Rewarding Failure with Patents

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Abstract:

It is axiomatic that patents promote success. And yet, a contrary notion—that the patent incentive for medicine should be sufficient to compensate for the losses incurred when other research fails—is quietly permeating modern court decisions, commentary, and Congressional discussions, coloring debates relating to pricing and regulation of medicine. The conceptualization is moving forward unchallenged, as if failure compensation follows logically from the innovation incentives built into the patent construct. As this Article demonstrates, however, the notion is antithetical to patent law, putting modern conceptualizations on a collision course with the history and theory of patents reaching back to this nation’s inception.

Reviewing patent theory, federal statutes and cases from 1790 to 1865, and the orientation of the patent system, this Article demonstrates the fallacy of creating incentives to fail. From a theoretical perspective, although patents are designed to encourage innovation, a patent is not a participation trophy. One does not receive a patent for an invention one tried and failed to create, and the patent reward is based on success, rather than failure. From an historical perspective, with limited exceptions, early patent law reveals no act or case suggesting that a patent grant is intended to compensate the patentee even for the costs of developing a successful (i.e., patented) invention, let alone other research failures. Finally, the notion of compensating for failures denies other strains evident in the patent system. Failure compensation in the context of the patent system has the effect of encouraging inefficient invention and can lead to a perverse reality in which the more one fails, the higher the compensation.

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INTRODUCTION

It is axiomatic that patents create incentives for success. Although much ink has been spilled over what types of inventions are patentable\(^1\) and how broadly patents should reach,\(^2\) no one would ever suggest that patents should create

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incentives for failure. And yet, if one were to actualize a theory being expounded today, that is precisely what is being advocated in modern arguments related to patent law and policy. In court decisions, halls of Congress, and industry boardrooms, analysis after analysis follows a simple logic that turns the patent system on its head. And what is that deceptively appealing notion? Quite simply, the notion is that the patent reward for pharmaceuticals should be sufficient to compensate for the losses incurred when unrelated research fails.

Although more familiar in pharmaceutical pricing discussions, the argument also is presented in the context of pharmaceutical patents. In the pricing context, the argument is that the price of drugs must be sufficient to compensate for failed research attempts. In the patent context, the argument is that the patent reward must include compensation for failed efforts at innovating products other than the one on which a patent has been granted.

This Article will show that the concept is antithetical to patent law. Specifically, the notion of compensating for failed research puts the modern application of patent law on a collision course with the history and theory of the controversy over Edmund Kitch’s prospect theory of patent with its recommendation for early and broad patent rights; Robert P. Merges & Richard R. Nelson, On the Complex Economics of Patent Scope, 90 Colum. L. Rev. 839, 848–49 (1990) (arguing that legal principles and objective evidence in areas including patent law often leave considerable room for discretion and discussing what policies should influence that discretion); Edmund W. Kitch, The Nature and Function of the Patent System, 20 J. L. & Econ. 268 (1977) (analogy of patents to mineral rights and patent system); Roger L. Beck, The Prospect Theory of the Patent System and Unproductive Competition, 5 Resch. in L. & Econ. 193 (1983) (suggesting lack of foundation in Edmund Kitch’s prospect theory, favoring broad patent rights); Robin Feldman, Rethinking Patent Law 32-40 (2012) (analyzing various patent analogies, including mineral rights, fishing rights and hunting licenses, and proposing the bargain theory of patents).


6 See infra text accompanying notes 30-34.
patents, reaching back to this nation’s inception.

From a theoretical perspective, the patent system is designed to reward success. Yes, patents are designed to provide incentives for innovation, but a patent is not a participation trophy. Perhaps no statement is as telling for underscoring this point than the Supreme Court’s language in *Brenner v. Manson*: “[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”

Thus, one does not receive a patent for an invention one tried and failed to create. Similarly, a patent’s reward should reflect the successful invention rather than compensation for attempts gone bad.

From an historical perspective, an examination of the nation’s early patent statutes and cases reveals that the notion of compensation for failures is entirely absent. Indeed, with limited exceptions, early patent law reveals no act or case stating that a patent grant is intended to compensate the patentee even for the costs of developing a *successful* (*i.e.*, patented) invention. These types of perspectives are not present in the historic construct of the patent system.

Moreover, the notion of compensating for failures denies the economic logic of the patent system, as well as common sense. As some economists explain, patents are a compensation for contribution to society, not for costs incurred by inventors. From this perspective, social contribution, not the development cost, is the touchstone for the value that a patent should confer to its inventor. Finally, and quite simply, compensating for failures in the context of the patent system has the effect of encouraging inefficient invention. Such an approach would lead to a perverse reality in which the more one fails, the higher the compensation when one succeeds.

In a perfect world, one might expect purchasers to create a natural brake on the system. Regardless of the compensation an industry views as its due, one cannot charge a price unless buyers are willing to pay. Health care is a strange market, however, and buy-side pressures can be dampened. Most important, modern strategic behaviors allow pharma companies to exploit the regulatory environment, further weakening the potential effects of price limitations. Thus, although one would expect certain constraints to counteract the inefficiencies of compensating for failure, characteristics of the pharmaceutical market prevent

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8 *See* Carl Shapiro, *Patent Reform: Aligning Reward and Contribution* (Nat’l Bureau of Econ. Rsch., Working Paper No. 1341, 2007); *see also* Mordecai Kurz, *The Market Power of Technology—Understanding the Second Gilded Age*, ch. 9.1 (Colum. Univ. Press ed., 2022) (describing the economics of patents in contribution-to-society terms by explaining the paradox in which the patent’s reward rises as our need for the product rises and the fact that the law’s allowance for monopoly prices permits higher prices where the need is greater).
9 *See supra* note 8.
such constraints from operating.

This is particularly problematic in light of an historic shift in the pharmaceutical industry over the last decade.10 Faced with stagnating innovation, the pharmaceutical industry has shifted to outsourcing innovation. Specifically, the majority of innovation in the pharmaceutical industry comes from academia or small life science companies.11 Large pharmaceutical companies then shepherd the drugs through the FDA approval process and into production.

Ordinarily, there should be little room for excess returns at the top. The little fish invent. The big fish pay the little fish the discounted present value of their invention, and the dollars flow through in an airtight system. Anecdotal evidence, however, suggests that significant leakage occurs in the system. For example, high-profile blockbuster drugs, such as Gilead’s Hepatitis C treatment, Sovaldi, and Merck’s cancer immunotherapy, Keytruda, demonstrate how the value of the acquisition can fail to reflect the true value of the drug. What results is considerable value leakage and a diluted incentive to take on basic, high-risk research. At the end of the day, society is not only encouraging failure, it is doing so at the wrong part of the innovation chain.

In short, the patent reward must be firmly and solely rooted in the successful invention alone, and the emerging modern notion of including failures in the patent reward threatens to cost society dearly. To be clear, this Article does not suggest that the current patent system has created failures, nor does it provide either empirical or anecdotal evidence of how the current patent system has done so. Rather, this Article presents the thesis that, if embraced in policy implementations, the logical conclusion of an argument that is increasingly propounded today is in tension with patent history and basic logic.

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10 This Article does not explore the question of whether related problems exist outside the pharmaceutical industry. However, the industry structure in health care does present issues that are not necessarily present in those arenas. See infra Section III.A (describing lessening of buy-side constraints in the pharmaceutical industry).

11 See Joanna Shepherd, Consolidation and Innovation in the Pharmaceutical Industry: The Role of Mergers and Acquisitions in the Current Innovation Ecosystem, 21 J. HEALTHCare L. & POL’Y 1, 2 (2018) (describing the primacy of startup innovation in the modern, vertically disintegrated pharmaceutical ecosystem); Ulrich Geilinger & Chandra Leo, HBM PARTNERS, HBM NEW DRUG APPROVAL REPORT: ANALYSIS OF FDA NEW DRUG APPROVALS IN 2018 (AND MULTI-YEAR TRENDS) 16-17 (2019) (observing that the proportion of new molecular entities that originated in smaller firms has grown from 31 percent in 2009 to 63 percent in 2018, while the new drug approval share of the ten largest pharmaceutical companies declined from 52 percent to 25 percent); Amirah Al Idrus, Biopharma Converts 24% of NMEs to Drugs, with Celgene Bringing up the Rear: Report, FIERCEPHARMA (Apr. 29, 2019), https://www.fiercebiotech.com/biotech/biopharma-converts-24-nmes-to-drugs-celgene-bringing-up-rear-report [https://perma.cc/8Q9R-7LK5] (finding that, of the forty-one new molecular entities launched by Celgene, a large drug-maker, between 2014 and 2018, only eight were innovated internally; most were the product of acquisition or licensing).
I. PATENT THEORY AND THE NARRATIVE OF FAILURE

The pharmaceutical industry today is beset by a staggering growth in prescription drug prices. The United States—where brand-name drugs cost more than triple what they do in other countries—spent 40 percent more on prescription drugs in 2017 compared to 2007, a trend that shows no sign of reversal. Even after accounting for rebates, brand-name net drug prices rose 60 percent during roughly the same period, causing many patients to skip doses or cease filling prescriptions altogether.

Balanced against these soaring prices is the need for innovation. Society would not have such life-saving therapies without an innovative industry to discover and develop them. Although estimates differ widely, pharmaceutical research and development is expensive, with more dry holes than successful wells and failure a constant companion. Perhaps it takes high returns such as these to keep the engines of innovation humming and to bring these innovations forward for the benefit of society. The nation’s founders may have understood such needs in establishing the patent system, providing the potential for healthy patent rewards so that pioneers would be inspired to soldier onwards and push through the failures, earning enough to compensate for the long journey.

But is that correct? Only partially. This Article will argue that an essential aspect of this logic is deeply and fundamentally flawed based on the history and theory of the patent system, as well as the modern structure of the pharmaceutical industry.

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13 See Why Are Prescription Drug Prices Rising and How Do They Affect the U.S. Fiscal Outlook, PETER G. PETERSON FOUND. (Nov. 14, 2019), https://www.pgpf.org/blog/2019/11/why-are-prescription-drug-prices-rising-and-how-do-they-affect-the-us-fiscal-outlook (reporting that the Centers for Medicare & Medicaid Services expect a further 60 percent increase in spending between 2017 and 2027).


15 See Steven G. Morgan & Augustine Lee, Cost-Related Non-Adherence to Prescribed Medicines Among Older Adults: A Cross-Sectional Analysis of a Survey in 11 Developed Countries, 7 BMJ OPEN e014287 (2017) (finding that older American patients reported cost-related non-adherence six times more frequently than patients in the U.K.).

16 Compare Vinay Prasad & Sham Mailankody, Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval, 177 JAMA INTERNAL MED. 1569 (2017) (finding that the cost to develop a cancer drug is $648 million), with Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, 47 J. HEALTH ECON. 20, 21 (2016) (study from academic center that receives industry funding concluding that the cost of bringing a drug to market ranges from $2.588 billion to $7.87 billion).
industry.

A. Patent Underpinnings

Patents constitute bargains between inventors and society. Rooted in constitutional language, the bargain grants inventors, in general, and pharmaceutical innovators, in particular, the potential to enjoy monopoly profits in exchange for providing new and useful therapies. Distributed through the patent system, these rights provide the opportunity for a handsome profit but are limited in time and scope. As Thomas Jefferson noted, “[c]ertainly an inventor ought to be allowed a right to the benefit of his invention for some certain time. It is equally certain it ought not be perpetual.”

As well as limitations in time, the grant of a patent is limited in scope. In 1790, Congress enacted the first patent statute, and George Washington signed the first U.S. patent to Samuel Hopkins for an invention related to making potash. Since then, patent law has required patent holders to disclose their invention so that those skilled in the art can make and use it. Patent law even contains a prohibition on patent misuse, which is broadly defined as an impermissible attempt to expand the time or scope of a patent. Moreover, the art of obtaining a patent involves the delicate dance of balancing the desire to draft claims that reach as broadly as possible with the requirement that claims reach no further than what is new, non-obvious, and fully disclosed. Only the invention that one has specifically

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17 See US CONST., art. I, § 8, cl. 8 (“The Congress shall have Power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries; . . . .”); see also Brenner v. Manson, 383 U.S. 519, 534 (1966) (“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.”).

18 Letter from Thomas Jefferson to Oliver Vans (May 2, 1807), in THE WRITINGS OF THOMAS JEFFERSON 200–02 (Andrew A. Lipscomb, ed. 1903); see also WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS 42–43 (1890) (historic patent treatise describing the importance of obtaining the use of every invention for society as soon as possible).


20 See 3 DONALD S. CHISUM, CHISUM ON PATENTS § 7.03 (2003); see also Jeanne C. Froemer, PATENT DISCLOSURE, 94 IOWA L. REV. 539 (2009); Sean B. Seymore, THE TEACHING FUNCTION OF PATENTS, 85 NOTRE DAME L. REV. 621 (2010); Robin Feldman, THE INVENTOR’S CONTRIBUTION, 2005 UCLA J.L. & TECH 6 (discussing the modern disclosure doctrines and their historic roots).

21 See, e.g., Blonder-Tongue Labs., Inc. v. Univ. Ill. Found., 402 U.S. 313, 343-44 (1971) (discussing in the context of fraud and inequitable conduct a series of decisions in which the Justices condemned attempts to broaden the physical or temporal scope of the patent monopoly); 6 DONALD S. CHISUM, CHISUM ON PATENTS § 19.04 (2001).

22 See also Robin Feldman, THE INVENTOR’S CONTRIBUTION, 6 UCLA J.L. & TECH 1, 4 (2005) (describing the disclosure doctrines and explaining that “[w]hat the inventor reveals must be
described will receive the golden patent crown.

Even within that limited concept, there is no guarantee that a patent will garner any returns or even that it will grant a monopoly. Scholars and commentators estimate that more than 90 percent of patents never generate any returns to those who hold the right.23 Similarly, as the Court has consistently made clear, the patent right does not necessarily convey a monopoly. There may be substitutes for the product invented, patents can overlap, or the market may not be ready to appreciate the value of the patented product during the patent term.

