme Court declined the opportunity to revisit this aspect of the law, and so a solution—if it will arise at all—lies in the hands of Congress. In September 2011, in enacting patent-reform legislation, Congress unfortunately declined to specify a balance-of-probabilities standard.

b. The Entire-Market-Value Rule and the Risk of Patentee Overcompensation

It is well settled that a patentee, in the event of established infringement, is entitled to damages, which cannot be less than a reasonable royalty. This principle is not controversial. The same cannot be said for the manner in which some courts have gone about calculating that royalty. As Part I explained, products in different industries differ dramatically in the number of patents to which they are typically subject. Marketed drugs are usually subject to a single patent, while hundreds, if not thousands, of patents may cover a single semiconductor or other components of computer hardware. Common sense suggests that the consequences of infringing a single patent should differ depending on whether the infringed technology subsumed the entire infringing product or merely covered a modest subset of it. Two tenets of patent jurisprudence obscure this distinction—one blatantly, the other more subtly.

In the first place, the courts have—until very recently—adopted a twenty-five percent rule of thumb in calculating a reasonable royalty, pursuant to which a fact finder would initially presume that a hypothetical licensee would pay the patentee a royalty equal to one quarter of the profit that the hypothetical licensee would expect to receive on sales of the product incorporating the patented technology. In early 2011, the Federal Circuit put this arbitrary presumption to rest.

A second feature of patent-damage jurisprudence bears more subtle potential for harm. In calculating damages, the courts have fashioned the so-called “entire-market-value rule,” by which they appeal to the actual profits realized through commercial sales of the infringing product. The courts treat those sales as a metric by which to

236. Microsoft Corp., 131 S. Ct. at 2252.
239. See FED TRADE COMM’N, supra note 103, at 179–212.
240. See Uniloc USA, Inc. v. Microsoft Corp., 632 F.3d 1292 (Fed. Cir. 2011).
241. Id. at 1315.
determine a reasonable royalty. Some observers have criticized this rule, contending that it has led juries to consistently overreward patentees, especially in the electronics and computer industries.  

The entire-market-value rule is subject to an important qualification, however, which one might expect to put concerns of bias to rest. By its explicit terms, the rule only applies when the infringed patented technology is the basis for consumer demand for the accused product.  

Without this condition, the rule’s potential to skew damages northward would be self-evident. In patent suits not involving biopharmaceutical products, mechanical devices, chemical processes, or certain biotechnology-driven medical diagnostic techniques, the accused product is likely to incorporate a large number of technological components, many of which will be either unpatented or subject to the proprietary control of third parties. As a question of economics, it is clear that a patentee’s proper measure of damages in the form of a reasonable royalty is that which reflects the patent’s technological contribution to the commercialized product. A “reasonable royalty” is the price that the company wishing to market the relevant product would have paid to obtain a license for the patented product or process ex ante. Importantly, this price reflects the royalty-depressing effect of competition between owners of substitute, patented technologies. The appropriate “hypothetical royalty” has no bearing on the other components in the final product that are outside the scope of the relevant patent. Nor does it track the royalty that the allegedly infringing company would rationally pay ex post—that is, post-commercialization. Ex post, a patentee can extract a far greater amount of value than it could have ex ante, due to the related effects of lock-in and the elimination of substitute technologies that lock-in entails.  

---

243. See generally Love, supra note 7.  
246. To elaborate, those operating in industries subject to anticommons effects must contend with strategic hold out by patentees who bring suit only after the industry or particular defendants lock into a technology, of which the patented claims constitute a small part. Such lock-in creates a gulf between the royalty that the prospective licensor and licensee would agree to ex ante, on the one hand, and that which they would agree to ex post, on the other. The asymmetry arises from the elimination of competition between functional substitutes that existed ex ante. One wishing to commercialize a technologically advanced product can often look to a variety of separately owned technologies that perform comparable functions. Owners of the relevant pat-
determination of an optimal damage award, are apt to be especially pronounced in patent cases involving IT, semiconductors, and other computer hardware.

It is now possible to appreciate the danger of the entire-market-value rule, which "permits recovery of damages based on the value of a patentee's entire apparatus containing several features."\(^\text{247}\) This unqualified statement of the rule would obviously be improper, regardless of bias. If a jury rendered factual determinations that were perfectly accurate in light of the instructions they have received, then juries so instructed in the law would grant patentees a windfall. Patent holders would receive damages that reflect a value that goes far beyond the scope of their claimed inventions. They would wrongly benefit from technologies that either lie in the public domain or were owned by third parties. Perverse results would include patentee overcompensation—and hence inefficiently high incentives to invent—and artificial impediments to commercialization that increase the cost, and thus reducing the level, of marketing products that require use of many technological components.

