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ARTICLES

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VOLUME 11 NUMBER 2

NEW YORK UNIVERSITY
JOURNAL OF INTELLECTUAL PROPERTY
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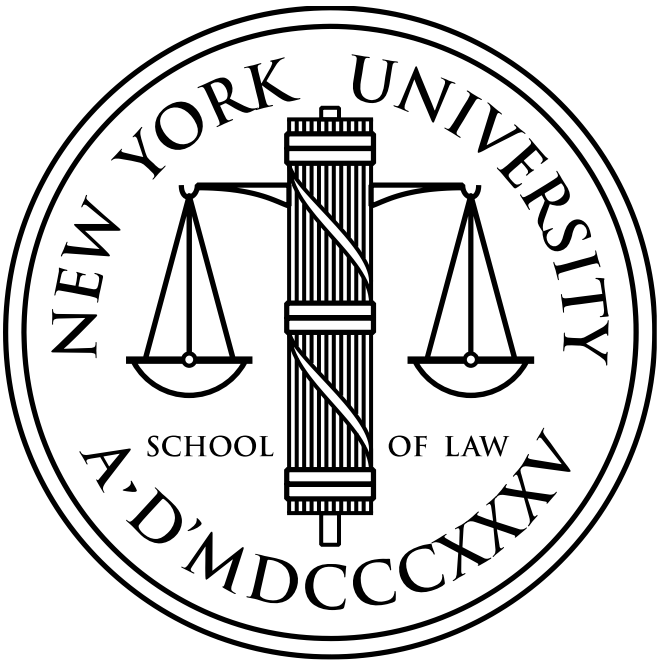

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Consistent with its unique development, the New York University Journal of Intellectual Property & Entertainment Law (JIPEL) is a nonpartisan periodical specializing in the analysis of timely and cutting-edge topics in the world of intellectual property and entertainment law. As NYU's first online-only journal, JIPEL also provides an opportunity for discourse through comments from all of its readers. There are no subscriptions or subscription fees; in keeping with the open-access and free discourse goals of the students responsible for JIPEL's existence, the content is available for free to anyone interested in intellectual property and entertainment law.

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PREFACE

Our Fall 2021 Issue—Volume 11, Issue 2—contains three articles that challenge current perceptions and practices in our intellectual property system. The articles not only offer rich analyses but also propose practical solutions to save money, improve health outcomes, and maintain international harmony.

First, Richard Gruner examines the impact of abandoned patents on technology development. Comparing the forward citation counts of 5,099 U.S. utility patents, Gruner discovers that abandoned patents—those allowed to lapse by their owners before their full available period of patent protection—are cited at much lower rates than non-abandoned patents. These citation differences occur almost immediately after patent issuance, suggesting ways to spot technological "dead ends" early on and shift attention toward more valuable prospects.

Meanwhile, Sam F. Halabi urges us to look beyond patents to consider the impact of trademark and trade dress in the pharmaceutical landscape. As Halabi points out, these laws raise the cost of prescription drugs and shape patient adherence to drug regimens. In highlighting these often overlooked impacts, Halabi encourages legislators, regulators, and judges to "address the law of medicine appearance."

Lastly, Jorge L. Contreras takes a global perspective, assessing the proliferation of anti-suit injunctions in litigation over the licensing of standards-essential patents. Contreras breaks down this seemingly complex topic and creates a compelling argument for judicial restraint.

Overall, these articles provide insightful assessments of various intellectual property concerns. I am honored to have worked with these authors and grateful for the JIPEL staff that made this issue a reality. I hope you enjoy it as much as I did.

Sincerely,

Taylor Peterson
Editor-in-Chief
NYU Journal of Intellectual Property & Entertainment Law

NEW YORK UNIVERSITY

JOURNAL OF INTELLECTUAL PROPERTY AND ENTERTAINMENT LAW

VOLUME 11 FALL 2021 NUMBER 2

DOES ANYBODY SEE WHAT I SEE?: ABANDONED PATENTS AND THEIR IMPACTS ON TECHNOLOGY DEVELOPMENT

RICHARD GRUNER*

"Is anybody there? Does anybody care? Does anybody see what I see?"†

Most patented advances are ultimately abandoned by their owners. Owners give up their patents apparently because the patented advances seem so worthless that the owners cannot justify paying modest maintenance fees needed to keep the patents in force. These voluntarily relinquished patents cover technological dead ends—advances of little interest to later innovators and commercial entities seeking marketable products that serve public interests. Abandoned patents are surprisingly common, comprising a majority of United States patents, and a largely overlooked feature of the United States patent system.

This article analyzes empirical evidence reflecting abandoned patents' roles in later technology development. The analysis relies on citations in later-issued patents to evaluate inventors' interest in advances covered by abandoned patents.

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† SHERMAN EDWARDS, *Is Anybody There?*, *on* 1776 (1969), https://www.allmusicals.com/lyrics/1776/isanybodythere.htm.

The results suggest that inventions described in abandoned patents have some influence on later technology development, but far less than their unabandoned counterparts. Citations per patent for unabandoned patents are over twice as high as for abandoned patents. Almost immediately after patent issuance, technologists see what patent owners take years to realize—that some patented advances are worthless, having very little potential as the basis for successful commercial products or as pointers toward future technology advances with commercial value. Later innovators appear to agree with owners that abandoned patents cover dead ends in technology development. Technologists avoid these dead ends by turning away from advances described in abandoned patents and pursuing other types of technology projects, leaving abandoned advances with few, if any, citations in later patents.

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INTRODUCTION

When a patent is abandoned by its owner[1] and remains largely uncited in later patents, does the abandoned patent have an impact?[2] Are abandoned patents (and the associated administrative costs to the patent system and patent applicants) wastes of time and resources? Are these patents—despite their threatened restrictions on infringing conduct—meaningless constraints on commercial competition and technology development because the patents restrict technologies that no one is interested in and no infringement is likely? Do these patents provide valuable information to later researchers even if they have little value to their owners? These questions are important because abandoned patents are common in all areas of technology, yet their impacts (if any) on technology development are largely unstudied.[3]

A. Measuring the Impacts of Abandoned Patents

This article analyzes empirical evidence of abandoned patents' roles in later technology development. It relies on citations in later-issued patents to measure inventors' interest in advances covered by abandoned patents. This evidence

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[1] "Abandoned patents" refer here to United States utility patents that are allowed to lapse by their owners before the end of the full available period of patent protection. This lapsing typically results from an owner's failure to pay patent maintenance fees due 4, 8, and 12 years after patent issuance. The failure to pay one of these fees causes the patent to lapse. *See* 35 U.S.C. § 41(b)(1)–(2).

[2] This question is a counterpart to the famous philosophical inquiry: "If a tree falls in a forest and no one is around to hear it, does it make a sound?" This inquiry—framed in terms of a falling tree and resulting sounds—invokes philosophical concerns regarding observation and perception. Key considerations include the possibility of unperceived existence, assumptions about the unobserved world, and the dissimilarities between perception and reality. *See generally If a Tree Falls in the Forest*, WIKIPEDIA, https://en.wikipedia.org/wiki/If_a_tree_falls_in_a_forest (last updated Dec. 21, 2021).