From the beginning, U.S. patent law has been framed in terms of the benefit to society rather than the benefit to inventors. As the Justices noted in *Graham v. John Deere*, “[t]he patent monopoly was not designed to secure the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge.” That knowledge, specifically, is the knowledge identified in the patent.24

The notion of bringing forth new knowledge embodies the core of the patent system. The patent system is designed to reward those who not only create, but also share those inventions openly with society.25 Inventors could decide to keep their inventions secret, and the law provides Trade Secret protection for those who choose the secrecy route. Nevertheless, society reserves the stronger, patent protection for those who are willing to disclose for the benefit of society.26 Of sufficient, regardless of whether any insufficiency is due to the fact that the patent holder has not given us enough of the invention or the fact that the patent holder simply does not have enough to give”). There are five elements of patentability, including also patentable subject matter and utility, but the three listed in the main text are the most relevant to the tension between claims and disclosure. See generally JANICE M. MUELLER, PATENT LAW, 296-329 (describing the elements of patentability).

23 See, e.g., Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PENN L. REV. 1, 5 n.3 (2005) (noting that most estimates suggest less than 5 percent of patents have any apparent value at all); Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U.L. REV. 1495, 1507 (2001) (opining that “the total number of patents litigated or licensed for a royalty (as opposed to a cross-license) is on the order of five percent of issued patents”); Stephen Key, *In Today’s Market, Do Patents Even Matter?*, FORBES (Nov. 13, 2017) (“Around 97% of all patents never recoup the cost filing them.”).

24 *Graham v. John Deere*, 383 U.S. 1, 9 (1966); see also WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS 42-43 (1890) (seminal patent treatise of the late 1800s explaining that “[t]he duty which the state owes to the people to obtain for them, at the earliest moment, the practical use of every valuable invention in the industrial arts is . . . a higher and more imperative duty than which it owes to the inventor”); Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), in 13 THE WRITINGS OF THOMAS JEFFERSON 326, 334-35 (Andrew A. Lipscomb & Albert Ellery Bergh eds., 1905) (declaring that the “embarrassment of an exclusive patent” is justified only because these “monopolies of invention” serve the “benefit of society”).

25 See, e.g., Bonito Boats, v. Thundercraft, 489 U.S. 141, 151 (1989) (observing that “the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure”).

course, there are altruistic souls who simply dedicate their work freely to the world without any reward at all, but society, understandably, does not rest on the hope that we will be blessed with a sufficient number of such generous folks. In short, the goal of the patent system is to benefit society, not simply by encouraging invention but also by encouraging the eventual dedication of that information to the public.

One could certainly imagine a different approach to patenting and innovation. Early American debates on intellectual property rights considered the possibility that intellectual property rights, particularly copyrights, might flow from the natural rights of the authors27 rather than the consequentialist notion of promoting the progress of “the useful arts.”28 Similarly, an innovation incentive system could provide more than merely offering an opportunity to garner a return through exclusive marketing rights. The government, for example, could grant prizes for successful invention,29 in exchange for making the information available to the public. And, of course, the system need not involve revealing one’s innovation to the public at all. Innovation incentives can be designed so that the invention remains confidential, as with trade secrets. And even in the context of providing incentives for invention in the interests of the public, an innovation system need not be grounded in an invention that has already been “conceived of or reduced to practice.” The government could provide funding for exploration in the hopes that innovation would result.

Nevertheless, since at least the time of the U.S. Constitution, the nation’s patent system remains firmly rooted in a basic conception: In exchange for bringing forth one’s ideas to the public, an inventor may receive the right to exclude others from the specific sphere of the invention for the term of the patent, during which time the patent holder can attempt to earn a return on that invention in the market. All of this, of course, is grounded in the invention specified in the four corners of the patent.

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28 See U.S. CONST., art. I, § 8, cl. 8. For a discussion of consequentialist versus rights-based approaches, see UTILITARIANISM AND BEYOND 3-4 (Amartya Sen & Bernard Williams eds., 1982) (describing the consequentialism in which actions are judged by the state of affairs that will result); and SAMUEL SCHARFNER, THE REJECTION OF CONSEQUENTIALISM 4-5 (1982) (explaining non-consequentialist or rights-based analysis in which actions are right or wrong independent of the resulting consequences). See also Feldman, supra note 22, at 2-3 (describing these constructs in the context of patents).

29 For a discussion of prizes and other systems, see Daniel J. Hemel & Lisa Larrimore Ouellette, Beyond the Patents-Prizes Debate, 92 Texas L. Rev. 303 (2013).
B. Failure Compensation in the Modern Lexicon

The patent theory grounding seems to have been forgotten in many modern patent discussions. The problem emanates from the judicial opinions on patent law, the halls of Congress, and some corners of academia in which it is argued that the returns available for a patent should include the costs of other failed inventions.

First, the logic of including failures has seeped into judicial characterizations of patents as companies seek to build the strongest walls possible around their patents. For example, in assessing the public interest effect of enjoining an alleged patent infringer, a decision from the District Court of New Jersey noted that “pharmaceutical research requires the realization of profits from successful drugs to make up for the losses from drugs that never make it to market or prove unsuccessful for other reasons.” Consequently, it reasoned, “the public interest weighs in favor” of enjoining the alleged infringer, protecting the brand drug’s monopoly.

The Southern District of New York went further, however. An opinion there argued that a litigated drug ought to be protected because its blockbuster earnings enabled the drug-maker “to expend the research and development costs for drugs that in fact never make it to market, or that make it to market but never recoup the costs associated with their getting there.” In other words, a patent serves to safeguard not only the novel drug’s earnings but the drug-maker’s other prospective drugs as well, however failing or unviable they may be. Thus, the inclusion of failed costs in the patent power has now traveled from the boardroom to the courtroom.

The pricing arguments also have spread to debates over patent law and policy. For example, congressional witnesses speaking on behalf of PhRMA (the pharmaceutical industry lobbying group) have explained over the last few years...

30 In re Depomed Pat. Litig., No. CV 13-4507 (CCC-MF), 2016 WL 7163647, at *80 (D.N.J. Sept. 30, 2016), aff’d sub nom. Grunenthal GMBH v. Alkem Lab’y’s Ltd., 919 F.3d 1333 (Fed. Cir. 2019), (“In enacting the patent laws, Congress recognized that it is necessary to grant temporary monopolies on inventions in order to induce those skilled in the ‘useful arts’ to expend the time and money necessary to research and develop new products and to induce them ‘to bring forth new knowledge.’” (citing Eli Lilly & Co. v. Premo Pharm. Labs., Inc., 630 F.2d 120, 137 (3d Cir. 1980))). Notably, the Depomed court interpreted this innovation inducement described in Eli Lilly forty years prior to implicitly include failed or economically unviable drugs.

31 Id.; see also Sanofi-Synthelabo v. Apotex Inc., 488 F. Supp. 2d 317, 346 (S.D.N.Y.), aff’d, 470 F.3d 1368 (Fed. Cir. 2006) (“Finally, protecting the patent for Plavix secures the public interest in innovation by providing commercial incentive for Sanofi to begin and continue clinical trials researching new uses for the drug. . . the Court finds the public interest lies slightly in favor of Sanofi.”).

32 Sanofi, 488 F. Supp. 2d at 346; cf. Wilbur, supra note 3 (pharmaceutical industry trade group publication arguing that the well-being of the industry relies on robust patent protections, including method-of-use and secondary patents that prolong drugs’ monopoly periods).
that patent protection supports innovation through compensation for the costly failures of the R&D process.\textsuperscript{33} Other congressional witnesses for individual pharmaceutical companies have spoken in the same vein, describing the need for patents to compensate for widespread failures.\textsuperscript{34}

Other academic commentators have evidenced similar thinking. For example, in discussing patents, Erika Lietzan noted that “the company may be able to recover the investment it made in developing the medicine as well as others that are less successful or that failed before approval, and it may be able to enjoy a profit.”\textsuperscript{35} In a slightly different vein, Emily Morris suggested that patents should compensate both for the patented drugs and for less profitable drugs, as opposed to those that failed.\textsuperscript{36} Each of these contexts, whether it is the need for injunctive relief, patent enforcement, or patent legislation, imagines the contours of patent rights themselves, and all of this thinking embodies a notion that the reward of the patent should encompass more than the product on which the patent was granted.


\textsuperscript{34} Unsustainable Drug Prices: Testimony from the CEOs (Part I): Hearing Before the H. Comm. on Oversight & Reform, 116th Cong. 47 (2020) (statement of Kare Schultz, Chief Executive Officer, Teva Pharm. Indus. Ltd.) (observing that “the system basically rewards innovation by granting patents. . . . And the reason why that’s necessary is that less than 1 out of 100 initial projects actually make it through all the way to the marketplace. The rest, they fail on the way, and that means that that risk nobody would take.”); The “Innovation Act”: Hearing on H.R. 9 Before the H. Comm. on the Judiciary, 114th Cong. 4 (2015) (statement of Hans Sauer, Deputy General Counsel for Intellectual Property, Biotechnology Indus. Ass’n) (describing how widespread failures in biopharmaceutical drug development necessitate the incentives of robust patent protections for successful drugs); see also Unsustainable Drug Prices, supra, at 49 (2020) (statement of Mark Alles, Former Chief Executive Officer, Celgene Corp.) (defending price increases on blockbuster drug Revlimid as a means of compensating for failures “across a number of years of development”).

\textsuperscript{35} See Erika Lietzan, The Drug Innovation Paradox, 83 Mo. L. Rev. 39, 56 (2018) (describing the period of protection granted by patents and government granted non-patent exclusivities such as protection of clinical trial data); see also Lee Branstetter, TPP and the Conflict over Drugs: Incentives for Innovation Versus Access to Medicines, in PETERSON INST. FOR INT’L ECON., ASSESSING THE TRANS-PACIFIC PARTNERSHIP, VOLUME 2: INNOVATIONS IN TRADE RULES 4, 5 (Cathleen Cimino-Isaacs & Jeffrey J. Schott, eds., 2016) (“Pharmaceutical innovation is especially dependent on patent protection . . . the cost of developing new drugs, inclusive of the cost of failures, lies in the billions of dollars per successful drug. Patents allow firms to recoup these costs . . . ”).

\textsuperscript{36} Emily Michiko Morris, The Myth of Generic Pharmaceutical Competition under the Hatch-Waxman Act, 22 FORDHAM INT’L J. L. & POL’YS 151, 172 (2016) (“Attacking flagship drug patents particularly damages the brand-name pharmaceutical innovators, however, for those are exactly the drugs that subsidize not only their own development costs but also the costs of other beneficial but less profitable drugs.”).
Of course, one cannot have one’s cake and eat it, too. If the patent system should compensate for investment in research, patents should not be awarded for discoveries that took little investment, and certainly not accidental discoveries. Creating an enantiomer of an existing drug may not require much investment (and may have different clinical effects in some cases but not in others), yet modern companies patent enantiomers of their drugs. To take a more extreme example, penicillin was an accidental invention. If the aim is to compensate for investment in research, these types of inventions—although currently patentable—would not fit the bill.

To some extent, the failure-compensation argument may have seeped into patent law from a broader societal discussion related to the price of medicine. As the price of drugs has climbed in recent decades, industry and some in academia have responded to criticism by arguing that high drug prices flow partly from the general need for funds to invest in innovation, rather than merely compensating for the cost of investment in the drug itself.

One should note that regardless of whether pricing should reflect innovation failures beyond the cost of R&D and manufacturing of the item itself, the patent discussion is fundamentally different from the pricing discussion. The question for patent law is not whether companies are taking advantage of desperate patients—after all, patents do offer an opportunity to garner monopoly returns—but rather whether the contours of those returns are faithful to the dictates of patent law’s underlying theory. To engage in hyperbole, one could create greater investment incentives for pharmaceutical companies by allowing them to pay no taxes, use electricity for free, or walk into a laboratory supply company and take materials without paying. Discussions of these sorts, however, would be unrelated to the notion that the patent system provides market exclusivity for a successful invention—and for nothing other than the specific invention. Nevertheless, they may have influenced the patent-related discussions.

The notion that the price of any particular drug flows from the general need to invest in innovation, rather than specific investment in the drug itself, is on

37 Using a simplified explanation, enantiomers are conformations that have the exact same molecular structure but are mirror images, similar to left and right hands. See Silas W. Smith, Chiral Toxicology: It’s The Same Thing . . . Only Different, 110 Toxicological Sci. 4, 16 (2009) (explaining that using just the right-handed molecule of thalidomide, however, would not have prevented the 1950s thalidomide crisis in Europe because conversions between the left- and right-handed forms of the molecule take place while the drug is being processed in the body), http://toxsci.oxfordjournals.org/content/110/1/4.full [https://perma.cc/JH5H-AEQX].

38 But see Robert P. Merges, Uncertainty and the Standard of Patentability, 7 High Tech. L.J. 1, 38-39 (1993) (arguing that accidental inventions could receive a patent because the cost of screening out accidental inventions is too great for the system and because there may have been investment in unrelated research that led to the accident). 39 See supra text accompanying notes 12-15.
display in a Johnson and Johnson report, which explains that “[w]e have an obligation to ensure that the sale of our medicines provides us with the necessary resources to invest in R&D to address serious, unmet medical needs.” The report is quite explicit in setting out the argument that the cost of a drug should not reflect the costs related to that drug alone but rather other expenses, as well. In that context, the company explains that failed investments in other drugs must also be one of the costs included:

“Some observers . . . argue that the price of medicines should be pegged to the costs of developing or manufacturing them. However, pricing a medicine based on its R&D or manufacturing costs alone would not take into account the full range of benefits a medicine provides. It would also leave out investments that we must make in drug candidates that fail in development. Pharmaceutical companies and the rest of the scientific community can learn from these failures to improve the research process.”

That characterization is part of the normal industry explanation of the reasons for high drug prices.

Similarly, including the cost of failure has become a standard approach for academic researchers investigating the cost of producing a novel drug. Although

40 See JOHNSON & JOHNSON, supra note 5.

41 Id. at 11.

42 See Ezekiel J. Emanuel, Big Pharma’s Go-To Defense of Soaring Drug Prices Doesn’t Add Up, THE ATLANTIC (Mar. 23, 2019) (noting that pharmaceutical companies often claim that the research costs of unsuccessful drugs also have to be taken into account), https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/ [https://perma.cc/F2UG-F7G2].