Critically, though, a court can employ the entire-market-value rule only if the allegedly infringed patent claims a technology that is the basis for customer demand.\(^\text{248}\) Does this solve the problem? Not necessarily. For one thing, in many cases it is not easy to identify which of many technological features in a product forms the basis for consumer demand. If 2,000 patents cover a particular microprocessor and the single asserted patent is indispensable to the operation of the chip, though neither prominent in the whole product nor the only necessary component of the same, does it drive consumer demand? As the concept of "the basis for consumer demand" displays an amorphous quality, courts are likely to apply the entire-market-value rule in circumstances they should not.

Beyond the problem of applying the Federal Circuit's abstract damages principle, this Article argues that the entire-market-value rule

\(^{247}\) Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1549 (Fed. Cir. 1995).

\(^{248}\) See, e.g., State Indus., Inc. v. Mor-Flo Indus., Inc., 883 F.2d 1573, 1580 (Fed. Cir. 1989).
invites systemic overcompensation and that the law should therefore jettison it. The problem lies in the reference point against which courts invite jurors to make damage determinations with respect to an infringed technology that, although residing at the heart of the accused device, constitutes merely one of several components that collectively constitute a functional unit. Instead of presenting fact finders with a neutral framework within which to determine the price that the parties would have agreed to ex ante for a license, the entire-market-value rule places the overall sales of the product, which incorporates multiple technologies beyond the patented one, at the heart of the inquiry. As a result, jurors’ reference point invites skewed damage determinations.

Specifically, this framing effect is apt to induce jurors to render damage figures that incorporate technological values greater than those represented by the asserted patent alone. This bias is likely to be systemic, meaning that jurors’ damage calculations over time will consistently depart from the optimal level. In other words, the average jury award in patent cases involving products that entail the use of numerous, discrete technologies will likely be inefficiently high on account of the entire-market-value rule.

Viewing this rule through the lens of systemic bias suggests that the courts should jettison it. Interestingly, practice would seem to reflect theory in this case, as there are numerous reports of entire-market-value rule inducing excessive rewards.\textsuperscript{249} As this rule presents fact finders with an inappropriate reference point, the courts should abolish it.\textsuperscript{250}

c. “Pay-for-Delay” Agreements in the Pharmaceutical Industry

Few phenomena in the patent realm have invited greater umbrage than pioneer-drug manufacturers’ practice of paying generic-drug producers to concede the validity of their patents and delay entering the market.\textsuperscript{249} See generally Love, supra note 7.

250. Of course, this is not an unchallenged view. Numerous industry participants characterize the rule as an important guide to calculating damages and contest the idea that patentees are the recipients of excessive pecuniary rewards in the event of proven infringement. Indeed, certain influential commentators have bemoaned the Supreme Court’s 2006 decision in \textit{eBay} to deprive patentees of automatic injunctive relief in the event of established infringement. See, e.g., Richard Epstein, \textit{Patent Injunctions and Repeat Offenders}, FT.COM, (Nov. 6, 2010, 12:12 AM), http://www.ft.com/cms/s/0/62e01bb0-e93a-11df-aec0-00144f5eab49a.html#axzz1tTP686pL. Such individuals, who are sometimes associated with the property-rights movement, lament the Court’s jurisprudence, which they see as leading inexorably to patentee undercompensation. See, e.g., Richard A. Epstein, \textit{The Property Rights Movement and Intellectual Property}, \textit{Regulation}, Winter 2008, at 58, 62.
To understand the context in which such agreements arise, one must appreciate that a generic-drug company can bypass much of the FDA regulatory-approval process by demonstrating that its drug is bioequivalent with, and has the same active ingredient, route of administration, dosage form, strength, and proposed labeling as, a drug listed in the Orange Book. Such a showing allows a company to obtain regulatory approval through the far-shorter ANDA process. The only major impediment to a company’s marketing a generic drug is the pioneer manufacturer’s patent. FDA regulations prohibit the agency from commencing the approval process until the applicant makes an appropriate certification—typically a paragraph IV certification that the incumbent’s patent is invalid or not infringed, which constitutes an act of patent infringement. The Hatch-Waxman Act creates an incentive for the patent-holding drug manufacturer to bring suit for infringement by prescribing a thirty-month stay that prevents the FDA’s approving the generic for that length of time if the patentee brings suit within forty-five days. Pioneer-drug producers thus find themselves embroiled in litigation, having to assert, and hence defend the validity of, patents that they acquired in order to protect their R&D investment.