The parallel question about abandoned patents might be: "If a patent issues and no one notices, does the patent have an impact?" Key considerations about abandoned (and perhaps unnoticed) patents include how to measure the impacts of patents (including impacts on technology development and commercial product availability), assumptions about the unobserved impacts of patents, and potential disparities between the impacts of well-known patents covering highly valuable advances and other patents that are valueless, unenforced, and abandoned by their owners.

[3] A few studies have described the large numbers of patents abandoned in recent years but have not examined reasons why patent applicants seek so many ultimately abandoned patents or the impacts of abandoned patents on later technology development. *See, e.g.*, Dennis Crouch, *Maintenance Fees 2015*, PATENTLY-O (July 21, 2015), https://patentlyo.com/patent/2015/07/maintenance-fees-2015.html (describing the large number of United States utility patents abandoned in 2015).

suggests that inventions described in abandoned patents have some influence on later technology development, but far less than their unabandoned counterparts.[4] Almost immediately after patent issuance, technologists see what patent owners take years to realize—that some patented advances are worthless, having very little potential as the basis for successful commercial products or as pointers toward future technology advances with commercial value. The worthless patents cover dead ends in technology development. Technologists express their assessment of worthless patents by turning to other types of technology projects, leaving worthless advances with few, if any, citations in later patents.

The opposite is also true. Advances ultimately seen as valuable by patent owners (as indicated by the owners' willingness to pay maintenance fees needed to keep the patents alive for their full potential terms) are also seen as valuable from the outset by numerous technologists and cited at much higher levels than abandoned patents.[5] Citations per patent for valuable patents are over twice as high as for abandoned patents. This elevated citation level starts soon after patent issuance and holds true throughout the life of valuable patents. The technologists responsible for these citations are not just everyday innovators, but rather inventors with unusual talents and insights leading to patented advances. These inventors are typically highly trained engineers and scientists able to conceive and construct nonobvious additions to past technology designs and thereby qualify for patents. These exceptional inventors see value (or the lack of it) very quickly in the life of patented advances and shape their own innovation choices accordingly.

Inventors' interest in valuable innovations appears to be constrained somewhat by restrictive patent rights applicable to such innovations.[6] Differences in citations before and after valuable patents expire provide insights into the impacts of patent rights in deterring and suppressing related inquiries. While valuable patents are in force, advances similar to the valuable patents receive substantial interest by inventors (as evidenced by citation levels much higher than those for abandoned patents). However, after the patents expire, citations rise to even higher levels. This suggests that the threat of patent enforcement while rights are in force has a significant effect in suppressing surrounding technology development. Innovation levels related to valuable advances go up when the legal threat of patent enforcement is relieved through patent expiration

[4] *See infra* Section II(A).
[5] *See id.*
[6] *See infra* Section II(C)(4).

Conversely, changes in enforceable rights do not seem to impact interest in advances described in abandoned patents. Citation levels for abandoned patents remain relatively constant across periods—that is, across the thresholds when the rights emanating from the patents disappear. This is consistent with the view that rights concerning abandoned patents matter little in the first place. Rights limiting actions that no one is interested in pursuing are little different from no rights at all.

These results indicate that advances covered by valuable patents, unlike abandoned patents, serve as magnets for subsequent innovation. These advances attract citations while the cited patents are in force because technologists seek innovations in the vicinity of the cited advances, hoping to share in the significant value of the heavily cited advances. Valuable patents that have expired attract even more citations because innovations in their vicinity are both valuable and newly unconstrained. Additional related innovations (and related citations) result once restrictions and royalty costs for reuse of a patented advance are removed with patent expiration.

Both before and after patent expiration, citations capture crowdsourced information from subsequent innovators, identifying technology neighborhoods with strong innovator interest and probable future value. This article describes the remarkable congruence between the views of patent owners and subsequent innovators about the lack of value of advances covered by abandoned patents.[7] The article also suggests ways that innovator disinterest in patented advances (as evidenced by low citation levels) can identify worthless patents relatively early in patent life and shift attention of innovators, entrepreneurs, and persons allocating technology development resources away from wasteful commitments directed at projects mistakenly building on the false leads of abandoned patents.[8]

B. Viewing Patents as Markers for Speculative Testing of Uncertain Innovations

Far from confirming the technological or commercial success of an advance, an issued patent is just an indicator of technological distinctiveness coupled with rights advancing market testing of the patented technology. The patent confirms that an advance is a technological outlier (as evidenced by the patent examiner's findings to this effect)[9] and potentially worthy of commercial testing (because the advance's

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[7] *See infra* Section II(C).

[8] *See infra* Section II(C)(2)(ii).

[9] United States patent laws require an invention to be "nonobvious" to a well-informed person of average skills in the field of the advance in order to qualify for a patent–in essence, a requirement that the advance be a technological outlier. *See* 35 U.S.C. § 103. Patent applications are reviewed

distinctive features may enable attractive consumer products and, if so, patent rights initially will reserve most of the resulting profits to the patent holder).[10] However, most patented advances fail commercial testing—either never being transformed into commercial products or failing in the marketplace because products incorporating the patented advance prove to be duds that are no better (and perhaps more costly) than non-patented substitutes.[11] Considering these often harsh results, an issued patent is only a speculative hunting license, indicating a market testing opportunity but hardly implying a likely success.[12] Indeed, the opposite is frequently the case—patented advances are more often losers than winners. Most patented inventions are found worthless by their owners[13] causing many related patents to be abandoned.

1. Commercial Dreams Denied—The Debris of Abandoned Patents

Abandoned patents corresponding to commercial failures of patented advances are surprisingly common. In recent years, more United States utility

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by patent examiners to determine if advances meet this and other patent law requirements; the issuance of a patent is confirmation that this requirement was met (at least in the eyes of the examiner). *See General Information Concerning Patents*, USPTO, https://www.uspto.gov/patents/basics/general-information-patents (last modified July 1, 2021, 9:13 AM) ("The examination of [a patent] application consists of a study of the application for compliance with the legal requirements and a search through U.S. patents, publications of patent applications, foreign patent documents, and available literature, to see if the claimed invention is new, useful and non-obvious and if the application meets the requirements of the patent statute and rules of practice. If the examiner's decision on patentability is favorable, a patent is granted.").

[10] A patent gives the owner the ability to control who is authorized to make, use, sell or import the patented invention. *See* 35 U.S.C. § 271. The resulting patent rights are commonly translated into profits by charging patent-mediated (that is, elevated) prices for patented items or by licensing other parties to make or sell such items and gaining profits through license royalties. *See, e.g.*, Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341, 358 (2010) ("[T]he patent system . . . allow[s] an inventor to earn a return on his efforts either by selling a commercial embodiment of the invention at higher-than-normal prices or by licensing the invention to others for a fee.").