43 Studies addressing this question tend to focus on the cost of bringing to market a new therapeutic agent or new molecular entity. Many new drug approvals are not new molecular entities, but existing drugs that are repurposed or slightly altered. Research and development of these drugs tends to cost much less, even as they frequently garner lucrative monopoly periods. For more on these “recycled drugs,” see Amy Kapczynski, Chan Park & Bhavan Sampat, Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents, 7 PLoS ONE e49470 (2012); Kate Gaudry, Evergreening: A Common Practice to Protect New Drugs, 29 NATURE BIOTECHNOLOGY 876 (2011); W. Nicholson II Price, The Cost of Novelty, 120 COLUM. L. REV. 769, 801 (2020), describing and exemplifying evergreening; and Robin Feldman, May Your Drug Be Evergreen, 5 J. L. & BIOSCI. 590, 590 (2018), noting that 78 percent of drugs associated with new patents are not new drugs but existing ones and some of these drugs may even garner new NDAs. See also Steve Shadoven, Keith Leffler & Joseph Lukens, Anticompetitive Product Changes in the Pharmaceutical Industry, 41 RUTGERS J.L. 1, 1-2 (2011) (discussing the prevalence of re-designed pharmaceutical products).
data inputs and results vary dramatically from analysis to analysis, a common feature of studies investigating this question is the inclusion of failed drug innovation efforts in the cost of developing a successful drug. Even the Congressional Budget Office cites that approach in examining R&D costs of drug development.

The costs of failed candidates may be the most significant driver of rising drug development expenses as they are measured by academics and researchers. DiMasi et al. cited the declining clinical success approval rate (i.e., increasing likelihood of failure) of new drugs to explain why their 2016 estimate of drug development cost more than doubled their 2003 estimate. Because research failures, according to contemporary academic researchers, help determine drug development cost estimates, new drugs become more expensive to bring to market as fewer are successfully approved.

44 Olivier J. Wouters, Martin McKee & Jeroen Luyten, Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018, 323 JAMA 844, 844 (2020) (noting that estimates have ranged from $314 million to $2.8 billion and reaching own median capitalized R&D investment of $985 million).

45 See, e.g., id. at 846 (“Accurate information on costs of failures, i.e., research and development outlays on candidates being developed by companies but not ultimately approved, is essential to estimating the costs of drug development.”); see also Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, 47 J. HEALTH ECON. 20, 21 (2016) (noting that “our approach explicitly links the costs of unsuccessful projects to those that are successful in obtaining marketing approval from regulatory authorities”). It is worth noting that the DiMasi (Tufts) estimate—whose $2.6B value checks in at one of the highest—has been challenged on multiple fronts. See Aaron E. Carroll, $2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions, N.Y. TIMES (Nov. 18, 2014), www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html [https://perma.cc/3F4N-LLEF] (suggesting that the disparity in the findings stems from methodological mistakes in the Tufts study and noting that the Tufts Center is funded by pharmaceutical companies); TUFTS CTR. FOR STUDY DRUG DEV., Financial Disclosure, https://csdd.tufts.edu/financial-disclosure/ [https://perma.cc/FK72-AEVB] (last visited Jan. 22, 2021).

46 CONG. BUDGET OFF., supra note 4 (describing in its “at a glance” section the expected cost to develop a new drug as including capital costs and expenditures on drugs that fail to reach the market).


48 In these analyses, researchers consider more than just the failed drug candidates that directly contribute to a successful drug. Instead, the failure costs researchers include in financing a successful drug are aggregated across all drug projects, as opposed to failures only in the same drug class or therapeutic area. See Wouters et al., supra note 44, at 846 (“We accounted for failures using data on aggregate clinical trial success rates . . . by dividing total research and development expenditures on a drug in a particular year by the corresponding aggregate phase-specific probability of success,
In a different rebuttal to the price-should-reflect-investment argument, some commentators point to the extensive amount of funding the federal government provides for pharmaceutical research.\textsuperscript{49} That funding is undoubtedly extensive. For example, one study found evidence of federal funding in the research history of all 210 new drugs approved by the FDA between 2010-2016.\textsuperscript{50} As one scholar notes, “[i]t is important to recognize that capital investments by shareholders contribute only a small fraction of the costs of research and development.”\textsuperscript{51} If the government is already shouldering part of the cost of research, then perhaps society has sufficiently contributed to the financial risks and burdens, at least to some extent.\textsuperscript{52}

The battle lines for this argument are set around the question of what constitutes society’s proper return from funding research (is it the benefit of disease treatments or a monetary return?)\textsuperscript{53} and what constitutes government


\textsuperscript{51} Rena M. Conti & Frank S. David, \textit{Public Research Funding and Pharmaceutical Prices: Do Americans Pay Twice for Drugs?}, F1000 RSCH, July 2020, at 8 (referee Fred D. Ledley’s response to the article as published in the open-access, peer-review report); see also Fred D. Ledley et al., \textit{Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies}, 323 JAMA 834 (2020) (finding that large pharmaceutical companies were more profitable than other large companies, although the difference was smaller when controlling for differences in company size, research and development expense, and time trends).

\textsuperscript{52} A variant of this argument suggests that high drug prices are a form of “paying twice,” in which the taxpayer pays once for funding the research and then again through exorbitant drug prices, See, e.g., Fran Quigley, \textit{Your Tax Dollars Are Making Big Pharma Rich—Twice}, JUST CARE (Nov. 8, 2016), https://justcareusa.org/your-tax-dollars-are-making-big-pharma-rich-twice/ [https://perma.cc/S48U-L2YQ].

funding of research for a particular drug. Government funding tends to finance basic research, while pharmaceutical companies conduct later-stage development such as clinical research and commercialization of drugs.\(^{54}\) Thus, some argue that government funding is beside the point given that such funding is highly attenuated from any particular drug or the role that private industry plays. In contrast, others contend that the underlying research supported by federal funds plays an important role in discovering the drugs that pharmaceutical companies later commercialize.\(^{55}\) Moreover, early stages of research are associated with more risks, particularly in comparison to clinical trials.\(^{56}\)

Although grounded in arguments about pricing, the government-funding issue theoretically relates to patenting. Specifically, when the government funds research that results in a patent, it retains the right to step in and license the patent to others under certain circumstances.\(^{57}\) When the 1980 Bayh-Dohl Act provided that those who receive government research funding may patent inventions flowing from that research, the government retained what are known as “march-in” rights, preserving the government’s power to use, or license others to use, such

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\(^{55}\) Compare Benjamin Zycher, Joseph A. DiMasi & Christopher-Paul Milne, *Private Sector Contributions to Pharmaceutical Science: Thirty-Five Summary Case Histories*, 17 ANNALS OF PHARMACEUTICAL THERAPEUTICS 101, 101 (arguing that “the scientific contributions of the private sector were crucial”), with Peter S. Arno & Michael H. Davis, *Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TULANE L. REV. 631, 640 (2001) (arguing that “[w]hatever can be said of the scientific advances made with this public investment, the concrete financial return to taxpayers is minimal. But perhaps more importantly than the absence of any concrete return is the inevitability of even greater public or consumer expenditures demanded by the monopolies obtained by industry over publicly financed inventions, and the resulting supracompetitive profits and prices. The public has already paid for the cost of research”), and Bhaven N. Sampat & Frank R. Lichtenberg, *What Are the Respective Roles of the Public and Private Sectors?*, 30 HEALTH AFFS. 332 (2011) (arguing that there is an indirect influence of public funding on drug development). See also Ashley J. Stevens et al., *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, 364 NEJM 6 (2011) (looking at patents from public-sector research institutions to argue that government funding has a more direct role in applied research for drug development than in previous decades).

\(^{56}\) See, e.g., Jonathan Stasior et al., *Valuing Pharmaceutical Assets: When to Use NPV vs rNPV*, ALACRITA (Aug. 2018); see also David A. Hyman & Charles Silver, *Pharmaceutical Pricing When Success Has Many Parents*, 37 YALE J. ON REG. 855 (criticizing the pay-twice theory and examining the complexities of the pathways of pharmaceutical research).

patents, assuming the government pays what is essentially a royalty.\(^{58}\)

In reality, however, these governmental rights are a paper tiger. The U.S. government simply has not exercised its powers against drug manufacturers since the 1960s and 1970s, although the George W. Bush Administration once threatened to exercise them against Bayer, resulting in a significant reduction of prices of the drug Cipro.\(^{59}\)

Regardless of the extent to which the pricing arguments have slipped into the patent discussion, the Part above details the fact that there are those in three commanding fields—modern courts determining whether to enjoin an alleged patent infringer, Congressional debates considering patent law provisions, and academics examining the contours of the patent quid pro quo—who approach analyses as if the patent reward appropriately includes compensation for failed research on other products. The following Part examines this argument through the lens of patent legal history.

II. CLASHING WITH THE HISTORY OF PATENT LAW

If it were true that the patent reward should be sufficient to include compensation for investment in failed research projects, one would expect to see historic patent law and theory embracing this conceptualization. On the contrary, historic patent statutes, cases, and classic theoretical discussions fail to reflect the notion that patents are intended to compensate for investment in failed research. Rather, they view the patent reward as tailored to the societal benefit and only the benefit provided within the narrow confines of the specific invention. Thus, the caselaw and statutory history demonstrate how far one would have to stray from the roots of patent law to support modern arguments that the patent reward should be large enough to include expenditures of money invested in failed research—at least as a matter of patent legal history.

The notion of including failed invention costs in the value of a patent finds no home in early American patent history. The nation’s early patent law—i.e., federal statutes and cases from 1790 to 1865—reveals no single act or case stating that


\(^{59}\) See Kapczynski & Kesselheim, supra note 58, at 794.
a patent grant is intended to compensate the patentee for the costs of developing a failed (i.e., never-patented) invention. Indeed, with limited exceptions, early patent law reveals no act or case stating that a patent grant is intended to compensate the patentee even for the costs of developing a successful (i.e., patented) invention.

A. Early Cases and Authorities

Early case law and venerable authorities cited therein state routinely that the reward of a patent grant is intended to encourage the creation of new and useful inventions. The same sources, however, routinely state that the costs of developing such inventions are irrelevant to patentability. Moreover, they only rarely state that the reward of a patent grant is intended to permit the recoupment of development costs and thus to encourage the incurrence of such costs (i.e., investment). George Ticknor Curtis’s treatise on patent law—"unquestionably the dominant work on patent law" from its initial publication in 1849 until at least 1873—quoted as a foundational articulation of the point, Chief Justice Tindal’s decision of 1842 in Crane v. Price:

[T]he labor of thought or experiment, and the expenditure of money, are not the essential grounds of consideration on which the question, whether the invention is or is not the subject-matter of a patent ought to depend. For if the invention be new and useful to the public, it is not material whether it be the result of long experiment and profound search, or whether by some sudden and lucky thought, or mere accidental discovery. . . .

60 See infra text accompanying notes 71-85.
61 GEORGE TICKNOR CURTIS, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS IN THE UNITED STATES OF AMERICA (Boston, Little, Brown, 2d ed. 1854) [hereinafter CURTIS].
64 CURTIS, supra note 61, at § 6 n.1 (quoting Crane) (emphasis added); see also Hotchkiss v. Greenwood, 52 U.S. 248, 269-71 (1850) (Woodbury, J., dissenting) (quoting Justices Story, Kent, and Tindal, and citing Curtis); Forbush v. Cook, 9 F. Cas. 423, 424-25 (C.C.D. Mass. 1857) (Circuit Justice Curtis charged the jury: “The true inquiries for you to make in this connection are, whether
For the same purpose, Curtis also quoted Justice Story’s famous statement of 1825, in *Earle v. Sawyer*, that, in the determination of whether an invention is patentable, “[i]t is of no consequence, whether the thing be simple or complicated; whether it be by accident, or by long, laborious thought, or by an instantaneous flash of mind, that it is first done. The law looks to the fact and not to the process by which it is accomplished.”

the combination made by Crompton was new and useful? If it was a new and useful combination within the meaning of the patent law, it was the subject-matter of a patent, and is not important whether it required much or little thought, study, or experiment to make it, or whether it cost much or little time or expense to devise and execute it. . . . A new or improved, or more economical effect, attributable to the change made by the patentee in the mode of operation of existing machinery, proves that the change has introduced a new mode of operation, which is the subject-matter of a patent; and when this is ascertained, it is not a legitimate subject of inquiry, at what cost to the patentee it was made . . . .” (emphasis added); *Carr v. Rice*, 5 F. Cas. 140, 142 (C.C.S.D.N.Y. 1856) (observing that “a patent can not be supported by proof that the invention was new to the patentees themselves, but the evidence must be satisfactory that they were actually the first, and original discoverers, of the thing patented. Their title is in no wise strengthened if their invention be proved to have been made at great expense of time, research, and money, even if they honestly believed it original with themselves, if in the end it is made to appear that others had previously known and used it.” (emphasis added)); *Many v. Sizer*, 16 F. Cas. 684, 685 (C.C.D. Mass. 1849) (charging the jury: “I have been requested to instruct you that it is of no consequence, as to the validity of a patent, how much, or how little labor, study, or thought the invention cost. And, gentlemen, this is so, if it be really a new and useful invention. The degree of labor and thought may be sometimes evidence to the jury, upon the question of invention; but although the invention be accidental, or a sudden flash of thought, the party is entitled to the benefit of his discovery.” (emphasis added)).