It should be unsurprising that settlements abound in this context, especially given the fact that generic-drug manufacturers have an incentive to challenge the most valuable patents—to which pioneer-drug companies will be risk averse—rather than the weakest patents. However, these agreements have entailed a controversial feature, which is that, in return for a large amount of money, ANDA filers agree not to enter the relevant patentees’ markets for a time—potentially until the expiration of the patents. Such “pay-for-delay”

253. Indeed, the fixed cost for a generic-drug producer to enter a market is typically around $2 million. See Henry G. Grabowski et al., Entry and Competition in Generic Biologics, 28 MANAGERIAL & DECISION ECON. 439, 443 (2007). Two million dollars obviously pales in significance compared to the costs of researching, developing, and marketing a pioneer drug, which commentators have estimated to be between $110 million (which is likely a significant underestimate) and $2 billion (which is probably an overestimate). See supra notes 60–80 and accompanying text.
257. Note, however, that brand-name drug manufacturers are the ones that bring suit under the Hatch-Waxman scheme, which encourages them to do so by granting a thirty-month stay on FDA approval of a generic equivalent of the pioneer drug. Id.
agreements are now commonplace within the industry and are immensely controversial.

Almost every court has found these arrangements to be lawful, although the courts differ on their scope of permissibility. Nevertheless, reverse-exclusionary payments have invoked the ire of America’s antitrust-enforcement agencies. Many academics condemn the arrangements, in particular, for foreclosing the generic competition that Congress intended to foster with the passage of the Hatch-Waxman Act. In March 2011, the Supreme Court surprisingly denied certiorari in a petition from the U.S. Court of Appeals for the Second Circuit, which had articulated a rule of conclusive legality when the patent litigation was not baseless and the settlement did not impose restrictions going beyond the scope of the relevant patent. In light of the Supreme Court’s decision not to hear the case, it is now clear that reverse-exclusionary arrangements are generally lawful when the underlying patents are not obviously invalid.

The author has previously argued that principles of decision theory suggest erring on the side of permissibility with respect to pay-for-delay agreements and that the courts’ treatment of these phenomena is generally correct. For the purpose of the present Article, however, the question is whether the concept of systemic bias can yield a valuable insight into how the law should receive these arrangements.

For the concept to do so, those employing it would have to embrace a common metric by which to judge the desirability of these arrangements. Likely because it is unclear whether pay-for-delay settlements enhance ex post returns for pioneer-drug inventors in a desirable way, many commentators seek a distinct metric against which to measure these arrangements’ permissibility. They take as a given that the optimal degree of patent protection is that which follows from an accurate application of the provisions of the Patent Act. From this perspective,

---


259. See, e.g., In re Schering-Plough Corp., No. 9297 (F.T.C. Dec. 8, 2003), rev’d, 402 F.3d 1056 (11th Cir. 2005).


society overcompensates a patentee if the latter successfully enforces its exclusive rights in circumstances when a scrutinizing examination would have denied it those rights. It is clear, then, why those who hold this view condemn reverse-exclusionary agreements. Such arrangements allow at least some patents to survive and generate profit for their owners in circumstances that courts would otherwise invalidate them or find them not infringed at trial. These critics object to arrangements that allow patentees to appropriate greater value from their IP rights than they would have garnered from an unfettered application of the rights granted them by Congress. Few ask whether the greater pecuniary rewards realized by patentees on account of these agreements in fact generate desirable incentives to devote further resources to the innovative process ex ante.

Within this framework, which deems an agreement objectionable if it yields an outcome different than what would have transpired had the parties proceeded to judgment, allowing pay-for-delay agreements clearly biases the outcome upward from the "optimal" level. Within the confines of that normative baseline, analyzing for bias reveals that the critics are indeed correct and that the law should not permit settlements that involve patentees' paying generic-drug producers not to enter the market. The only qualification to this conclusion lies in the possibility that allowing generics and brand-name drug manufacturers to settle could lead to more "bad-patent" invalidation because such a facilitative rule increases the rate of ANDA filings. Some scholarship supports this possibility, though the better reasoned literature is to the contrary.