[11] *See* Sichelman, *supra* note 10, at 341 ("About half, probably more, of all patented inventions in the United States are never commercially exploited.").

[12] *Cf.* F.M. Scherer, *The Innovation Lottery*, *in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY 3 (Rochelle Dreyfuss et al. eds., 2001) (analogizing the patent system to a giant lottery with an individual patent having the features of a lottery ticket: generally worthless but highly valuable in the rare cases where it pays off).

[13] *See* Jonathan A. Barney, *A Study of Patent Mortality Rates: Using Statistical Survival Analysis to Rate and Value Patent Assets*, 30 AIPLA Q.J. 317, 329 (2002) ("A relatively large number of patents appear to be worth little or nothing while a relatively small number appear to be worth a great deal.").

patents have been abandoned by their owners than have been maintained for their full terms.[14] Inventors (or the organizations that back them) invest large sums in research[15] and additional amounts in patent applications,[16] presumably with the expectation that the future potential of the patented advances merits these investments in gaining intellectual property. Yet, within a period as short as four years after patent issuance, some patent owners lose faith in their patents and abandon them as worthless.[17] Most inventions receiving United States patents in recent years have produced similar disillusionment. The high rates of patent abandonment reflect one of the hard lessons of the patent system: patents are speculative investments in technology development and most such investments fail.[18]

2. Patents Reflect Bets on Unproved Invention Value

Separating valuable from worthless patents at patent issuance or even soon after is, unfortunately, highly difficult. The patent system encourages speed in seeking patents rather than care before applying to determine whether particular advances are likely to produce commercial successes.[19] Once innovators produce research results covering the minimum information needed to qualify for patents,

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[14] *See, e.g.*, Crouch, *supra* note 3 (showing that in 2015, owners of only about 45% of United States patents paid the third maintenance fee required for their patents at 12 years after patent issuance).

[15] In some fields, the research costs to produce a patented advance are staggeringly large. For example, developing a new prescription medicine that gains marketing approval is estimated to cost drugmakers $2.6 billion, according to a report by the Tufts Center for the Study of Drug Development. *See* Thomas Sullivan, *A Tough Road*, POL'Y & MED., https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html (last updated Mar. 21, 2019).

[16] *See* Gene Quinn, *The Cost of Obtaining a Patent in the US*, IPWATCHDOG (Apr. 4, 2015), https://www.ipwatchdog.com/2015/04/04/the-cost-of-obtaining-a-patent-in-the-us/id=56485/ (estimating that typical costs for obtaining patents range from $12,000 to $20,000).

[17] A substantial fraction of patents lapse at the 4-year point. For example, in 2015, 15% of patents issued four years before lapsed due to nonpayment of maintenance fees. *See* Crouch, *supra* note 3.

[18] *See* Robert G. Cooper & Elko J. Kleinschmidt, *An Investigation into the New Product Process: Steps, Deficiencies, and Impact*, 3 J. PROD. INNOVATION MGMT. 71, 71 (1986) ("[P]roduct innovation is plagued by high risks [due to] both the large amounts at stake and the high probability of failure.").

[19] Patents are frequently sought and granted for inventions "at the initial stages of conception" when the minimum operative features of the invention are barely understood (and, in some cases, not yet even reduced to a working prototype). *See* Sichelman, *supra* note 10, at 351; *see also* Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 72-75 (2009).

they frequently submit patent applications describing operative but superficially understood inventions.[20] These applications are based on hope and speculation regarding the commercial value of the inventions described. Patent applicants frequently lack information on a broad range of commercial factors affecting the value of their advances.[21] Applicants seek patents at early stages of invention development to secure their bets on the potential future value of the patented advances—ensuring that they, and not others, will reap the early-stage gains from products incorporating the patented advances.[22] The payoffs on their bets are only ascertained much later through market forces reflecting commercial success (if any) while the patents are in force. Relevant valuation information is typically gained after patent applications are filed, including insights into the full features of patented advances (both good and bad), the best ways to implement the advances to produce maximum functionality, the types of products or services that can be developed from these advances, and consumer interest in these products or services.[23]

The large number of patents abandoned as worthless by patent owners reflects how little these owners know about their patented advances when patents are issued. Patent applications are simply poorly informed bets on patent value. The inability of innovators (and the organizations that back their research and gain associated

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[20] *See* Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 805, 807 (1988) ("[A commercial product resulting from a patented invention] will in all likelihood be different in significant respects from the [patented] invention due to the changes necessary to turn the invention into a commercial product."); Dennis Crouch, *The Trade Secret Value of Early Patent Filing*, PATENTLY-O (Oct. 23, 2008), http://www.patentlyo.com/patent/2008/10/the-trade-secre.html ("[M]any if not most patent applications are filed well before the associated product or method is ready for public consumption—before the inventor knows the best *commercially viable* mode.").

[21] For an overview of the information gathering problems facing patent holders seeking to commercialize their advances, see Sichelman, *supra* note 10, at 348-54.

[22] One of the main purposes of granting patent rights to inventors is to ensure that "free riders" are not able to reap the benefits of a patented advance without compensating those parties (holding patents) who have made the advances and borne associated research costs. *See Innovation and Intellectual Property*, WIPO, https://www.wipo.int/ip-outreach/en/ipday/2017/innovation_and_intellectual_property.html (last visited Jan. 2, 2022) (noting that a key advantage of extending patent protection to an inventor is that "[a] patent can help stop unscrupulous third parties from free riding on the efforts of the inventor."); *see also* Sichelman, *supra* note 10, at 358 ("The reward theory [of patent law] justifies patents as necessary to induce the invention and disclosure of new and non-obvious knowledge, which inventors would otherwise be reluctant to do in the fear that others may free ride off their efforts.").

[23] *See* Sichelman, *supra* note 10, at 351-54 (describing typical product development and market testing steps undertaken in attempts to commercialize patented advances and the types of new information acquired by patent owners after patent issuance).

patents) to accurately predict the value of advances at early stages of innovation development and commercialization produces many inefficiencies. The following subsection highlights the uncertainties that may account for these valuation errors and lead to large numbers of patent filings that patent owners ultimately see as mistakes, warranting patent abandonment.[24]

C. Unknowns Potentially Undercutting Patent Value

Innovators and others attempting to value patented advances often lack information about many factors affecting the practical uses of the advances. The impediments to fully understanding (and correctly valuing) a patented advance stem from what Ted Sichelman describes as the difference between an "invention" and an "innovation".[25] The former is an early-stage technology design which—if sufficiently new, distinctively different from past technical designs, and otherwise in compliance with patent law requirements—can qualify for a United States utility patent. An "innovation", by contrast, is a problem-solving device or process produced by learning about and expanding upon an invention through commercialization processes. As Sichelman notes, extensive information gathering and design improvements are often needed to transform an invention into an innovation:

> Although "innovation" includes the act of invention, it is not so limited; rather, innovation encompasses the entire process of identifying a problem to [be] solved; conceiving a solution to the problem; identifying a market; building a prototype; testing the prototype;

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[24] A number of commentators have concluded (based on patent abandonment data and other empirical evidence such as low patent licensing rates (estimated at 5%) and litigation rates (estimated at 2%)) that "most [patented] technologies will not be economically viable or commercially successful." Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 603 (1999); *see also* Michael Abramowicz, *The Danger of Underdeveloped Patent Prospects*, 92 CORNELL L. REV. 1065, 1074 (2007) ("[M]any patents go unlicensed and thus appear to be worthless.").