65 *Earle v. Sawyer*, 8 F. Cas. 254, 256 (C.C.D. Mass. 1825). Kent, whose commentaries on American law were commonly cited throughout the early period, was probably the inspiration for Justice Story’s comment: “The law has no regard to the process of mind by which the invention was accomplished, whether the discovery be by accident or by sudden or by long and laborious thought.” 2 JAMES KENT, COMMENTARIES ON AMERICAN LAW 371 (O. Halsted 1827). While the cost of developing an invention is irrelevant to whether the invention is patentable (as noted by Justices Kent, Story, Tindal, et al.), the cost of commercializing an already-patented invention has, on occasion, been regarded as relevant to patent law. The relevance arises insofar as patent law has been regarded as incentivizing patentees and, especially, their assignees to make whatever expenditures are necessary to bring the patented invention to market. See, e.g., *Day v. Union India-Rubber Co.*, 7 F. Cas. 271, 275 (C.C.S.D.N.Y. 1856) (“These privileges are granted for the additional purpose of inducing inventors, and their assignees and grantees, to make the required expenditures and investments in order to put the patented inventions in practice, and thereby to give the public the benefits to be derived from a successful use of the inventions, at the earliest day, and to the fullest extent, required by the public interests.”) (emphasis added); see also Rohm & Hass Co. v. Crystal Chem. Co., 722 F.2d 1556, 1571 (Fed. Cir. 1983) (finding that patent rights can “stimulate the investment of risk capital in the commercialization of useful patentable inventions so that the public gets some benefit from them, which may not occur in the absence of some patent protection.”) (emphasis added)). See generally Blanchard’s Gun-Stock Turning Factory v. Warner, 3 F. Cas. 653, 657 (C.C.D. Conn. 1846) (noting that it was typically assignees that expended funding necessary to bring patented inventions to market and observing that “[t]he assignees of the original patentee are frequently most instrumental in putting the invention into general use, and bringing it successfully before the public, by the expenditure of their time and money. More than half, probably, of the useful patented inventions have been thus brought into general public use . . . .” (emphasis added)).
These authorities give the purest expression of a view prevalent in the early period: That what is rewarded, and thus encouraged, by the patent grant is the creation of an invention new and useful to the public and that the costs incurred to develop the invention are irrelevant to patentability and play only a minor role in the statutory incentive structure. According to this view, what matters greatly is the statutory requirement of novelty and utility; what matters little is whether the invention resulted from arduous, expensive experimentation or, rather, from one cost-free flash of genius. Thus, the view bespeaks a practical, if hard-nosed, understanding of the purpose of patents: To create a societal benefit and not to give an A for effort. If the proposed invention fails to satisfy the law’s uncompromisingly utilitarian prerequisites, then no point can be served by granting a patent, even if the inventor’s entire life and fortune have been devoted to the failure.

None of the foregoing is to say that courts in the early period did not permit patentees to recoup the costs of developing the patented inventions when suing for infringement. Nor is it to say that such courts did not occasionally attribute to patent law the purpose of promoting investment. But it is to say that the rarity of such attribution in the early period is itself meaningful.

What does it mean? It cannot mean that a purpose of patent law was so widely understood to be the promotion of investment as to need no articulation. Other deeply held concepts are explicitly expressed. Indisputably, a purpose of patent law was widely understood to be the promotion of invention, and that

66 See, e.g., Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, 119 (noting that “any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on” the same).

67 See, e.g., Pitts v. Edmonds, 19 F. Cas. 751, 758 (C.C.E.D. Mich. 1857) (observing that, in a patent infringement suit, infringer’s profit is not necessarily sufficient measure of damages because it does not reflect the patentee’s cost of developing the invention: “[A] party concerned in infringing a patent stands in a different position from the patentee, not having been previously subjected to the expense and labor to which the latter is frequently exposed in the process of invention and experiment. Hence, the person who enters upon the business without previous expense, may very well afford to sell machines at less profit than the patentee. The latter must have his profit, not only for the expense of putting in operation the improvement, but by way of indemnity for the previous time, labor and money which he has been obliged to bestow on the invention. He must, therefore, charge a higher price, to cover these greater expenses. Thus, profits which the party infringing might be satisfied with, and which would afford him compensation, would not afford indemnity to the patentee.”).

68 See, e.g., Lowell v. Lewis, 15 F. Cas. 1018, 1020 (C.C.D. Mass. 1817) (“The law confers an exclusive patent-right on the inventor of anything new and useful, as an encouragement and reward for his ingenuity, and for the expense and labor attending the invention.”), abrogated on other grounds as recognized in In re Fisher, 421 F.3d 1365, 1370-71 (Fed. Cir. 2005). Apparently, Justice Story’s comment about “encouragement and reward . . . for the expense and labor attending the invention” has never been quoted or cited in subsequent case law. Lowell, 15 F. Cas. at 1020.
understanding is repeated endlessly throughout the early case law.

Rather, the rarity of the attribution more likely reflects the premise that a purpose of patent law is to reward, and thus to encourage, invention and not necessarily investment. Recall that, technologically, this was an era in which invention was just as likely to result from a momentary flash of genius as from years of expensive toil in the laboratory. According to this premise, the patented invention is the goal, and whether a particular inventor incurs low or high costs in developing the patented invention or chooses to labor in a low-cost field (e.g., business methods) rather than a high-cost field (e.g., pharmaceuticals), or decides to devote the income from the patent to personal entertainment rather than cost recoupment, is the inventor’s private choice, regarding which patent law takes no position.69

B. The Patent Term Extension Provision of 1836

Of the exceptions mentioned above,70 the most important is a statutory provision enacted in 1836 and repealed in 1861. That provision authorized a seven-year extension for any patent upon the patentee’s showing that the original fourteen-year patent term was insufficient to allow recoupment of the expense incurred during the development of the patented invention.71 Under that provision, the application for an extension had to be submitted in writing, with a fee, to the Commissioner of the Patent Office, who was then bound to publish notice of the application and invite any person to oppose the application.72 A board consisting of the Secretary of State, the Commissioner of the Patent Office, and the Solicitor of the Treasury would then review the evidence submitted for and against the application.73 In particular, the applicant was obligated to submit, under oath, a written statement of the invention’s value, along with the inventor’s receipts and expenditures, sufficient to show the inventor’s profit and loss from the

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69 Some cases mention *en passant* the inventor’s “fruitless experiments” or “unsuccessful experiments.” But these phrases refer to the ordinary trial and error leading to the patented invention (say, vulcanized rubber) rather than to a failed, non-patented invention (say, invisible fabric). See, e.g., *Wilson v. Simpson*, 50 U.S. 109, 117 (1850) (noting that plaintiff’s counsel argued: “By reason of great poverty, occasioned by many years of *fruitless experiments* in search of *this* great discovery, [Charles Goodyear] was compelled to grant licenses far below their actual value.” (emphasis added)); *McClurg v. Kingsland*, 42 U.S. 202, 205 (1843) (citing fact that inventor’s employer bore cost of “unsuccessful experiments” as proof of implicit license from inventor to employer). In any event, these cases do not cite the cost of the “fruitless” or “unsuccessful” experiments as a reason to grant or extend a patent.

70 See supra text accompanying note 69.


72 Id.

73 Id. The authority given to the board in 1836 was given to the Commissioner alone in 1848. See Act of May 27, 1848, ch. 47, § 1, 9 Stat. 231, 231.
invention.  If the board decided that the applicant failed, without fault, “to obtain, from the use and sale of his invention, a reasonable remuneration for the time, ingenuity, and expense bestowed upon the same, and the introduction thereof into use,” the Commissioner was obligated to grant the extension.

The provision is instructive for several reasons. First, the only unrecouped “expense” that could justify an extension was an expense incurred for the patented invention (“expense bestowed upon the same” (emphasis added)). The patentee who applied for an extension could not base the application on expenses incurred for a failed invention, or, indeed, on expenses for a successful invention other than the patented invention at issue.

Second, the extension provision was short-lived. In 1861, Congress withdrew the extension provision and replaced it with a provision permitting a single seventeen-year patent term starting from the grant of the patent. That seventeen-year provision remained the law until 1994 when it was amended to provide a twenty-year patent term running from the time of the application. Congress could

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75 Id. (emphasis added). A later committee print understood the phrase “expense bestowed upon the same” to mean “expense [invested in its development].” STAFF H. COMM. ON JUDICIARY, 96TH CONG., THE HISTORY OF PRIVATE PATENT LEGISLATION IN THE HOUSE OF REPRESENTATIVES 7 (Comm. Print 1979) (hereinafter HISTORY) (bracketed material added by Staff of House Committee).
76 Id. The precursor of this provision was a provision in the Act of July 3, 1832, ch. 162, § 2, 1 Stat. 559, 559, that authorized a patentee to petition Congress directly for a private act to extend the patentee’s patent, provided that the petition be “accompanied by a statement of the ascertained value of the discovery, invention, or improvement, and of the receipts and expenditures of the patentee, so as to exhibit the profit or loss arising therefrom.” Id. The 1832 Act did not include any reference to “reasonable remuneration,” “time,” “ingenuity,” or “expense.” Between 1808 and 1836, Congress passed eleven private acts extending patents pursuant to requests of patent holders. See Simon Lester & Huan Zhu, Rethinking the Length of Patent Terms, 34 AM. U. INT’L L. REV. 787, 793 (2019). Even after 1836, many petitions to Congress for a private act to extend a patent were submitted, though few were granted. HISTORY, supra note 75, at 8-9. Typically, these petitions were denied because the petitioner had already made a significant profit or because the petition’s claim that the petitioner’s “expectations of profit [were] not fully realized” was considered an insufficient basis for an extension. Id. Ultimately, these petitions, premised as they were on desire for a “guaranteed income” from the patent at issue, proved “too time-consuming and open to frivolous claims.” Id. at 14.
77 To be clear, the 1861 Act’s withdrawal of the extension provision was prospective; patents issued before passage of the 1861 Act were still eligible for extension under the 1836 Act. See Act of Mar. 2, 1861, ch. 88, §§ 16-17, 12 Stat. 246, 249 (providing that “all patents hereafter granted shall remain in force for the term of seventeen years from the date of issue; and all extension of such patents is hereby prohibited” and that “all acts and parts of acts heretofore passed, which are inconsistent with the provisions of this act, . . . are hereby repealed” (emphasis added)). The 1861 Act also expressly provided for seven-year extensions for design patents (which were first authorized in the Act of Aug. 29, 1842, ch. 263, § 3, 5 Stat. 543, 544); in the Act of 1870, Congress made clear that only design patents issued before passage of the 1861 Act were eligible for extension. See Act of July 8, 1870, ch. 230, § 74, 16 Stat. 198, 210.
78 In 1994, the provision for a seventeen-year term was replaced by a provision for a twenty-year term. See Lester & Zhu, supra note 76, at 788, 794.
have designed the current patent system to provide an extension of the patent term when needed to allow for recoupment of development expenses, but it rejected that approach. In other words, one could characterize the extension provision as a failed experiment of its own.

Third, extensions were infrequent. By 1846, the government had granted 14,526 patents, but only ten extensions were granted under the 1836 Act.79 The number of extension applications is unknown. It is, therefore, unknown whether the infrequency of extensions was due to a paucity of applicants or to the parsimony of decision-makers.80 The only thing known for sure is that, for this representative ten-year period, one extension a year on average was granted.

Fourth, whatever the term “expense” meant to the drafters of the 1836 Act,81 the legislative history reveals that by 1860 the greatest, and perhaps the only significant, “expense” incurred by extension applicants was the cost of the litigation following the patent grant, rather than the cost of developing the patented invention in the first place. In a discussion regarding whether the multiple levels of administrative review necessary for the granting of a patent had created too great a burden for the patent applicant and thus whether judicial review would unnecessarily add to that burden, one senator stated:

“[Inventors’] patents are rendered worthless because of the litigation they are subjected to in regard to them; and in every application for an extension of a patent filed here, that I remember since I have been a member of Congress and have been upon this committee, I do not recollect a single instance where the applicant has not based his application upon the ground that he has been unable to make the invention remunerative because of the litigation to which he has been subjected.”82

79 Wilson v. Rousseau, 45 U.S. 646, 708 (1846)
80 A guide to patent practice, published in 1855, notes that “[t]he presumption is always against [the extension] application. . . . Rarely, indeed, are patents extended in this country.” J.G. Moore, Patent Office and Patent Laws: Or a Guide to Inventors and a Book of Reference for Judges, Lawyers, Magistrates and Others (Philadelphia, Parry & M’Millan 1855). The post-1836 history of petitions for private acts to extend patents shows that Congressional decision-makers were reluctant to grant such petitions, and that such petitions were not generally viewed as meritorious—though there was apparently no lack of interest on the part of patentees in filing such petitions. See supra note 76; History, supra note 75, at 8–9.
81 See Act of July 4, 1836, ch. 357, § 18, 5 Stat. 117, 124–25 (providing for “a reasonable remuneration for the time, ingenuity, and expense bestowed upon the same” (emphasis added)).
82 Cong. Globe, 36th Cong., 1st Sess. 1733 (Apr. 16, 1860) (statement of Sen. Trumbull); see also Pitts v. Edmonds, 19 F. Cas. 751, 752 (C.C.E.D. Mich. 1857) (“No patent in this country has been so much litigated as Woodworth’s planing machine. While this affords the highest evidence of
Finally, the 1861 withdrawal of the extension provision was a considered decision, not an unconsidered result of some omnibus legislative overhaul. A proposed amendment to a draft of the bill that became the 1861 Act included a provision permitting a patent extension only where the applicant for the extension had earned from the invention a net profit of less than $100,000. After debate about whether the net-profit figure should include the net profit of the patentee’s assignees and whether the patentee had the power to obtain profit and loss figures from the assignees, the proposed amendment containing the $100,000 limitation...
was rejected, and, on the same day, the extension provision was replaced with the provision for the single, unextendible, seventeen-year term.85

In sum, early American patent law contains no statement that patent grants are intended to enable recoupment of the costs of a failed invention and—with telling exceptions—no statement that patent grants are intended to enable recoupment of the costs of the patented invention. The extension experiment itself saw few extensions granted and was soon abandoned. The language of the extension provision demonstrated that even where Congress made the inventor’s cost relevant to the patent-protection determination, the only cost that could be properly considered was the cost of the patented invention for which the extension was sought, not the cost of a failed invention or the cost of any other patented invention. The infrequency of extension, while perhaps indicating a reluctance by decision-makers to grant extensions, might also indicate a lack of merit among extension applications. In any event, inventors’ costs could not have been significant in the main, as inventors were typically too undercapitalized to have incurred major expense in developing the patented invention. That the costs almost universally cited in extension applications were the costs of litigation following the patent grant rather than the costs of development preceding the patent grant shows that those costs of development were a relative non-issue in the determination of whether to grant patent protection. Most important, the notion of including the costs of failed inventions is nowhere to be found.