Yet, are critics right to condemn a reverse-exclusionary arrangement that allows a patent to survive when it would have floundered in court? The author believes that the answer is not necessarily, and this point reveals that the systemic-bias inquiry provides useful guidance only when observers can agree on a common normative metric.

One might suppose that society gains by denying patent protection to pharmaceutical products and processes that do not meet the requirements of nonobviousness, novelty, utility, and disclosure. Yet, this view is not accurate in an absolute sense. A well-known example involves drugs that, though socially valuable, are unpatentable and

---

263. To emphasize, "optimal" here refers not to the actual correct level for maximizing long-run social welfare, but to the return that would follow from an accurate application of the principles of the Patent Act to the relevant compound or formulation drug patent.


265. See Hemphill, supra note 194.
hence underproduced absent regulatory exclusivity or some other solution. There are many drug patents of probable, though uncertain, validity ex ante. Where drug patents are likely (albeit not definitely) valid and protect a vast amount of capital investment, it is far from clear as a normative matter that society gains by denying IP protection. For this reason, ANDA-litigation settlements with reverse payments need not always be problematic.

There are a number of reasons to be concerned that the pharmaceutical regulatory structure affects pioneer-drug manufacturers' incentives to invent and commercialize the most important drugs in a potentially problematic way. First, the "policing function" performed by ANDA filers is heavily biased toward blockbuster drugs because generic-drug producers tend not to challenge the weakest drug patents, but rather the most valuable ones. Although consumers do stand to gain the most—in static-efficiency terms—from invalidation of the most lucrative drug patents, consumer benefit is less clear from a dynamic-efficiency perspective. This is because pioneer-drug manufacturers are desperately reliant on a small number of highly profitable blockbuster drugs to cross-subsidize their R&D costs with the far greater number of failed drugs. There is no doubting the social value of these products, and so it is not clear that the law should deny patent protection on technical grounds.

Second, and as a result of the above, brand-name drug producers are highly risk averse in defending their most valuable drug patents. This suggests that denying such companies the ability to settle patent-infringement suits will impose significant disutility on them, and thus harm incentives to invent and market new drugs.

Third, ANDA filers enjoy a far-superior litigation position than brand-name drug manufacturers because they have made no sales, and they are merely subject to nominal damages in the event that the

266. See generally Roin, supra note 60.
268. Static efficiency refers to the conditions of allocative and productive efficiency associated with perfect competition (when price equals marginal cost).
269. Dynamic efficiency refers to the efficiency gains created by technological innovation.
270. Indeed, a majority of FDA-approved drugs do not cover their own costs, and it is well known that the odds of an initially researched chemical compound's producing a viable drug are between 1 in 5,000 and 1 in 10,000. See, e.g., PHRMA, DRUG DISCOVERY AND DEVELOPMENT: UNDERSTANDING THE R&D PROCESS 11 (2007).
patentee prevails in court.\textsuperscript{272} By contrast, a finding of nonvalidity is devastating to the brand-name-drug producer, which, by virtue of nonmutual defensive issue preclusion, loses its patent protection forever. Lastly, patent litigation is notoriously expensive—the typical cost of litigating a patent-infringement suit is between $3 million and $6 million.\textsuperscript{273}

Combined, these factors reveal that the process of ANDA filing and subsequent litigation is heavily skewed against incumbent drug producers. In this respect, there is a systemic institutional bias against pioneer-drug manufacturers that complicates the question of bias in analyzing pay-for-delay arrangements. What is clear is that brand-name drug producers are better off in a world in which the law allows them to pay ANDA filers to stay out of their markets for a time than if the courts only permitted them to enter into settlements without payments. Whether this feature of paying for delay is desirable depends in part on whether one accepts the prescription that an antitrust rule is efficient if it reorients patentee compensation closer to the optimal level. This inquiry is distinct from whether reverse-exclusionary agreements allow some patents to survive that do not meet one or more of the technical requirements of patentability that Congress has established.

A number of academics criticize pay-for-delay agreements on the ground that without payments, the parties would enter into settlements allowing ANDA filers to enter the relevant markets sooner. The clear premise is that something is "pro-competitive" and hence desirable if it results in earlier competition and concomitant consumer savings. Illustratively, the FTC regularly propounds the result of its 2010 study that pay-for-delay agreements cost U.S. consumers $3.5 billion per year.\textsuperscript{274} By this logic, however, one would have to support the wholesale abolition of the patent system.