Patent owners' assessments that patented advances are worthless may be temporary, leading to later revivals of interest in advances covered by abandoned patents. Ted Sichelman suggests that some abandoned patents reflect patented advances that were not capable of successful commercialization while patent rights were in force–leading to patent abandonment–but were shown to be valuable advances in later periods. Sichelman, *supra* note 10, at 372.

[25] Sichelman, *supra* note 10, at 365-66.

> making a commercial product embodying the invention; marketing, selling, and distributing the product; and improving upon that product.[26]

An invention may lack value (and fail in attempts at commercialization) based on problems at any one of the steps along the path toward commercialization. For example, an invention may be relatively valueless because it never works well and its functionality is limited no matter how much effort is spent on improvements.[27] Or an advance may be valueless because, once incorporated into products, the products function no better than already available substitutes. Or a patented advance may be prohibitively expensive to make and distribute at scale, making the overall value of the advance very low. Or consumers may perceive difficulties in using the advance (or other adverse features of the advance) leading to a rejection of products incorporating the advance and low invention value. These problems correspond to information gaps that must be filled to accurately project the value of patented advances.

Foreseeing many of these problems and their impacts on the commercial value of an invention may be impossible when a patent is sought. Errors in estimating the outcome of the various steps toward commercialization may mean large errors in estimating value. Given the many factors involved and the substantial range of information and unknowns affecting valuation results, it is hardly surprising that inventors (or the organizations that back them) often make valuation errors and mistakenly project high value for patented advances when in fact the advances are worthless.

D. Filling the Valuation Gap: The Slow Path Toward Understanding Invention Value

Several features of patented inventions make early-stage valuations challenging. Patented designs embody technological insights departing from conventional wisdom and prior lines of technology development. They are screened in patent application processes for technological distinctiveness, not superior commercial value. Patented inventions are often poorly understood when patents are

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[26] *See id.* at 366-67; see *also* Jan Fagerberg, *Innovation: A Guide to the Literature*, *in* THE OXFORD HANDBOOK OF INNOVATION 3, 4 (Jan Fagerberg et al. eds., 2005) ("Invention is the first occurrence of an idea for a new product or process, while innovation is the first attempt to carry it out into practice.").

[27] An invention qualifies for a United States patent if it has *some* modicum of utility (in addition to meeting other patent law requirements). *See* 35 U.S.C. § 101. No particularly high or distinctive type of utility must be shown. The ability of patented advances to gain consumer acceptance over prior tools or devices for the same purpose is left to competition in the marketplace.

sought because the inventions depart materially from earlier knowledge and related frames of reference and analysis. Their distinctiveness and often unproven qualities make patented advances especially hard to translate into commercial products and to value in light of both the features and acceptance of these products. These invention features impeding the early-stage valuation of patented advances are summarized in this subsection.

1. The Starting Point: New Technological Outliers with Unexpected Features and Unproven Applications

i. Selection for Speed: Patent Law Pressures for Quick Application Filings on Poorly Understood Innovations

United States patent laws strongly encourage speed in pursuing patent applications and thereby promote initial ignorance about invention value at the time applications are filed. Patent laws encourage an inventor (or an entity backing the inventor) to promptly file a patent application following completion of an invention lest someone else develop the same advance and snap up the opportunity for a patent.[28] This need for speedy filing cuts off pre-application factfinding about the attributes and value of an advance. Inventors are strongly pressured—at the threat of completely losing their patenting opportunities—to file patent applications with little or no information about invention value.[29]

Valuation gaps follow because valuation information is not needed to obtain a patent. The minimum invention information needed to qualify for a patent involves no more than bare bones findings about a few functional aspects of an invention. Patent applicants must understand all of the features of their advances that are needed

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[28] A second, subsequent inventor producing the same advance can undercut a patent opportunity for the first inventor in either one of two ways. If both of the inventors' advances are not publicly revealed, the first to file for a patent will cut off the ability of the second to file regardless of who was first to invent. Alternatively, if a second inventor produces and discloses an advance before the first inventor of an advance files for a patent, the first inventor's opportunity to gain a patent for the advance will be lost. The only way for an inventor to be sure of avoiding these problems is to be the first to file a patent application for a given advance. The pressure to do this and to beat other possible inventors in the race to the patent office (even if such other inventors are merely phantoms in the minds of innovators and do not really exist) accounts for the strong pressures on inventors to seek patents promptly.

[29] *See* Sichelman, *supra* note 10, at 367 ("For patent law to promote innovation, it must rely on a variety of activities that occur only after an inventor has completed the work necessary for patenting."); Mark A. Lemley, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129, 137 (2004) ("Creators are often terrible managers. They frequently misunderstand the significance of their own invention and the uses to which it can be put.").

to produce functional results, and these results must have some modest practical impacts.[30] They must include this minimum information in patent applications[31] and convince patent examiners that they have sufficiently described this required information in their applications.[32] If examiners are so convinced, the applicants will receive issued patents; little (if any) information bearing on the likely commercial value of advances needs to be gathered or submitted to the United States Patent and Trademark Office (USPTO) to gain patents.

Because speed is important and detailed knowledge about invention value is not, the net pressures of patent laws make it rational for many parties to defer valuation assessments and submit patent applications on inventions with highly indeterminate value. Haste in applying is needed if patents are not to be lost; greater knowledge of an invention's value is of little initial consequence and can be left for later. In short, extensive ignorance of an invention's value is commercially rational at the time key decisions about submitting a patent application are made by many applicants.

ii. Selection for Distinctive Features Instead of Commercial Success

Beyond promoting speed in patent application filings, additional patent law features encourage selective development and patenting of advances that emphasize new and distinctively different technology designs with hopes that the commercial value of these advances will later emerge. This is a case of "seeing what you look for." Innovators seeking patentable advances aim for advances that will meet substantive patent law tests; these generally require that a patentable advance include new and distinctively different features in comparison with prior technologies with

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[30] To qualify for a patent, a party must invent a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. The requirement that an invention be "useful" implies both that all of its components needed to produce a functional result are specified and that this result provides some practical benefit to users (although this benefit need not be superior to that from other items used for the same purpose). *See generally* Brenner v. Manson, 383 U.S. 519 (1966).