That concept has remained steady in the various legislative changes to the patent laws in the later centuries. This is not for lack of other comparative models. There is another model in which government ensures that those making the investment are fully compensated for costs, as well as a guaranteed level of return. Beginning with the Energy Policy Act, signed into law by Franklin D. Roosevelt in 1935, Congress established a regulated electric utility regime, which includes the right to a return.86

Rate of return regulation is a method for setting the prices of government-regulated monopolies such as public utilities.87 Under this method, regulators

establish a given “rate of return”—the amount of money the monopoly needs to finance the capital it uses to provide its services—which is then combined with the company’s operating and depreciation expenses to generate a target revenue or the amount of money the company must earn in order to make a reasonable profit.\textsuperscript{88} The target is then used to determine how much the company should charge consumers. The goal of rate of return regulation is to protect customers from the high prices that can result from a monopoly market while still ensuring the company can cover its costs and satisfy its investors.\textsuperscript{89}

Congress certainly could have followed that model when it amended the Patent Act in 1952,\textsuperscript{90} but it remained steadfast in following the patent path—a path that stands in strong contrast to regulated utilities. With patents, there is no guarantee of a return. There may be substitutes available, other patents may overlap, or the market may not be ready to appreciate the invention during the patent term. Unlike regulated utilities, the vast majority of patents never garner a return for those who hold them. This is not to suggest that patents and regulated utilities are derived for similar goals or through similar logic. The point is simply that Congress could have chosen an entirely different route for pharmaceutical innovation, one ensuring that those making the investment are fully compensated for costs, as well as a guaranteed level of return. And yet, Congress chose a very different path.

Regulated utilities continue to this day in certain parts of the country,\textsuperscript{91} with returns far below those of the pharmaceutical industry.\textsuperscript{92} The system certainly insulates companies from risks, but it carries downsides for companies and the nation. From the company perspective, rate of return regulation guarantees the monopoly company a steady profit, just not a dramatic one. From society’s perspective, critics and scholars have pointed out that employing rate of return can inhibit efficiency by contributing to the Averch–Johnson effect, wherein a


\textsuperscript{89} See, e.g., Kenton, supra note 87.


\textsuperscript{92} See, e.g., Aswath Damodaran, Return on Equity by Sector, N.Y.U. STERN (Jan. 2022), http://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/roe.html [https://perma.cc/WFC3-JJZ2] (showing return on equity for pharmaceutical industry as 14.55 percent (unadjusted for R&D) and 11.04 percent (adjusted for R&D) versus return on equity for general utilities of 8.44 percent (unadjusted) and 8.44 percent (adjusted)).
company makes excessive and unnecessary investments in order to increase its total profits. That is analogous to the type of problem described in this Article in relation to the drive to include failed pharmaceutical costs. Even with a regulated utility model, however, the costs taken into account would be the costs of the specific plant built in Baton Rouge, for example, not other expenditures.

III. HOW REWARDING FAILURE IS COUNTERPRODUCTIVE

As shown in Part II, patent legal history did not conceptualize patents as providing sufficient reward to compensate for the cost of investing in failed drug development. Moreover, providing a patent reward of this kind would raise questions under modern, conventional economic thinking. This Part explores the economic implications within the contours of the patent system.

It is crucial to note the narrow and specific aims of the patent system within any notion of economic incentives. The patent system is not designed to provide incentives for the nation’s general economic output. Thus, a broad notion such as “incentivizing investment in innovation” or even “compensating for the risks of invention” would fail to capture the essence of the patent system. As noted in Section I.A, more than 90 percent of patents never garner any return for their owners. If risk-compensation or incentivizing investment were the design, one could easily conclude that the system itself is an abject failure, or at least a grand waste of regulatory time.

Nor is the patent system merely designed to encourage dollar investments. As described in Section II.A, the patent system is agnostic as to the costs of an endeavor, that is, whether the invention took fifty years and billions of dollars or whether the invention came in an instant, cost-free flash. The system’s lack of focus on dollar investment is reflected again in the notion of what is rewarded. One is rewarded not just for inventing but also for sharing those inventions for the benefit of society, opting for the patent system’s openness over the closed system of trade secrets. Thus, the entire notion that the patent system’s sole design is to attract people into the business of investing in invention misses the mark. These are important caveats before embarking on a discussion of economics and incentives.

As an initial matter, patents provide an opportunity to garner a return in the market through the exclusion of competitors from the sale of a particular product. Patent statutes, cases, and classic theory do not suggest that patents are designed

to provide some additional return beyond the profit-maximizing price on that item—such as the costs of failed investment. From an inventor-specific perspective, once a drug is awarded a patent monopoly, the profit-maximizing price should be determined by setting marginal revenue equal to marginal cost. On the other hand, research and development costs are sunk costs, meaning they should not bear on the profit-maximizing price of the drug or the reward available through that price.

More specifically, allowing the patent reward to include the cost of failures has a perverse effect when looking at the invention-specific level. Ideally, one would want to design a system that encourages companies to succeed—and succeed in the most efficient manner possible. When the cost of other failures is included, however, the drive for efficiency is turned on its head. Quite simply, the more one fails, the higher the reward, at least from an invention- or inventor-specific level, rather than system-wide.

One can understand the point on an intuitive level. If I can charge whenever I fail, then the more I fail, the more I get to charge. From a numerical perspective, consider the following example. Imagine that Mega Pharma acquires two promising arthritis treatments—Treatment A and Treatment B—both of which recently advanced through phase II trials. Mega estimates that each drug has a

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96 See id. at 574. (“The sunk cost fallacy. Once you have bought something, the amount you paid is sunk, or no longer recoverable. So future behavior should not be influenced by sunk costs”); see also Jack Scannell, Four Reasons Drugs Are Expensive, Of Which Two Are False, FORBES (Oct. 13, 2015) https://www.forbes.com/sites/matthewherper/2015/10/13/four-reasons-drugs-are-expensive-of-which-two-are-false/?sh=48b89aa34c3b [https://perma.cc/Q7JD-7397] (“Sunk costs are sunk. If companies are going to spend on R&D, they need to believe that there are decent odds that they will make a good return on investment”); Cong. Budget Off., Research and Development in the Pharmaceutical Industry 1-2 (2021) (“A drug’s sunk R&D costs—that is, the cost for developing that drug—do not influence its price.”); David Encaoua et al., Patent System for Encouraging Innovation: Lessons from Economic Analysis, 35 ELSEVIER 1423, 1425 (2006) (“By giving some temporary exclusionary rights to inventors, the government delegates the R&D decision and leaves in the hands of the inventor the responsibility of recovering his R&D investment.”).

97 Note: the example would work equally with internally developed drug candidates (i.e., spending $1 million on internal R&D for each one of two arthritis drug candidates). The acquisitions in this example, however, better reflect the changing pharmaceutical innovation pipeline, in which startups now increasingly tackle risky early-stage development, while large firms handle late-state trials and regulatory approval. For more on this structural shift and its possible implications, see Barak Richman, Will Mitchell, Elena Vidal & Kevin Schulman, Pharmaceutical M&A Activity: Effects on Prices, Innovation, and Competition, 48 Loy. U. Chi. L.J. 787 (2017); Shepherd, supra note 11; and Robin Feldman, Drug Companies Keep Merging. Why That’s Bad for Consumers and Innovation, WASH. POST (Apr. 6, 2021), https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/ [https://perma.cc/2SB6-WTNU]. It is also worth noting that phase II trials tend to be the most selective phase in the road to new drug approval, so advancing past phase II would significantly boost a prospective drug’s risk-adjusted net
50 percent of advancing through the remaining regulatory stages and that, if successful, each would be worth $200 million.

As a result of the likelihood of success versus failure and the potential rewards, Mega would pay at least $100 million to acquire each candidate. In other words, a 50 percent likelihood of success on a $200 million drug leads to a value of $100 million. Given that Mega buys both drugs for their respective values, the total cost is $200 million for the two together.

Treatment A is eventually approved for marketing; Treatment B fails to demonstrate efficacy in clinical trials and is shelved. Using the researchers’ methodology, the $200 million cost of both acquisitions would be factored into the R&D cost, and therefore the price, of Treatment A. Thus, Mega should be able to earn $200 million on the sale of the successful Treatment A.

Now consider Goliath Pharma. Goliath, also excited by the arthritis market, decides to acquire five different treatments in the pipeline. As with Mega’s acquisitions, these carry a 50 percent chance of success and expected earnings of $200 million each. Thus, Goliath would have to pay at least $100 million for each drug candidate. In total, then, Goliath spends $500 million. Four of the five treatments fail: After all, Wall Street is littered with stories of drugs that had promising results in phase II but crashed and burned in phase III. With its five acquisitions and four failures, Goliath needed $500 million to successfully develop an arthritis treatment, compared to Mega’s $200 million (two acquisitions, one failure). If a drug’s price ought to offset its development costs, including failures, Goliath should be able to earn $500 million. Mega, however, was only justified in earning $200 million. The one who fails more, brings in more—dampening the incentive to be efficient. This is hardly the outcome the patent system is meant to encourage.

And of course, the fact that a company invests in five companies with each

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present value. Phase III drug candidates have become increasingly likely to earn market approval in recent years. See Helen Dowden and Jamie Munro, Trends in Clinical Success Rates and Therapeutic Focus, 18 NATURE REV. DRUG DISCOVERY 495, 495 (2019).

98 For simplicity’s sake, this hypothetical does not include the discount rate that is used in order to calculate present value of an investment. Robert Shaftoe, How to Calculate a Risk-Adjusted NPV, SAPLING (last visited Mar. 20, 2023), https://www.sapling.com/6708011/calculate-riskadjusted-npv [https://perma.cc/5M7M-92F3].

99 For descriptions of disastrous Phase III failures, see, for example, Frank Vinluan, Theravance’s Lead Drug Fails in Phase 3, Triggers a Restructuring Cutting 75% of Staff, MEDCITY NEWS (Sept. 15, 2021), https://medcitynews.com/2021/09/theravances-lead-drug-fails-in-phase-3-triggers-a-restructuring-cutting-75-of-staff/ [https://perma.cc/9HHU-WBNJ], reporting corporate shakeup after a Phase III failure. See also U.S. FOOD & DRUG ADMIN., 22 CASE STUDIES WHERE PHASE 2 AND PHASE 3 HAD DIVERGENT RESULTS (Jan. 2017), https://www.fda.gov/media/102332/download (noting that 90 percent of drugs tested in humans are never submitted to the FDA for approval and examining twenty-two publicly available cases from 1999 through 2017 in which phase II and phase III obtained divergent results).
having a 50 percent chance of success does not guarantee that one will hit. Consider the simple example that each time one flips a coin, the chance of landing on heads or tails remains at 50 percent. Only if one could flip an enormous number of times, or invest in an equivalently enormous number of companies, would one approach a different result.

The illogic of folding research and development costs related to other drugs into the reward for a successful drug can be seen from other perspectives. Imagine that a company tries to develop a cancer drug, a diabetes therapy, and a drug for heart disease. Suppose all three are successful. Would you then allow each drug to be priced to include the costs of all three research programs?\textsuperscript{100}

To justify including the steep costs of failure in calculating the price tag of bringing a new drug to market, drug-makers often assert that research failures enable or inform future pharmaceutical innovation by allowing drug-makers to “learn from their mistakes.”\textsuperscript{101} Research, however, casts doubt on this proposition. One preliminary found that failed drug development efforts in a therapeutic area have no significant impact on future drug development in that field and in fact, tend to predict future failures in other therapeutic areas.\textsuperscript{102} Failure, it seems, simply begets more failure.

Focusing in more specifically, some scholars writing on drug prices, rather than on drug patents, have proposed that prices should be tied to risk-adjusted R&D costs. These proposals are intended to demonstrate the excessive nature of pricing and offer a method of reining in the current runaway prices.\textsuperscript{103} These approaches do an admirable job of showing the gulf between investment and pricing, highlighting the extent to which companies are garnering profits well beyond risk-adjusted R&D costs. However, by linking prices with risk-adjusted

\textsuperscript{100} An extensive literature has explored game theoretic views of patent races, describing ways in which a system might over-incentivize R&D, distorting the innovative result.

\textsuperscript{101} See Johnson & Johnson, supra note 5, at 11 (“Pharmaceutical companies and the rest of the scientific community can learn from these failures to improve the research process.”).

\textsuperscript{102} See Daniela Silvestri, Sowing Failures, Reaping Success? Evidence from Pharmaceutical R&D Projects (Druid Society, 2017) (unpublished manuscript) (on file with author) (finding that failed drug development projects have no significant impact on the success of the firm’s future drug development in the same therapeutic area, and actually predicts increased failure in drug development in other therapeutic areas).

\textsuperscript{103} See Frederick M. Abbott, Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health, 6 U.C. Irvine L. Rev. 281 (2016) (arguing against the use of patents as a justification for exorbitant drug price and in favor of comparing a drug’s price to the costs of R&D, including failed attempts, drug production and future R&D, to assess the reasonableness of a drug’s price); Kapczynski & Kesselheim, supra note 58 (arguing that compensation to drug companies should be based on the amount invested in the drug, adjusted for the risk of failure and awarding the drug company reasonable profit margin); Suerie Moon et al., Defining the Concept of Fair Pricing for Medicines, 368 BMJ I4726 (2020) (arguing that the fair price for medicine falls between the buyer’s maximum affordability and the seller’s costs plus the minimum sustainable profit margin).
investment, the proposals could inadvertently create an incentive to artificially inflate R&D costs to justify additional returns. In other words, if a company’s returns will be based on R&D costs, the company has an incentive to inflate those returns. Thus, particularly if extended beyond the pricing context to the patent context, they could serve to spur prices on rather than rein them in.

Similarly, some scholars suggest that the patent obviousness doctrine should be risk-adjusted by tailoring it to reflect uncertainty. Merges, in particular, argues that the standard for obviousness should be lowered when the inventor faces a high degree of uncertainty in order to encourage the assumption of that risk.

104 See Kiu Tay-Teo, André Ilbawi & Suzanne R. Hill, Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Drug Companies, 2 JAMA NETWORK OPEN 1, 7 (2019) (comparing the incomes generated by sales of cancer drugs to their R&D costs, finding that returns were much higher than “a justifiable return for rewarding and incentivizing innovation” and noting that these excessive returns might contribute to inefficiencies in R&D).