Presumably, most critics of reverse-exclusionary agreements do not advocate such a course, but instead harbor concerns for both short-term (static) and long-term (dynamic) consumer welfare. They are right to do so. Yet, one can legitimately criticize their condemnation of pay-for-delay agreements on account of their neglecting dynamic

\textsuperscript{272} See Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1347 (Fed. Cir. 2000) ("An ANDA filing by its very nature is a highly artificial act of infringement . . . ." (quoting Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990)) (internal quotation marks omitted)).

\textsuperscript{273} See AM. INTELLECTUAL PROP. LAW ASS'N, REPORT OF THE ECONOMIC SURVEY 29 (2009).

effects. It is entirely possible—though no one points it out—that these assailed agreements could, with respect to likely-valid patents, align brand-name drug manufacturers’ incentive to invent more closely with the social optimum. One disclaiming such a possibility need only observe the pharmaceutical industry’s fragile dependence on patents, as evidenced by the industry’s sharply reduced expected revenue in 2011 on account of the “patent cliff” that will see a small number of valuable patents expire,275 as well as the extraordinary capital investment required to innovate. When, as in the biopharmaceutical sector, average costs far surpass marginal costs, open competition—facilitated by patent invalidation or abolition—will render first movers insolvent. Dynamic incentives matter enormously in this setting, and yet critics pass insufficient attention to them.

Of course, the preceding discussion does not warrant per se lawful treatment of pay-for-delay agreements. Statistics suggest that pay-for-delay agreements can protect patents of dubious validity, and for these drug products and processes, we can afford to be more skeptical of the claimed benefits of exclusivity. Any sensible analysis of such arrangements must be grounded on the facts specific to each one and must involve an examination of the likelihood of patent validity and infringement. In the author’s view, courts should be cognizant of the particular kind of patents before them. For instance, the FTC found that generics won seventy-three percent of patent-infringement cases between 1992 and 2000,276 but these figures may be misleading in light of selection bias (brand-name drug manufacturers are unlikely to litigate their most valuable or strongest drug patents to trial) and because they conflate different kinds of drug patents. In this respect, the value and likely validity of drug-substance, drug-product, and method-of-use patents may be significantly different. Drug-substance patents covering new chemical entities that are useful for treating significant conditions, for instance, are likely to be valid, lucrative, and most importantly, of great social value. More prosaic patent-protected innovations—such as reformulating a drug from capsule to tablet form—may be of less (though not insignificant) value and also less likely to meet the statutory conditions of patentability enshrined in the Patent Act. Courts should be cognizant of the kind of patents being challenged, as well as the investment that underlies it.


276. See FED. TRADE COMM’N, supra note 76, at 16.
IV. Conclusion

The patent field is beset with policy challenges. Cries that the patent system is broken abound and emanate from an eclectic range of industries.\(^\text{277}\) Once a radical view, contemporary advocates of patent abolition now include respected economists.\(^\text{278}\) Although few outside the patent bar and pharmaceutical industry\(^\text{279}\) maintain that the current regime operates desirably, still fewer agree on what exactly is wrong with the status quo and which features of the patent system are fitting candidates for revision.\(^\text{280}\) Powerful vested interests with divergent views take entrenched positions, such that consensus for an overhaul of patent law is likely to remain elusive. To confirm this view, one need merely observe the continuous string of failed congressional attempts at patent reform each of the last several years. When everyone has a different view, but strong evidence exists that the current patent system is in at least some respects imperfect, what can policy-makers do?

At a high level, there is at least one clear answer. As Dan L. Burk and Mark A. Lemley convincingly argue, the heterogeneous nature of industrial innovation suggests that a one-size-fits-all approach to patent law is mistaken.\(^\text{281}\) As numerous constituent elements of patent jurisprudence lend themselves to flexible, and hence asymmetric, application, courts should construe patent doctrine in light of the distinct industrial characteristics presented by each case. In this manner, judges could more closely align the incentives generated by the patent system with the unique innovation features displayed by different industries.\(^\text{282}\)

The author supports such an approach to patent policy, though he believes that such context-specific analysis is desirable only in a second-best sense. Tailoring ostensibly identical principles of law to a variety of settings arguably comes at some expense to the patent system’s legitimacy. Furthermore, obvious limits exist as to how far courts can go in tailoring what purport to be rules of horizontal application to the distinct characteristics of different settings. Nevertheless, insofar as a larger legislative solution aimed at incorporating

---

\(^{277}\) The Patent Crisis, supra note 17, at 3-4.