[31] As part of a valid patent application, an applicant must provide a "written description" of his or her invention. U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2162 (9th ed. 2020). "The 'written description' requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." Capon v. Eshhar, 418 F.3d 1349, 1357 (Fed. Cir. 2005).

[32] Patent examiners working for the United States Patent and Trademark Office review patent applications to determine if inventions and the patent applications describing them meet patent law requirements. *See* 35 U.S.C. § 131.

similar functions.[33] Innovators (or the organizations that back them) look carefully for distinctively new technologies that produce functional results because advances with these features can qualify for patents; they do not—at least prior to the patent application filing—generally explore the full commercial implications of their discoveries.

Patented advances are accordingly selectively developed to emphasize technological distinctiveness and to stake out new design directions. The resulting advances are evaluated for patenting along this same dimension of technological distinctiveness. At least three filtering processes ensure that most patented advances involve poorly understood outlier technologies. First, innovators, lured by patent rewards, may selectively direct their research toward work on distinctively new technologies that will qualify for patents. These research targeting choices skew the outputs of their research (and patents resulting from the research) toward distinctively new results.[34] Second, where innovators seek and produce a range of advances in the course of research, they may still select only the distinctively new advances for submission in patent applications.[35] This filter, applied in targeting and preparing patent applications, also tends to ensure that only distinctively new advances are described in issued patents. Third, if innovators submit patent applications that do not describe departures from earlier technologies, patent

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[33] *See* 35 U.S.C. §§ 101, 103.

[34] One of the key goals of the patent system is to shift research investments toward new levels and types of research that would not occur absent the lure of patent rewards. *See, e.g.*, Heidi L. Williams, *How Do Patents Affect Research Investments?*, 9 ANN. REV. ECON. 441, 442 (2017). Several empirical studies have confirmed that patent protections materially affect the types of research that certain firms pursue, with especially high impacts on research in particular industries such as pharmaceutical drug development and chemical research. *See, e.g.*, Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173-75, 177, 180 (1986) (stating that company managers reported as many as 60% of company innovations in certain industries would not have been pursued without patent protections); *see also* C.T. TAYLOR & Z.A. SILBERSTON, THE ECONOMIC IMPACT OF THE PATENT SYSTEM (Cambridge Univ. Press 1973) (reporting similar results based on a smaller study); Edwin Mansfield, Mark Schwartz & Samuel Wagner, *Imitation Costs and Patents: An Empirical Study*, 91 ECON. J., 907 (1981) (reporting similar results based on smaller studies).

[35] A patent application will be a futile waste of resources (and, hence, generally not pursued) if an invention fails to meet patent law requirements because it involves no more than an adjustment to prior technology that, for most persons of average skill in the relevant field, would seem obvious to pursue. This will be the case if there "was motivation in the prior art to do what the inventor has done, or if there is some reasonable expectation that the combination of elements [in the invention] would achieve a successful result." *See* Gene Quinn, *Patentability: The Nonobviousness Requirement of 35 U.S.C. 103*, IPWATCHDOG (June 17, 2017), https://www.ipwatchdog.com/2017/06/17/patentability-nonobviousness-35-usc-103/id=84716/.

examiners are charged with rejecting the applications as failing to meet patent law requirements.[36] In the face of such a rejection, an applicant will typically have the choice of withdrawing their patent application or rephrasing it to describe the distinctively new features of their advance. Either way, reviews by patent examiners tend to limit successful patent applications to those describing distinctively new advances. As a result, the patented designs are outliers in their respective fields.

The processes leading to issued patents emphasize technological novelty and distinctiveness, but not necessarily the commercial superiority of the inventions. Inventors are technological risk-takers who explore and develop unproven technologies. Their endeavors are risky because they must often expend extensive time and resources on directions of study with few grounds in past technologies to expect success. Sometimes, their work proceeds in the face of traditional knowledge indicating that their projects will probably fail. Inventors are often single-minded in pursuit of technological solutions, consumed by their most important task—determining whether a new, untried, and somewhat unpredictable technology can be made to produce functionally desirable results. They often fail to produce working advances many times before they succeed.[37]

Amidst the numerous burdens of producing a new technology in basic, workable form, detailed commercial assessments are ignored.[38] Patent application processes—including reviews by patent examiners—do not create additional pressures for commercial assessments. An applicant will qualify for a patent with a

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[36] Patent examiners are required to reject patent applications that fail to describe inventions meeting patent law requirements—including the requirement that an invention incorporate nonobvious differences from prior technology designs. Inventions lacking such departures from prior technology are thereby filtered out of issued patents. *See* 35 U.S.C. §§ 103, 131.

[37] The tendency of inventors to fail in attempts to produce workable advances are rooted in human imagination processes that cause parties to imperfectly project future events including the features and operations of imagined inventions. *See* Richard S. Gruner, *Imagination, Invention, and Patent Incentives: The Psychology of Patent Law*, 2017 U. ILL. J.L. TECH. & POL'Y 375, 424 (2017).

[38] Beyond just a lack of time and resources to undertake commercial analyses while minimally workable advances are still in development, the deferral of commercial studies until a working advance is on hand ensures that commercialization analyses are on point—that is, that they address actual features of realized advances. Efforts to assess commercial characteristics of partially completed advances may waste time evaluating speculative ideas about what a (hypothetical and not yet realized) advance might look like and what the commercial implications of the advance might be. Commercial evaluations are best deferred until a concrete advance is on hand; earlier assessments might evaluate the wrong features (not present in the final version of the advance) and overlook features that are present in a final design but that were not yet understood at earlier stages when speculative commercialization analyses were completed.

minimally functional technology that is distinct from past designs in some unexpected way even if there is no evidence of any commercial potential for the application.[39] The resulting patent does not indicate that the patented advance is superior to other similarly functional items or that it has other desirable commercial characteristics. Rather, patent requirements ensure only that a patented advance has some minimal practical results.[40] Questions of functional superiority and commercial success are left to later market tests.[41]

Inventions presented for patenting often possess unappreciated features that will ensure their commercial failure. These features are rarely caught before filing patent applications because no one is looking for them. Patented advances are analogous to hits in a baseball game: they have the distance to be home runs but are aimed without regard to foul lines. Patents are awarded for technological outliers without regard to commercial value—they go the distance of a home run, but whether the hits are in the right direction to be commercially successful is yet to be determined. While costly research efforts to develop patentable advances (and further costly efforts to apply for patents) are typically not undertaken without some expectation of positive commercial returns from the inventions involved, these expectations are often no more than unconfirmed hopes. The very newness and distinctively different characteristics required to meet patent law standards mean that patented advances serving as starting points for commercial products and services frequently incorporate many technological and commercial unknowns.

2. Missing Accounts of Commercial Products Derived from Patented Advances

The outlier features embedded in patented advances often make these advances hard to transform into new products and services and, accordingly, hard to value in terms of projected products and services. Patented advances distinctively departing from past technologies will often have characteristics and functions that are hard to assess and extend using existing technical knowledge and engineering frameworks. The operation of the new advances and how they should be incorporated in commercial products may be difficult to project because normal analytic tools based on past technologies are insufficient to account for and interpret

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[39] *See* 35 U.S.C. §§ 101, 103.