105 Cf. Samson Vermont, A New Way to Determine Obviousness: Applying the Pioneer Doctrine to 35 U.S.C. § 103(A), 29 AIPLA Q.J. 375, 387 (2001) (arguing in the context of the obviousness doctrine that if cost were the sole criterion, applicants would have an incentive to drum up costs). Pharmaceutical literature does suggest that pharmaceutical deals and assets, as opposed to prices, should be valued at risk-adjusted net present value (rNPV). This literature, however, focuses on expected future returns for the purpose of asset valuation. The calculation of rNPV also includes pricing, itself, as an input, and it would make little sense to say that price should be based on rNPV if price is an assumption used to calculate rNPV. In other words, it would be circular to use the current state of expected returns in the market to justify the notion that returns should be this amount, let alone that optimal innovation incentives or patent value should be determined in this manner. For examples of recommending rNPV for deal and asset valuation, see, for example, rNPV: Approaches to Net Present Value (NPV) in Pharmaceutical Research and Development (R&D), CONDUCTSCIENCE (Jul. 20, 2018), https://conductscience.com/npv-approaches-to-net-present-value-npv-in-pharmaceutical-research-and-development-rd/ [https://perma.cc/NCK7-RW6K], explaining that rNPV is a tool helpful to investors in assessing the potential profitability of a project; Jonathan Stasior, Brian Machinist & Michael Esposito, Valuing Pharmaceutical Assets: When to Use NPV vs rNPV, ALACRITA (2018), explaining that rNPV is calculated to allow investors to account for risk of failure in each stage of development and that extensive historical data on the probabilities of success for R&D across different therapeutic areas are used to calculate the probability of success at each stage of development; and Aitana Peire & Patrik Frei, What is the Value of a Deal?, NEWS FEATURE (Jun. 29, 2016), https://www.nature.com/articles/d43747-020-00160-x [https://perma.cc/4UQT-A9NT], explaining that rNPV is a valuation based on assumptions, including assumptions about the pricing of drugs. See generally Laura Entis, Why Does Medicine Cost So Much? Here’s How Drug Prices Are Set, TIME (Apr. 9, 2019), https://time.com/5564547/drug-prices-medicine/ [https://perma.cc/4Q9F-XL4L] (explaining the complex process of how drug prices reach consumers and how the absence of regulations governing drug pricing results in pharmaceutical companies pricing drugs based on what they expect the market will withstand).

His economic model concludes that patents are more valuable for developing technology than spurring its initial innovation. Thus, the patent system should create incentives to develop and commercialize an invention rather than as an incentive to invent in the first place.

Merges’s doctrinal recommendation has been criticized for its unintended potential to create perverse effects on innovation. As scholars have noted, weakening the obviousness standard creates incentives for companies to make minor adjustments to existing innovations rather than undertaking more risky and challenging research. Merges notes an offshoot of the problem in a later article, explaining that in using cost to demonstrate nonobviousness, courts may have “steered biotechnology researchers toward an increasing amount of mundane and repetitive lab work--precisely the opposite of what the patent system seeks to promote.” Once again, the goals of the patent system should be the clear focus alongside other “economic indicia” to evaluate the invention’s importance; Ryan Abbott, *Everything Is Obvious*, 66 UCLA L. REV. 2, 45 (2019) (drawing on Merges and other scholars to advocate “a more economic than cognitive nonobviousness inquiry”); Karen I. Boyd, *Nonobviousness and the Biotechnology Industry: A Proposal for a Doctrine of Economic Nonobviousness*, 12 BERKELEY TECH. L.J. 311, 337-38 (1997) (proposing an additional economic nonobviousness test to provide patent protection for socially useful but economically risky inventions such as those produced by the biotech and pharmaceutical industries); cf. Gregory Mandel, *The Non-Obvious Problem: How the Indeterminate Nonobviousness Standard Produces Excessive Patent Grants*, 42 U.C. DAVIS L. REV. 57, 117-19 (2008) (citing Merges to advocate for a nonobviousness standard based on the probability of invention by a person with ordinary skill in the art, but not accounting for the cost of the invention); Michael Abramowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 YALE L.J. 1590, 1652 (2011) (building on Merges’s nonobviousness criteria of cost and uncertainty to propose an inducement test that assesses patentability based on whether or not an invention significantly accelerates commercialization).

107 See Merges, *supra* note 106, at 3 (arguing that “[t]he patent system is shown to have a stronger effect on the incentive to develop inventions as opposed to the incentive to invent”).

108 See W. Nicholson Price II, *The Cost of Novelty*, 120 COLUM. L. REV. 769, 787 (2020) (contending that, in the context of pharmaceuticals, a weaker nonobviousness doctrine serves to incentivize minor adjustments to existing drugs rather than “exploring innovation” that may lead to more socially beneficial discoveries); Dan L. Burk & Mark A. Lemley, *Biotechnology’s Uncertainty Principle*, 54 CASE W. RSRV. L. REV. 691, 737 (2004) (arguing that “[l]owering the obviousness threshold makes it more likely that marginal inventions will be patented, but does nothing to encourage inventions that would have met the (already rather modest) obviousness standard anyway”); cf. Rebecca S. Eisenberg, *Pharma’s Nonobvious Problem*, 12 LEWIS & CLARK L. REV. 375, 378 (2008) (noting that, in contrast to the “hindsight bias” that makes inventions in other industries seem more obvious ex post, chemical and pharmaceutical inventions tend to “appear less obvious in hindsight than they seemed ex ante”).


While it may seem at first blush that any reduction in patent scope -- indeed, any
of the incentive efforts, rather than the more diffuse goal of encouraging the national production of any output.

Nevertheless, perhaps the problem is simply the obviousness lever chosen, while the insight that patents should be sensitive to uncertainty (and the investment costs of that uncertainty) remains valid. The theoretical problem, however, is that Merges’s recommendation of including uncertainty flows from the expressly stated perspective that patents do not provide much incentive to invent, at least not in most cases. As he explains, “it is safe to say there is a consensus among economists that in the aggregate, patents offer only a very limited incentive to invent.” If patents do not provide much incentive to invent as an initial matter in most cases, then it is difficult to embrace a vision of patents as being essential for creating the incentive to invest in that invention or to embrace the notion of investment in invention as the key goal of the patent system. Rather, the stronger argument emerges from modern economists such as Shapiro and Kurz, who have explained that patents should compensate for the level of contributions to society, irrespective of the cost inventors incur along the way. This economic analysis dovetails with the historical approach of U.S. patent law described above. From this perspective, manufacturing cost is irrelevant to the societal benefit of a drug. Thus, including the costs of failed inventions would overcompensate the patent holder for the value provided to society.

At the end of the day, not all innovation efforts are worth it. If the costs outweigh the value, a company should not invest. And when society creates a

110 Burk & Lemley, supra note 108, at 737 (noting that “it seems to us that while Merges is right to suggest that the standard of patentability should be responsive to the cost and uncertainty of innovation, obviousness is the wrong lever to use in biotechnology”).

111 See Merges, supra note 106, at 5 (citing Paul Stoneman, The Economic Analysis of Technology Policy 115 (1987)) (providing a summary of the economic consensus and observing that “despite a long-standing concern over the nature and impact of the patent system, the importance of the system, in practical terms, may not be particularly great”).


113 See supra text accompanying notes 59-93.
buffer that insulates companies from the impact of poor decisions, innovation can become distorted.114 Worse yet, two features of the pharmaceutical industry could enhance the distortion of incentive structures if society were to follow the notion of compensating inventors for the cost of failed inventions: The lack of buy-side constraints and the value leakage of a fragmented drug development supply chain.

A. Lack of Buy-Side Constraint in the Pharmaceutical Industry

Ordinarily, one would expect buy-side constraints to create downward pressures on prices, limiting the impact of incentivizing failure. After all, pharmaceutical manufacturers cannot charge a price unless buyers are willing to pay. Characteristics of the modern pharmaceutical industry, however, dampen any potential effect. These include strategic patent behaviors, strategic behaviors within the reimbursement system, constraints on insurers related to mandated coverage of drugs and limited negotiations, and dampened patient price-sensitivities.

First, modern strategic behaviors allow pharma companies to exploit the regulatory environment, seriously weakening the potential effects of price limitations. These behaviors allow brand companies, who hold market power through patents, to extend their periods of protection and keep cheaper competitors from gaining much traction when they do get to market. Some of these behaviors involve changing aspects of a drug, such as its dosage or delivery system, often by making minor modifications.115 Companies pile these protections on over and over again, extending the length or breadth of protection. Other strategies manipulate the system of regulatory exclusivities. For example, many of the world’s top-selling drugs boast Orphan Drug designations, which are intended as incentives to develop disease treatments for small segments of the population.116 Additional behaviors include exploiting the so-called citizen petition process at the FDA. Originally designed to allow the public to participate in regulatory decision-

114 Of course, society may choose to fund efforts that will not turn a profit for companies. Consider the public funding of the COVID-19 vaccine hunt. That, however, is an entirely different approach from the patent system. For implications of the innovation incentive strains, see the controversy over the FDA’s approval of Biogen’s Alzheimer’s drug, despite limited disease effects, launched at a high price.
115 See generally sources cited supra note 33
116 In 2018, five of the world’s six top-selling drugs, including Humira and Keytruda, had received Orphan Drug indications. Consequently, more than 70 percent of spending on “orphan drugs” was directed to non-orphan indications. See Kao-Ping Chua, Lauren E. Kimmel & Rena M. Conti, Spending For Orphan Indications Among Top-Selling Orphan Drugs Approved to Treat Common Diseases, 40 HEALTH AFFS. 453, 453 (2021). The allure of the Orphan Drug designation and its ease of abuse has also helped direct new drug focus toward expensive areas like oncology. See Robin Feldman, The Cancer Curse: Regulator Failure by Success, 21 COLUM. SCI. & TECH. L. REV. 1 (2019).
making, brand companies file more than two-thirds of citizen petitions that pertain to prescription drugs, usually to block a competitor from gaining approval.117 Others involve abusing the FDA’s Risk Evaluation and Mitigation Strategies system;118 engaging in pay-for-delay schemes, in which the brand company provides value to the generic in exchange for the generic staying off the market for a period of time;119 and product-hopping, in which the brand company shifts patients to a slightly updated, patent-protected version of the drug before a generic can enter to capture any of its market share.120

The most powerful strategic behavior, however, involves the health insurance reimbursement system. Through rebates and volume discounting, companies can share monopoly rents with other players in the system in exchange for agreements to disfavor cheaper competitors.

The process centers on actors, such as pharmacy benefit managers (PBMs), who negotiate rebates from drug companies on behalf of health plans and help those health plans design reimbursement formularies.121 PBMs are paid by health plans to secure discounts from pharmaceutical companies, who are, in turn, ensured a pool of customers.

Through this system, pharmaceutical companies are able to offer volume discounts—ones that newer entrants cannot meet—in exchange for disadvantaging generic competitors. Imagine a beer company making the following offer to a bar

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121 For an extensive discussion of conflicts of interest inherent in the PBM system, including practices like volume rebating, see Joanna Shepherd, Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs, 38 YALE L. & POL’Y REV. 360 (2020); and Robin Feldman, Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills, 57 HARV. J. ON LEGIS. 303 (2020).
I will give you a rebate of 50 cents a bottle if you sell a million bottles of my beer. Better yet, I will give you $1 a bottle if you don’t put any of that craft beer on the menu. If the craft beer is only selling a handful of bottles, it could never offer enough of a discount to compensate for the million dollars that the bar owner would forgo by turning down the major company’s offer.

In the context of pharmaceuticals, brand companies whose patents are expiring command the volume to engage in this form of rebating. Generic companies, which will start out with only a small number of sales and cannot make a competitive offer, can be unable to gain much traction in the market. For example, a study of all claims for roughly one million Medicare patients over seven years found that generic drugs are increasingly losing out in formulary placements. Specifically, the percentage of generics on the most-favorable tier dropped from 73 percent to 28 percent, and the percentage of generics placed inappropriately in relation to the brand version of the drug increased from 47 percent to 74 percent.

In antitrust terms, one can think of this behavior as a form of raising rivals’ costs, in which a brand company imposes costs on a generic competitor that are out of proportion to the impact on the brand itself. As one Medicare health plan administrator noted in describing the volume rebate system for the blockbuster dry-eye medication, Restasis, a new entrant could give the drug away for free, and the numbers still would not work.

In addition, certain federal regulations enhance the ability of manufacturers to exercise the market power that allows above-marginal-cost pricing by limiting health insurers’ ability to control pricing. For example, the 2010 Affordable Care Act mandates that all health insurers must cover: 1) at least one drug per class of drugs and 2) all drugs in certain protected classes. The protected classes are anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants. The six protected classes, which include treatments for cancer and HIV, cover a large number of drugs. When an insurer is required to provide coverage for a drug, the insurer’s ability to negotiate is severely hampered

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122 See Robin Feldman, The Devil in the Tiers, 8 J.L. & BIOSCIENCES 1, 15 (2021) (setting out the beer analogy to explain volume discounting); see also sources cited supra note 103.
123 See Feldman, supra note 122.
124 Id.
125 Id. at 15; see also Thomas G. Krattenmaker & Steven C. Salop, Anticompetitive Exclusion: Raising Rivals’ Costs To Achieve Power over Price, 96 YALE L.J. 209 (1986) (seminal work coining the term raising rivals’ costs to describe certain forms of anticompetitive behaviors).
because it cannot threaten to walk away if the price is exorbitant. Even when insurers are required to cover only one drug in a class, an insurer’s ability may be limited if all of the manufacturers in the class engage in parallel pricing.\textsuperscript{129}

The key federal medical insurer, Medicare, is particularly handicapped in controlling drug pricing because congressional legislation generally precludes Medicare from negotiating drug prices.\textsuperscript{130} Instead, each individual health plan under Medicare must negotiate prices without the benefit of the considerable buying power that could be exercised by the federal government if Medicare were permitted to negotiate for plans as a whole.

Most importantly, any analysis of buy-side constraints should note that health care is no ordinary market. In particular, prescription drug users are far less price-sensitive than consumers of other products, which limits the potential effects of buy-side discipline. Thus, prescription drug price increases do not fluidly translate to a decline in demand.