\(^{278}\) See, e.g., Boldrin & Levine, supra note 2, at 11.

\(^{279}\) Generic-drug producers, of course, do not share pioneer-drug manufacturers’ zeal for strong patent protection.

\(^{280}\) The Patent Crisis, supra note 17, at 3-4.

\(^{281}\) Id. at 5.

industry-specific considerations into law remains unavailable, one can welcome the Burk–Lemley approach.

This Article offers a distinct, though complementary, method of analysis. Observing that hostility to particular features of the patent regime emanates not from the abstract quality of those features, but from the courts’ and examiners’ capacity to misapply them, the author suggests that policymakers reorient their analysis toward the nature of each challenged tenet of patent law. The Article observes that even pervasive ex post error on the part of important actors within the patent system need not result in skewed, and hence inefficient, incentives. Over time and a sufficiently large number of cases, the expected reward from obtaining a patent should approximate the optimal level if judges, juries, and examiners strive to reach the correct answer in every case, given the information at hand.

There are identifiable circumstances in which this assumption is unlikely to hold. Desirable outcomes in which long-run deviations from the (optimal) mean cancel each other out are unlikely to materialize when actors are subject to powerful systemic biases. The author argues that one way to approach divisive policy issues is to scrutinize them for their tendency to significantly skew outcomes in a particular direction.

Viewed in this light, one can question the desirability of certain tenets of the law that would be innocuous in an error-free patent system. A clear example is the entire-market-value rule in circumstances when the asserted patent claims but one aspect of the technology underlying a commercialized product. By framing a jury’s determination of damages in light of the profitability of the infringing device, the rule invites jurors to reach conclusions that depart upward from the accurate level. The correct reference point is the relevant patent’s technological contribution to the marketed product, which informs the price to which the parties would have rationally agreed on a license ex ante. By substituting this reference point for one founded on the overall profitability of the commercialized good, which incorporates multiple technological components, the law consistently induces fact finders to reach artificially inflated damage awards. Instead, the law should strive to orient jurors’ reasoning with a neutral metric that invites long-run conclusions that approximate the correct result.

The clear and convincing evidence standard for invalidating a patent also invites systemic bias. It does so by acting as an artificial impediment to the courts’ important screening function, which involves skimming improvidently granted patents from the pool of enforceable IP rights. Were the relevant evidentiary threshold equal to the default
standard in civil cases—preponderance of the evidence—courts in approaching the question of nonobviousness, novelty, and enablement would strive to make correct determinations in a neutral environment. Congress upset that neutrality in mandating a presumption of validity, which the courts have compounded with their clear-and-convincing interpretation of the same. This feature of the law ensures that, other things being equal, courts overcompensate patentees in the long run by bestowing a subset of them with a windfall. As many prospective patentees will not know ex ante whether their claimed invention will run afoul of a provision of the Patent Act, the clear-and-convincing standard serves to enhance the expected return of obtaining a patent.

This enhancement applies across all industries, and one cannot support it by reference to the particular characteristics of a given industry. Given that there is no justification for such an across-the-board bolstering of patents, which otherwise would be subject to unbiased judicial scrutiny, Congress should reject it in light of the Supreme Court's failure to do the same. This conclusion is bolstered by the fact that the clear and convincing evidence standard increases the expected cost of litigating a patent's validity, thus further exacerbating the public-goods problem of challenging bad patents.283

Finally, there exists the more vexing issue of pay-for-delay arrangements, which—uniquely amongst the tenets of patent law addressed in this Article—arise in a single industry. Given the context-specific environment in which they occur, reverse-exclusionary payments raise an important question whether they affect patentee compensation in a way that desirably promotes dynamic efficiency. Lacking effective means to undertake this analysis, however, most commentators rely on the technical requirements of patentability. From this perspective, the optimal reward for companies operating in the biopharmaceutical sector is that which flows from patents that meet the requirements of the Patent Act. The courts' facilitation of pay-for-delay agreements unquestionably shields some patents that would fail to survive judicial scrutiny. So viewed, there is little doubt that they introduce significant systemic bias into the patent system and facilitate long-term patentee overcompensation. As explained above, though, the regulatory infrastructure in the pharmaceutical field introduces a bias in the opposite direction by curtailing the rewards of those companies that invent and commercialize the most valuable drugs. As a result, the

optimal rule governing pay-for-delay settlements is a complicated matter. Though, in the author's view, the courts largely have it right in employing a rule-of-reason inquiry.