[40] *See generally* Brenner v. Manson, 383 U.S. 519 (1966).

[41] A market test involves designing useful products based on a patented design, producing numerous units of the products, and marketing the products to gauge consumer interest. Many patented technologies are not seen as having enough commercial value to justify the creation of related commercial products and the submission of the technologies to market tests. Others fail in the tests, lacking sufficient consumer interest to produce profits. *See, e.g.*, Sichelman, *supra* note 10, at 351-52.

the distinctively new advances. The distinctiveness that ensures advances can qualify for patents also ensures that the advances exist somewhat apart from past technical knowledge and are, accordingly, hard to evaluate and extend with analytic tools that depend on past technical understanding.

Projecting the ultimate commercial value of a minimally functioning prototype may also be difficult because innovators and other analysts are unable to accurately imagine future invention capabilities and problems with operation. Imagining the altered and perfected versions of advances embedded in commercial products may be especially hard for patented advances.[42] Patented advances—as inventions distinctively different from past technologies in some way—may lead to commercial products with features that are unusually hard to imagine. The more inventions depart from past technology designs, the more parties projecting the features and uses of related commercial products must imagine rather than rely on past knowledge. The more they must imagine, the more mistakes they are likely to make, and the more their valuation estimates may err.

When parties imagine future products based on patented technologies, they may stumble due to weaknesses in human cognitive abilities.[43] These weaknesses impair all human efforts to imagine the future. Errors in projecting the future features and value of applications built on new technologies stem from at least three types of weaknesses in imagination: (1) assumptions in imagining future activities that the activities will be like similar ones today, leading to imagined future invention usage and results that are too much like counterparts in the present (that is, unfounded presentism); (2) a tendency to treat imagined circumstances and events like real ones, leading to insufficient doubt about the accuracy of imagined ideas of future invention use and results and inadequate testing of the veracity of these imagined visions (that is, excessive realism); and (3) difficulties in projecting human reactions to future invention use and results even when parties imagine such use accurately (that is, inaccurate rationalization).[44] All of these types of imagination errors directly impact the accuracy in projecting future invention uses and undercut the accuracy of invention valuations based on the projected uses.

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[42] I have written previously on the features of human cognition—particularly our abilities to project future actions, values, and circumstances—that make the imagination of successful inventions difficult. *See* Gruner, *supra* note 37, at 391-421. Even when a minimally functional invention is imagined and patented, imagining commercially successful implementations of these advances will still be impaired by weaknesses in the processes for imagining future events. *See id.*

[43] *See id.*

[44] *See id.*

3. Missing Valuation Tools

Even if future commercial products based on distinctively new advances are accurately imagined, the value of the projected products may be difficult to measure. The necessary valuation tools may not be available. Old valuation frameworks and criteria may be irrelevant or incomplete for assessing fundamentally new technologies. The very differences from past technologies that qualify advances for patents may make them difficult to value.

Valuation problems may arise because the special value of patented advances—relative to prior items or processes for accomplishing the same ends—is linked to the distinctively new features of the advances. But, as distinctively new departures from past technologies, these new features may have functional and practical implications that are unfamiliar and thus hard to fully value using past experience and valuation methods.

Past experience may be of little use in interpreting the value of distinctively new features of patented inventions. If past experience or well-known methods for extrapolating technological characteristics were sufficient to predict and understand the functionality of the new elements of an advance, the new elements would likely be deemed obvious variations of old technologies and, as such, the advance would not qualify for a patent. Patented advances are inventions that have cleared this hurdle—that is, advances that parties in the relevant field could not easily design with commonly used analytic tools and methods.[45] These same commonly used analytic tools and methods may therefore be insufficient to understand and project invention value. Interpreting patented invention use and the resulting value may only be possible when actual products are realized and placed in widespread use after which the net value of the inventions can be measured concretely. Until then, the unfamiliarity of the patented advances and the lack of trusted methods to understand and project the features of the advances when placed in products may make the early-stage valuation of patented advances highly problematic.

4. Biases Undercutting Invention Valuations

Beyond problems resulting from commercialization uncertainties, parties owning patents may be highly biased in making post-innovation valuation assessments, leaning toward overly high estimates of patented invention value.[46] As they learn about the strengths and weaknesses of an advance as a commercial

[45] *See* 35 U.S.C. § 103; Graham v. John Deere Co., 383 U.S. 1, 17 (1966).
[46] *See* Gruner, *supra* note 37, at 391-421.

vehicle, patent owners will tend to be unduly optimistic about the value of raw advances resulting from their discoveries.[47]

Pride may foster unsupported estimates of high invention value.[48] Inventors of a patented invention may be proud of their discovery of an outlier advance that was beyond the capabilities of most of their peers and distinctively different from past technologies. Alternatively, they may be proud that their advance qualified for a patent and assume (often wrongly) that the distinctive features of the patented advance will directly translate to significant commercial value. Pride in their advances may encourage estimates of high commercial value even if there is little or no evidence supporting that value.

Other factors may also bias valuation assessments by inventors or their backers. These stakeholders may be highly selective in information they seek and evaluate, emphasizing (or even exclusively considering) information that supports a desired conclusion (such as a finding of high value in a hard-won invention) and blinding themselves to contrary information about the limitations of an advance.[49] Or they may become attached through ownership to a patent and suffer from unappreciated "endowment effects" in valuing the patent; endowment effects cause parties possessing an asset to assign a higher value than a neutral non-owner would give to the same asset.[50] Endowment effects tend to cause inventors and backing organizations to overvalue owned patents early in commercialization processes.

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[47] "[D]esigners [including inventors] are human beings first and as such are . . . subject to the failings of the species, including complacency, overconfidence, and unwarranted optimism." HENRY PETROSKI, SUCCESS THROUGH FAILURE 194-95 (Princeton Univ. Press 2006).

[48] Pride is a feeling that typically tracks how much others in a person's local world value the actions of an individual. *See* Andrea Estrada, *The Value of Pride*, SCIENCEDAILY (Aug. 6, 2018), https://www.sciencedaily.com/releases/2018/08/180806175957.htm. For inventors, pride may increase following the discovery of inventions that impress the inventors' scientific or engineering peers—perhaps because the inventions incorporate nonobvious features that others in the field were not able to formulate or appreciate. But technological insights, while furthering additional technology development and having design value (as measured by the esteem of peers), do not guarantee commercial value. Great pride in an invention may cause an inventor to conflate these two types of value and to project commercial value in a new advance even when there is little basis for anticipating favorable commercial results.

[49] *See* Gruner, *supra* note 37, at 401-05.