The price inelasticity characteristic of prescription drug markets can be attributed partly to the necessary, often life-saving quality of medication for consumers. Individuals may place great, even unquantifiable, value on their own health. In contrast to other products, there may not be a limit on how much one is willing to pay for a health-preserving drug, especially when taking a drug is, without hyperbole, a matter of life or death.\textsuperscript{131} Unlike other products, prescription drugs require a physician’s authorization, often creating immovable brand loyalty. Even when generic alternatives arrive on the market, physicians may continue to prescribe the brand version, especially for older or at-risk patients. Furthermore,

\textsuperscript{129} See Staff of H. Comm. on the Oversight & Ref., 117th Cong., Drug Pricing Investigation: Majority Staff Report 136-143 (Comm. Print 2021) (describing “shadow pricing” by insulin manufacturers, a pricing practice in which companies raise list prices in lockstep with one another); see also id. at 143-147 (describing shadow pricing for the rheumatoid arthritis drugs Humira and Enbrel).

\textsuperscript{130} Specifically, the legislation establishing the Medicare Part D benefit that covers prescription drugs obtained from a retail pharmacy, as opposed to a hospital, states that the Secretary of Health and Human Services, who oversees Medicare, “(1) may not interfere with the negotiations between drug manufacturers and pharmacies and [health plans]; and (2) may not require a particular formulary or institute a price structure for reimbursement of [drugs covered by Medicare].” 42 U.S.C. § 1395w–111(i) (2018). The Inflation Reduction Act, signed into law in 2022, opened the door to changing this approach by giving Medicare the power to negotiate over a limited number of drugs in certain circumstances.

\textsuperscript{131} Prescription drugs exemplify what the philosopher John Rawls termed a “primary good”: a good that makes anyone more likely to achieve one’s wants, no matter what one’s wants are. See Fritz Allhoff, Daraprim and Predatory Pricing: Martin Shkreli’s 5000% Hike, STAN. L. & BIOSCIENCES BLOG (Oct. 5, 2015), https://law.stanford.edu/2015/10/05/daraprim-and-drug-pricing/#:~:text=Daraprim%20was%20developed%20in%20the,is%20in%20fairly%20widespread%20distribution[https://perma.cc/ECP4-M97Q]. But cf. Morgan & Lee, supra note 15 (finding that patients in the United States, which consistently boasts the highest drug prices among developed countries, are more likely to skip doses or not fill prescriptions due to cost).
widespread direct-to-consumer advertising can induce more expensive brand-name drug prescriptions, even though physicians, not patients, make final prescribing decisions.\textsuperscript{132}

Most important, patients are generally insulated from the full force of prescription drug costs by insurance or drug payment assistance.\textsuperscript{133} Depending on the insurance plan, even the most staggering drug costs may be at least partially absorbed before they can make their mark on a patient’s wallet.\textsuperscript{134} Similarly, a drug-maker’s price increases, however frequent,\textsuperscript{135} may be sufficiently dulled by rebates and coupons from the manufacturer to retain the patients who do have the option to switch or stop taking a drug. The gap between what is charged and what many patients ultimately pay further dismantles the usual relationship between increasing prices and decreasing demand.\textsuperscript{136}

Price distortion in the pharmaceutical industry, in fact, exemplifies a paradox that has afflicted patent law since its inception.\textsuperscript{137} Patent law promotes innovation

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\textsuperscript{132} See Richard L. Kravitz et al., \textit{Influence of Patients’ Requests for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial}, 293 JAMA 1995, 1998 (2005) (finding that 55 percent of patients who made a brand-specific request received an antidepressant prescription, versus just 39 percent who made a general drug request); see also Tongil Kim, \textit{Direct-to-Consumer Advertising for Doctors? Uncovering the Effect of Pharmaceutical Advertising on Health Care Providers’ Prescribing Behavior} 1 (Naveen Jindal Sch. of Mgmt., Working Paper, 2020) (on file with author) (finding that physicians exposed to more televised direct-to-consumer advertisements tend to write more prescriptions for the drugs advertised).

\textsuperscript{133} For a primer on drug manufacturer coupons and co-pay assistance, see generally CONG. RSLT. SERV., R44264, \textit{PRESCRIPTION DRUG DISCOUNT COUPONS AND PATIENT ASSISTANCE PROGRAMS} (PAPs) (2017). Co-pay assistance, distributed for more than 600 brand drugs, helps push patients toward more expensive drug options (a discounted co-pay for an expensive brand drug often costs the patient more out-of-pocket than the generic option), while not reducing the amount the health plan owes the drug-maker. At the same time, the drug-maker’s contribution is tax-deductible.

\textsuperscript{134} Health insurance plans vary significantly in their coverage and out-of-pocket requirements. Medicare Part D, for instance, has four stages of coverage during a given year, ranging from full coverage to the “donut hole” period, during which time the patient is responsible for 25 percent of all their drug costs. Patients may display greater price sensitivity during the “donut hole” phase as compared to the subsequent catastrophic coverage phase, when patient contribution is much lower. See \textit{The Four Coverage Stages of Medicare’s Part D Program}, BLUE MEDICARERX (Oct. 1, 2020), https://www.rxmedicareplans.com/Learn/Stages [https://perma.cc/7NEJ-AVS5].

\textsuperscript{135} See Nathan E. Wineinger, Yunyue Zhang & Eric J. Topol, \textit{Trends in Prices of Popular Brand-Name Prescription Drugs in the United States} 5 JAMA OPEN 4791, 4791 (2019) (finding that of the forty-nine top-selling drugs, forty-eight experienced annual or biannual list price increases between 2012 and 2017).


\textsuperscript{137} See \textit{KURZ, supra} note 8, at ch. 5 (identifying the patent paradox).
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to increase social welfare.\textsuperscript{138} However, the more we need a patented invention, such as a prescription drug, the more difficult it becomes to obtain: The more we need it, the lower our sensitivity to changes in its price.\textsuperscript{139} Consumers’ low price sensitivity, coupled with the monopoly of patent protection, confers significant power to drug companies in setting drug prices at the expense of affordable access and, therefore, the social welfare that the patent system means to promote.\textsuperscript{140}

To mitigate this dilemma and limit monopoly pricing power, the government enacts market regulations and policies (e.g., the Hatch-Waxman Act that facilitates generic drug entry). Each policy affects the market value of a patent because any limitation on pricing diminishes the economic value of a patent to its owner.\textsuperscript{141} Drug-makers, thus, can trumpet the high cost of drug development as a means of dissuading or compromising the passage of policies and regulations that decrease patent value. A discussion of the cost of invention, then, becomes the hidden response to the fear of actual or pending regulation that decreases patent value. Essentially, it is a form of demand for the government to reimburse companies for the cost of regulation. The operation of the Hatch-Waxman Act may actually enhance these effects. Litigation causes companies to focus on the value of what is being litigated.\textsuperscript{142} This heightened focus on the value of patents may encourage the instinct to petition the government to pay for the costs of regulation, along with the failure-compensation justifications used to buttress those arguments. In spawning extensive patent litigation, Hatch-Waxman and its sister regime, the Biologics Price Competition and Innovation Act, may spur these effects.

In short, health care market characteristics, along with opportunities for gaming the regulatory and reimbursement systems, dampen the potential disciplining effects of buy-side constraints on price increases. These factors render the normal constraints unable to limit the price impacts of creating incentives to fail. More failure brings more reward, reducing the drive towards efficient innovation. Thus, in addition to clashing with the history and theory of patents, encouraging failure has the potential to harm innovation.

\textsuperscript{138} See sources cited supra, note 97.
\textsuperscript{139} KURZ, supra note 8, at ch. 5 (explaining that “the more we need an innovated product the more difficult the law makes it for us to use it, since the more we need it the higher is the monopoly price the law allows the innovator to charge us. In short, the more we need a product the more the law requires us to postpone using that exact product whose use by the public was the reason for the law to begin with”); N. GREGORY MANKIW, THE PRINCIPLES OF ECONOMICS, 90 (Jane Tufts ed., 8th ed., 2018) (explaining the relationship between consumer’s level of need and sensitivity to price).
\textsuperscript{140} KURZ, supra note 8, at ch. 5.
\textsuperscript{142} Cf. KURZ, supra note 8, at ch. 5 (explaining the relationship between litigation over patents and an enhanced focus on value of patents in the context of large pharma buying smaller companies).
B. Value Leakage

As explained in the prior section, creating incentives to fail can lead to inefficient innovation. Moreover, the weakened buy-side constraint means that the normal counterpressures will not operate to limit the price increases that can result from including failure in the value of a drug. Beyond buy-side constraints, a significant restructuring of the pharmaceutical innovation pipeline has the potential to enhance these effects and further distort the innovation incentive by directing dollars to the wrong part of the innovation chain and diluting the incentive to engage in basic, high-risk research.

Specifically, over the last decade, the pharmaceutical pipeline has undergone a complete transformation. Faced with declining innovation, large pharmaceutical companies now outsource much of the industry’s innovation. Small startups, universities, and other non-profits increasingly handle high-risk, early-stage drug development, while larger pharmaceutical players specialize in navigating late-stage clinical trials and regulatory approval.

Academia as an innovation engine is not a new phenomenon. For example, one study looking at transformative medicines approved between 1985 and 2009 found that “the vast majority had intellectual origins in academic research, most of which was funded by the NIH.” Nevertheless, the shift in industry structure over the last decade is striking. The majority of new drug molecules now originate in small startups, even many of those that are marketed by major pharmaceutical


144 For more on the restructured pharmaceutical industry, and its consequences for new drug innovation, see sources cited supra note 97.

145 See Jeffrey S. Flier, Academia and Industry: Allocating Credit and Discovery for Development of New Therapies, 10 J. CLINICAL INVEST. 1172 (2019); see also Robert Kneller, The Importance of New Companies for Drug Discovery: Origins of a Decade of New Drugs, 9 NATURE REVS. 867 (2010) (examining the origins of the 252 new drugs approved by the FDA between 1998 and 2007); Jonathan M. Spector, Rosemary S. Harrison, & Mark C. Fishman, Fundamental Science Behind Today’s Important Medicines, 10 SCI. TRANSLATIONAL MED. 438 (2018); Derek Lowe, Where Drugs Come From: The Numbers, SCI. TRANSLATIONAL MED. (Nov. 4, 2010) (discussing the Nature Reviews article and pointing out that the drugs from academia outperformed the ones from pharmaceutical companies for which 65 percent companies lacked scientific novelty).
REWARDING FAILURE WITH PATENTS

houses.\textsuperscript{146} As one scholar explained, “a culture of nimble decision-making and risk-taking facilitates discovery and innovation” at smaller firms.\textsuperscript{147} Some commentators, to this point, have characterized pharmaceutical startups as an alternate research & development source for large pharmaceutical companies.\textsuperscript{148} Acquisition is the common exit strategy for small firms.\textsuperscript{149} Modern innovation, consequently, is driven by larger pharmaceutical firms acquiring, licensing, or co-developing the drug portfolios of smaller companies.\textsuperscript{150}

In theory, profits should flow smoothly throughout the system without the opportunity for excess returns at the top. Large pharmaceutical companies—acquiring the smaller companies—and the venture capitalists—directing the sale for small companies—should be able to calculate the discounted present value of the asset sold.

There is a dearth of empirical literature evaluating whether, in practice, the flow of revenue through the modern pharmaceutical supply chain properly reflects risk-adjusted net present value calculations. Anecdotal evidence suggests, however, that large firm earnings on a drug may far outstrip what the company paid for its acquisition in present value terms.

Sovaldi (sofosbuvir), the revolutionary hepatitis C treatment, offers one example. Pharmasset, a small startup that licensed university-based research, developed sofosbuvir with significant federal grant funding. Pharmasset successfully advanced the drug through phase II trials,\textsuperscript{151} elevating its chance of eventual FDA approval.\textsuperscript{152} Pharmasset was acquired for $11 billion in 2012 by the

\textsuperscript{146} See Geilinger & Leo, \textit{supra} note 11, at 16-17 (finding that, in 2018, startups originated 63 percent of new molecular entities); Idrus, \textit{supra} note 11 (noting that, of the forty-one new molecular entities Celgene added between 2014-2018, thirty-three were sourced through external acquisitions or licensing).

\textsuperscript{147} See Shepherd, \textit{supra} note 11.\textsuperscript{148} See Shepherd, \textit{supra} note 11, at 2 (“Today, most drug innovation originates not in traditional pharmaceutical companies, but in biotech companies and smaller firms . . . . In the later stages of the drug development process, the biotech companies routinely partner with large pharmaceutical companies to advance through expensive late-stage clinical trials and to effectively manufacture, market, and distribute the drugs”).

\textsuperscript{149} See Rahul Khetan, \textit{Biopharma Licensing and M&A Trends in the 21st-Century Landscape}, 25 J. COM. BIOTECHNOLOGY 37, 49 (2020) (noting that acquisition is the optimal strategy for small firms whose drug candidates require considerable resources to be fully developed and tested).\textsuperscript{150} See \textit{id.} at 38-39 (noting that startups often depend on larger firms to bring a drug through the approval process; noting also that, in addition acquisitions, firms may pursue licensing or other partnership arrangements).