[50] Endowment effects arise where persons owning or "endowed" with assets tend to overvalue those assets and refuse to part with the items when offered purchase amounts determined through market processes. Christine Jolls, Cass R. Sunstein & Richard Thaler, *A Behavioral Approach to Law and Economics*, 50 STAN. L. REV. 1471, 1484 (1998). These effects are particularly strong where—as with many inventors of patented items (or organizations that have backed the inventors and gained associated patents)—the owner of an asset feels that he or she has "earned" ownership or that he or she particularly deserves it. *See id.* at 1498.

Indeed, optimism born of invention "possession"—and the associated endowment effects—may attach as early as the invention's discovery. The optimism of inventors (and others seeking patents) propels them to file for patents on many apparently valuable advances only to find later that their value estimates were biased and faulty.

Patent holders may also find it difficult to reconsider erroneous valuations once they have reached them. Patent applicants' initial commitments to the positive value of their advances—commitments reflected in large expenditures on costly patent applications—undercut neutrality in later evaluations of an invention's value. Parties making such commitments are loath to admit their mistakes. Given their initial conclusions that the advances have sufficient value to justify expensive patent applications, inventors and their backing organizations remain vested in this assessment and biased against contrary findings of an invention's worthlessness.[51] Carried forward by their biases, these parties are often slow to appreciate the information in front of them indicating low innovation value.

E. Consequences of Delayed Recognition of Worthless Inventions

For the various reasons just summarized, most patent owners only gain an accurate idea of the value of their patented advances long after receiving their patents. They start the patent application process with early but largely unfounded enthusiasm and then learn the hard truth that most of their patents are valueless. The number of valueless patents is enormous but identifying which are worthless takes time.

The number of valueless patents in the United States patent system is staggering, in part due to the large number of patents issued in general. Hundreds of thousands of new utility patents are issued in the United States each year—354,507 new patents in 2019 alone.[52] Given these many patents (each corresponding to an outlier invention capable of qualifying for a patent but often imperfectly

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[51] This bias against recognizing a patent's worthlessness following an initial assessment of substantial value is a form of confirmation bias. Confirmation bias makes a person somewhat insensitive to adverse information and biased in favor of keeping an original conclusion rather than changing one's mind. *See* Univ. of Iowa, *See! I Was Right*, SCIENCEDAILY (Nov. 16, 2015), https://www.sciencedaily.com/releases/2015/11/151116143602.htm (noting research confirming that, once people reach a conclusion, they are not likely to change their minds, even when new information shows that their initial belief is likely wrong and that clinging to that belief has costly implications). In the context of invention valuation, early-stage projections of high invention values will bias patent owners against later realizations that their patents are worthless.

[52] Dennis Crouch, *How Many Patents Issued in 2019?*, PATENTLY-O (Dec. 31, 2019), https://patentlyo.com/patent/2019/12/many-patents-issued.html.

understood), numerous patent valuation errors and associated commercialization failures are to be expected.

What is surprising is the high percentage of patents that are apparently valueless. A majority of patent owners ultimately conclude that their patents are essentially worthless and refuse to pay modest maintenance fees to keep the patents in force. For example, in 2015, owners of only 45% of patents saw sufficient value to justify paying maintenance fees needed to extend their patents for their full potential duration.[53] The remainder of patents (55%) were treated by their owners as essentially worthless.[54]

The high levels of patent abandonment have significant implications for the patent system. Assuming that the abandonment rate in 2015 (55% of patents abandoned) holds true for recent patents issued in 2019,[55] about 194,979 of the patents issued in 2019 are probably worthless.[56] These worthless patents—likely to be abandoned by their owners—come at a high cost. Application costs for patents can vary widely but are typically large. One analyst has estimated that typical patent applications cost about $12,000 to $20,000 to prepare and pursue (with costs for particular applications depending on an invention's complexity and technology type).[57] These application costs are in addition to the costs of the underlying research producing the inventions being patented. Ignoring research costs and assuming just an average patent application cost at the low end of the range, the number of abandoned patents projected above for 2019 corresponds to about $2.34 trillion per year in wasted patent application costs (not counting the further costs to the government in processing patent applications on worthless inventions).

F. The Price of Patent Speculation: Recognizing Frequent Worthlessness Late and from Hard Experience

Despite the enormity of these costs, bearing them may be a necessary evil in a patent system aimed at rewarding valuable inventions but operating in technology spaces where valuable and worthless advances are initially difficult to distinguish. The costs of patenting failed inventions may need to be paid to enable patent rewards

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[53] Crouch, *supra* note 3.

[54] *Cf.* Sichelman, *supra* note 10, at 362-63 ("[P]atentees fail to pay maintenance fees on more than 60% of patents within twelve years after issuance.").

[55] The percentage of maintenance fee payments has been decreasing, meaning that figures quoted in the text for payments related to 2003 patents may *understate* the percentage of 2019 patents that will be allowed to lapse prior to the end of their full patent terms. *See id.*

[56] This figure results from the following calculation: (Total Issued Patents) x (Fraction Abandoned) = 354507 x .55 = 194,979.

[57] Quinn, *supra* note 16.

for other advances that have substantial value. Losses for abandoned patents reflect a patent system in which patented invention wheat and chaff cannot be separated at patent issuance—that is, a system in which the future value of outlier inventions qualifying for patents cannot be determined without significant information only available after patent issuance.

Despite the obvious economic advantages to innovators and backing organizations of earlier invention value assessments (in making better research-initiation decisions and avoiding the costs of patent applications for ultimately abandoned inventions), patent owners generally can only identify worthless patents via additional invention, application, and market information gained over extended periods. This explains their significant delays in recognizing and abandoning worthless patents (in many cases, not abandoning their patents until 12 years after patent issuance). Oftentimes, the slow realization is that patent owners have made bad bets on worthless innovations.

Patent owners seem to accumulate more and more disillusioning information about low patent values over time, leading to increasing numbers of abandonment decisions as later and later maintenance fees come due. At each of the 4-, 9-, and 12-year fee due dates, patent owners must decide whether their patents appear valuable enough to justify paying the next maintenance fee. All of the fees at stake are relatively modest.[58] In 2015, approximately 85% of patent owners paid maintenance fees due 4 years after patent issuance (thereby retaining patents issued in 2011); approximately 66% of patent owners paid maintenance fees due 8 years after patent issuance (thereby retaining patents issued in 2007); and approximately 45% of patent owners paid maintenance fees due 12 years after patent issuance (thereby retaining patents issued in 2003).[59] This means—assuming similar maintenance fee payment percentages apply across recent years—that about 15% of patents were found

[58] The fees needed to keep patents in force vary with both the number of years from patent issuance and the size of the entity owning a patent. The highest fees apply to large organizational patent owners, which are defined as organizations with at least 500 employees. Vic Lin, *Small Entity vs. Large Entity USPTO Filing Fees*, PAT. TRADEMARK BLOG, https://www.patenttrademarkblog.com/small-entity-vs-large-entity-uspto-filing-fees/ (last visited Jan. 2, 2022). For such entities, the maintenance fees are: $2,000 due 4 years after patent issuance; $3,760 due 8 years after issuance; and $7,700 due 12 years after issuance. The amounts due from patent owners that are smaller organizations or individuals are less at every maintenance fee due date. *USPTO Fee Schedule*, USPTO, https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule#Patent%20Maintenance%20Fee (last updated Jan. 1, 2022).