\textsuperscript{152} See David W. Thomas et al., \textit{Clinical Development Success Rates 2006-2015}, Bio 1, 16 (2016) (showing that phase II trials feature the lowest success rates of any phase in the FDA approval
major pharmaceutical house, Gilead, which was struggling with a shortage of new drugs under development.\textsuperscript{153} Gilead ushered the drug through phase III clinical trials and the FDA approval process, which was expedited by “priority review” and “breakthrough therapy designation” awards for sofosbuvir.\textsuperscript{154}

Although some analysts perceived Gilead’s $11 billion acquisition of Pharmasset to be a risky play,\textsuperscript{155} Gilead ensured a generous return on its investment by pricing a course of Sovaldi at $84,000, more than double what Pharmasset projected the treatment would cost.\textsuperscript{156} One analysis calculated that if Sovaldi were even priced at $50,000 for a twelve-week course (already well higher than Pharmasset’s prediction of $36,000), then Pharmasset ought to be worth 30 percent more than what Gilead ultimately paid for the company.\textsuperscript{157} As a result of Gilead’s Sovaldi pricing, the company more than recouped its acquisition investment in the first year of drug sales alone.\textsuperscript{158} In the first five years, the company reaped more than $58 billion from sales of the drug, more than five times what the company paid to acquire the drug from the startup that took the initial risk and engaged in the innovation.\textsuperscript{159}

One can see a similar pattern with Merck’s cancer immunotherapy Keytruda. Organon, a small biotech division of a Dutch conglomerate, conducted the benchwork that identified and isolated pembrolizumab, an antibody for which Organon researchers identified promising oncology applications.\textsuperscript{160} As Organon

\textsuperscript{153} PRICE OF SOVALDI, supra note 151, at 15-16.
\textsuperscript{154} Id. at 26.
\textsuperscript{156} PRICE OF SOVALDI, supra note 151, at 17.
\textsuperscript{157} Id. at 19.
\textsuperscript{158} See id. at 17 (noting that Gilead reported more than $12 billion in 2014 earnings from hepatitis C treatment sales).
\textsuperscript{159} See Keith Speights, Did Gilead Sciences Make an $11 Billion Blunder? Spoiler Alert: The Answer Is “No,” THE MOTLEY FOOL (Dec. 9, 2018) (discussing the fact that Wall Street prefers drugs that patients need to take for a lifetime, rather than drugs that cure).
\textsuperscript{160} See generally David Shaywitz, The Startling History Behind Merck’s New Cancer Blockbuster, FORBES (Jul. 26, 2017), https://www.forbes.com/sites/davidshaywitz/2017/07/26/the-startling-history-behind-mercks-new-cancer-blockbuster/?sh=23b8ca89948d [https://perma.cc/8WQF-TEN7]. Pembrolizumab, a PD1 antagonist, was accidentally discovered by researchers looking for promising PD1 agonists, which are thought to have applications treating autoimmune diseases. In so doing, the discovery behind Keytruda offers a case study in the generative, unpredictable value of the basic research that, ironically, the success of a drug like Keytruda may threaten to disincentivize.
began preparing its investigative new drug filing, however, a series of mergers transferred the program to Merck in 2009, where it was promptly shut down until news of a competitor’s successful phase III trials for a similar treatment revived the pembrolizumab program.

Although the creation of pembrolizumab preceded Merck’s acquisition, the drug giant secured the commercial success of Keytruda through its regulatory savvy and aggressive pursuit of new indications for the drug. A Merck executive, formerly employed by the FDA, gained insight into the agency’s new breakthrough designation program, which initiated closer cooperation between regulators and the drug-maker to expedite approval. Merck elected not to publicize their breakthrough designation for advanced melanoma in order to preserve its competitive advantage, helping the drug-maker close the gap on other immunotherapy developers. The company’s decision to initially target advanced melanoma was similarly strategic. Drugs for life-threatening diseases that lack an available treatment may gain approval with fewer trials. At the same time, Merck embarked on a blitz of clinical studies to search for more applications to monetize their new drug. Consequently, the firm has managed to acquire an impressive ten breakthrough designations for Keytruda—

161 The road pembrolizumab traveled from Organon to Merck went through two major acquisitions, although the drug candidate was a factor in neither. First, Schering-Plough acquired Organon and its parent company in 2007 to expand its women’s health and nervous system therapeutics footprint. See Press Release: Schering-Plough Corporation Completes $14.43 Billion Acquisition of Organon, Fierce Biotech (Nov. 20, 2007), https://www.fiercebiotech.com/biotech/press-release-schering-plough CORPORATION completes-14-43-billion-acquisition-of-organon [https://perma.cc/LKP7-MQEQ]. Two years later, Schering-Plough merged with Merck. See Merck, Schering-Plough Set to Complete Merger, Reuters (Nov. 3, 2009), https://www.reuters.com/article/us-merck-scheringplough/merck-scheringplough-set-to-complete-merger-idUSTRE5A23Y20091103 [https://perma.cc/7CF2-JVRG]. When it arrived at Merck, the pembrolizumab program was relegated to a term sheet, which meant preparations were made to out-license the product to another firm, reportedly for a negligible price. See Shaywitz, supra note 160 (explaining that “[a]fter the program finally wound up at Merck, in 2009, it was considered such a low priority that it was shut down and placed on the out-license list”).

162 See Shaywitz, supra note 160.

163 Gilead benefitted from the same breakthrough designation with Sovaldi.

164 Shaywitz, supra note 160.

165 Id.

166 See U.S. Food & Drug Admin., Development & Approval Process: Drugs (Oct. 28, 2019) (observing that “a drug intended to treat patients with a life-threatening disease for which no other therapy exists may be considered to have benefits that outweigh the risks even if those risks would be considered unacceptable for a condition that is not life threatening”).

167 See Shaywitz, supra note 160 (“Former Merck executive Reicin recalls presenting Perlmutter with a prioritized list of potential Keytruda clinical studies and asking him, based on resources, where to draw the line. ‘There is no line,’ Perlmutter reportedly responded. ‘Do them all.’”).

168 See U.S. Food & Drug Admin., CDER Breakthrough Therapy Designation Approvals (2020).
each for a distinct type of cancer—and twenty-two different indications overall in the first handful of years following its approval. Merck continues to aggressively test new applications for the drug, efforts that have seen handsome recompense: In 2020 alone, the drug’s sales topped $14 billion, with no signs of flagging. Forbes estimates the value of Keytruda as $200 billion—a far cry from the $300 million the company paid to acquire the drug.

There is no question that Merck assumed significant risk and expense with its aggressive agenda for Keytruda, but the rewards offered by the patent system are earmarked for new innovation, not business savvy. One has to differentiate between marketing and innovation. Adapting something to a new market does not constitute creating something new. Rather, the company has simply developed a different way to sell it—a new market to pitch it in. Patents do not reward marketing. For that, the company should be able to earn its reward in the market for its marketing prowess.

As its history makes clear, Merck’s principal contributions to the development of Keytruda were its expeditious approval and broad dissemination across the oncology sphere. These efforts, to be sure, did not come cheaply. Clinical trials are expensive to conduct and require extensive networks of physicians and

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171 See id. (Keytruda’s $14 billion worth of sales in 2020 represented a 30 percent increase from 2019).


173 See supra Part II.

174 It is true that, in contrast to Sovaldi, Merck brought Keytruda through all FDA trial stages, but their risk was mitigated by the observed success of a similar competitor, in addition to the regulatory cooperation and acceleratory measures they enjoyed.

175 See DiMasi et al., supra note 45, at 23 (showing that, since 2003, the proportion of phase III costs had risen considerably relative to other phases of development); see also Thomas J. Moore, Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the US Food and Drug
hospitals, as well as good relations and experience with the FDA. All of this underscores the investment required to secure Keytruda’s range of indications. Although no doubt beneficial to many patients, these measures are far removed from the initial benchwork that conceived the drug and substantiated its patents.

On the topic of value leakage, one should also consider the case of Ridgeback Biotherapeutics and Merck’s COVID-19 drug, Molnupiravir. Scientists at Emory University developed the drug with funding that included millions of dollars from the National Institutes of Health and the Defense Department. Ridgeback, a young company that had no labs or manufacturing capacity, licensed the drug from Emory and conducted clinical trials in the U.K. through a contract research organization. Two months after signing the deal with the university, Ridgeback sold the drug to Merck in a move that some commentators have called “molecule-flipping.” Thus, in this case, the U.S. government provided the funding, a university made the discovery, and a contract research organization performed the initial clinical trials. None of those parties will walk away with the lion’s share—or, in some cases, any share—of the returns. Any gold at the end of the rainbow will go to speculators and Merck, which raises questions of for whom are we designating lucrative incentives and for what contribution to the process of innovation.

Value leakage can also occur when acquisitions facilitate combined drug products, which can serve as a means of recycling existing drugs for additional profit. A decade before Sovaldi, for instance, Gilead acquired a “cash-strapped” specialty drug company, Triangle Pharmaceuticals, in order to pair Triangle’s HIV

Administration, 2015-2016, 178 JAMA INTERNAL MED. 1451 (2018) (finding that clinical efficacy trials cost an average of $19M, with some larger trials veering toward half a billion dollars; trials for rare diseases cost much less on account of size and lack of a control group).

176 See Richman et al., supra note 97, at 817-18 (noting the importance of personal relationships in the clinical trial and approval space).


178 See Rowland, supra note 177.

179 Id.
drug Coviracel with Gilead’s own Viread.\textsuperscript{180} The one-pill combination of these two drugs—marketed as Truvada—earned annual sales revenue that approximately quadrupled the amount Gilead paid to acquire Triangle.\textsuperscript{181} Although viewed one way, the acquisition offers an example of the synergy often cited by proponents of consolidation,\textsuperscript{182} the reward in this case redounded overwhelmingly to Gilead—in spite of Triangle’s sizable contribution to Truvada.

Truvada’s blockbuster revenue is hardly approximated in the “net present value” of their 2002 acquisition of Triangle. Rather, Triangle’s financial situation may have compelled a buyout,\textsuperscript{183} an exit strategy depended on by many pharmaceutical startups.\textsuperscript{184} As such, the history of Truvada exemplifies how the pharmaceutical industry structure can favor the larger players with a disproportionate share of new drug profits. Once again, the reconfigured pharmaceutical industry may generate significant value leakage, overpaying large downstream acquirers while under-rewarding innovators. The risk is a diluted incentive to take on basic, high-risk research, not only promoting failure but doing so at the wrong part of the innovation chain.

The shift in industry structure also may have the effect of invigorating drug companies’ demands to be compensated for their failures. Drug companies have shifted from engaging in internal innovation to the purchase of initial innovation and handling later-stage trials and regulatory approval.\textsuperscript{185} As with Hatch-Waxman litigation, focusing on patent value may embolden companies to petition the government to pay for their various costs—including the regulatory costs involved in the clinical trial and approval processes that occupy much of large company activity—along with the “failure compensation” justifications that are used to buttress those arguments.\textsuperscript{186}

In short, encouraging failure is counterproductive. Rather than promoting

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  \item \textsuperscript{180} Brady Huggett & Christopher Scott, Gilead’s Deal of a Lifetime, 27 Nature Biotechnology 423, 423 (2009).
  \item \textsuperscript{181} See id. (comparing Gilead’s acquisition of Triangle for $525.2 million with Truvada’s $2.1 billion in 2008 sales).
  \item \textsuperscript{182} See, e.g., Jan Bena & Kai Li, Corporate Innovations and Mergers and Acquisitions, 69 J. Fin. 1923 (2014) (finding that synergies in drug development pipelines drive many acquisitions in the pharmaceutical industry).
  \item \textsuperscript{183} See Andrew Pollack, Acquisition by Gilead to Expand Drug Line, N.Y. Times (Dec. 3, 2002), at C3 (“The acquisition could be one of a spree of mergers that analysts say might take place because many biotechnology companies are running out of cash at a time when low stock prices make raising money difficult. Triangle, based in Durham, N.C., had $60 million in cash, which would have lasted less than a year.”).
  \item \textsuperscript{184} Khetan, supra note 149, at 38 (noting that early-stage companies lack the experience, sales and marketing competence, and funds necessary to bring drugs over regulatory hurdles and swiftly to market, relying as a result on larger pharmaceutical firms).
  \item \textsuperscript{185} See supra text accompanying notes 139-150.
  \item \textsuperscript{186} See supra text accompanying notes 141-142.
\end{itemize}
efficient innovation, creating incentives to fail leads to circumstances in which the one who fails more earns more. The problem is exacerbated by a weakened buy-side constraint, which interferes with the normal counter-pressure that could limit the price increases resulting from including failures in the value of a drug. And finally, the recent restructuring of the innovation pipeline risks further distorting innovation by directing dollars to the wrong part of the innovation chain and diluting the incentive to engage in basic high-risk research.

**CONCLUSION**

The notion of allowing drug companies to recoup the cost of their failures through the rewards of the patent system has steadily progressed from industry to academia and into judicial opinions. Despite the notion’s superficial appeal, it is antithetical to the patent system and the innovation interests embodied therein. Patent theory rests on the notion of rewarding success, providing the opportunity to garner a return from an invention that one succeeds in conceiving of or reducing to practice—limited carefully to the actual boundaries of the invention itself. Society does not grant patents for things that an inventor tries and fails to produce. Nor should the patent reward reflect anything but the invention itself.

From an historical perspective as well, federal statutes and cases from early patent law’s history reveal not a single act or case stating that a patent grant is intended to compensate the patentee for the costs of developing an invention that was not patented. Even in terms of compensating for the costs of developing the invention itself, patent history suggests the opposite. Despite a brief flirtation in the mid-1800s with the possibility of providing an extension of the patent term, when needed for recoupment of development expenses, Congress rejected that approach. Moreover, the current system does not operate in a manner that links the patent reward to the costs of development; most patents provide no return to the inventor, and returns can be lavished on inventions with no more development costs than a moment of inspiration. One could conceivably design a patent system based on the costs of research and development, but this is not the system in place.

From a practical perspective, creating incentives to fail has the effect of motivating pharmaceutical companies to be less efficient, rather than more efficient, in their innovation efforts, at least on an inventor- and invention-specific level. If the reward one receives includes the costs of failures, then the more one fails, the greater one’s reward. Although one might ordinarily expect buy-side constraints to operate to prevent such inefficiencies, characteristics of the pharmaceutical markets, including opportunities for regulatory gaming, serve to dampen such constraints. Moreover, recent shifts in the industry structure, in which universities and small pharma do the heavy lifting of invention while large pharmaceutical companies take the drugs the last mile through approval and
manufacturing, create further distortions of the innovation incentive. Rather than
distributing the flow of rewards appropriately throughout the supply chain,
pharmaceutical markets demonstrate significant value leakage, in which large
pharmaceutical companies are over-rewarded, and innovators are under-rewarded.
Such a process dilutes the incentive for research, not only promoting failure but
doing so at the wrong part of the innovation chain.

In short, creating incentives to fail is as counterproductive as the phrase
sounds. Unless academics, legislators, regulators, and the judicial system
recognize that problem, the nation may find itself sliding quietly into an approach
that undermines the contours of the patent system from time immemorial,
distorting innovation in the process.