[59] Crouch, *supra* note 3.

valueless and allowed to lapse after 4 years, another 19% after 8 years, and a further 21% after 12 years, for a total of 55% lapsed patents.[60]

This pattern suggests a growing body of adverse information—or increasing levels of disillusionment for other reasons—indicating low perceived value in more and more abandoned patents over time. Patent holders appear to have high initial hopes for many of their patented advances—as evidenced by their willingness to invest in application costs—but have less and less confidence in their patented advances over time. The growing fraction of advances abandoned at each successive maintenance fee due date reflects the hard lessons that many patent holders learn about the worthlessness of their advances through growing bodies of adverse information accumulated over time.[61]

G. The Residual Value of Abandoned Patents

Even if valueless to its owner (and accordingly abandoned), an abandoned patent may have value in the development of further technologies. Information disclosed in abandoned patents may shape subsequent technology development in at least two ways. First, abandoned patents may disclose germs of ideas or design approaches that are more successfully implemented by later innovators. While the

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[60] *Id.*

[61] Beyond the effects of growing information about patent worthlessness, two other mechanisms may explain the growing fraction of patents abandoned at successive maintenance fee due dates.

First, the fees due at later deadlines are higher than earlier ones, meaning that a patent which was perceived as valuable enough to justify paying a low fee might not be seen as sufficiently valuable to justify paying a later, larger fee.

Second, earlier maintenance fee payments may gain patent owners more valuable options regarding patent enforcement than later payments, making owners more willing to make the earlier payments. Early payments keep the option of future enforcement available for longer periods than later payments. For example, payment of the fee due 4 years after patent issuance keeps open patent enforcement for the remainder of the life of a patent (assuming later maintenance fees are also paid). The full potential duration of patent rights is 20 years from patent application filing. Assuming a typical delay between patent application filing and patent issuance of about three years, patent rights will typically last a total of about 17 years from patent issuance if all maintenance fees are paid. A fee payment at 4 years from issuance therefore keeps open the option of about 13 more years of patent enforcement while a payment at the 12-year point only keeps the patent in force for about 5 more years. The option of retaining a longer period of potential enforcement—and a longer period to learn about actual patent value and to detect patent infringement—may be seen as worth more than a shorter period. Hence, a patent holder may perceive a patent as having enough commercial potential to warrant keeping enforcement open over 13 additional years but see the same patent as not having sufficient perceived value to justify a payment to keep enforcement open for only 5 additional years.

invention versions covered by abandoned patents may not be wanted by consumers, the advances disclosed in the patents might aid later innovators in producing related technology advances that modify or extend the abandoned inventions. Second, failed advances covered by abandoned patents may provide valuable guidance on where *not* to pursue new technologies, warding subsequent innovators away from what would have been wasteful innovation projects. Both of these potential sources of value are explored in this subsection, along with empirical evidence highlighting each of these types of abandoned patent value.

1. Aiding More Successful Attempts in Similar Technological Directions

Inventions covered by abandoned patents might advance technology development by providing jumping off points for later designs. Such might be the case, for example, if a patented advance reveals a new analytic insight or technology design potential but has applied that insight or potential in a poorly functioning way, or in a field where the insight or potential did not have much commercial importance. The same insight or potential applied somewhat differently elsewhere might produce a more useful and commercially significant result.

Empirical evidence suggests that abandoned patents rarely enhance future research in this way. If advances described in abandoned patents were frequently used as jumping off points for further designs, one would expect there to be a substantial upward jump in citations when abandoned patents lapsed (and the related legal constraints on using similar technologies were removed). As discussed in Section II of this article, there is no evidence of high citation counts for abandoned patents either before or after abandonment. Rather, citations to such patents are generally low and stay at the same low levels after patent abandonment.[62] It does not appear to be that subsequent inventors see much value in following technology design directions embedded in abandoned patents.

2. Directing Research Away from Failed Technological Directions

The residual value of patented advances once the relevant patents are abandoned may lie in increasing knowledge about what *not* to try—that is, about failed directions of technology development. Even failures have educational value. However, this value will be realized only if an understanding of abandoned inventions and how they failed informs later efforts to undertake similar inventions. Abandoned patents and the unwanted inventions they describe may have some value in forestalling wasteful efforts to pursue further projects that not only waste resources in duplicating the failed invention but that are likely to fail as well. In

[62] *See infra* Section II(C)(2).

effect, abandoned patents may warn future inventors where not to go in subsequent innovation efforts. The value in this type of warning would lie in research not undertaken and associated costs not incurred. The size of these savings is hard to measure, as is the mechanism (if any) whereby abandoned patents are assessed for information on how they failed to meet consumer needs.

There is evidence that subsequent innovators avoid further work on the technology and development directions described in abandoned patents. Abandoned patents are cited at much lower rates than valuable patents, suggesting that the advances described in the abandoned patents and closely-related innovations (which would have resulted in citations to the abandoned patents) are rarely of much interest to innovators.[63] However, there is no evidence that innovators' avoidance of these technologies occurs because the innovators are warded away from the technologies by knowledge of the abandoned inventions' failures.[64] More likely, later innovators make their own evaluations of the technologies described in abandoned patents (through independent research about those technologies without necessarily accessing the abandoned patents) and conclude that these technologies lack probable value.[65] Based on their separate but similar analyses, both patent owners and later innovators see the technology neighborhoods of abandoned inventions as essentially worthless.

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[63] *See id.*

[64] The problem in evaluating the implications of low citations to abandoned patents is a bit like analyzing why a dog at the scene of a crime did not bark: was the dog just ignoring relevant facts, or was it reacting to a familiar party who was the criminal? In the context of abandoned patents, low levels of citations can be interpreted in at least two ways. Subsequent technology innovators may have been aware of the abandoned inventions and been warded away from similar research projects, in which case the informative but abandoned patents would not be cited as there would be no line of citing patents resulting from inventions not produced. Or later innovators may just have made their own assessments of valuable research directions, been attracted to different directions than those pursued in abandoned patents, produced new advances in the new directions, and failed to cite the abandoned patents because they were not relevant to the new directions. This would also result in low citation counts for the abandoned patents. Which of these mechanisms was in play cannot be ascertained from low citation counts alone—that is, from the citation "dog" that did not bark.

[65] In general, inventors tend not to read patents, meaning that they are unlikely to be influenced by the content of abandoned patents and the negative technical design information (such as indications of technology directions not to pursue) that inspection of these patents might reveal. *See* Mark A. Lemley, *Ignoring Patents*, 2008 MICH. ST. L. REV. 19, 22 n.16 ("Empirical research suggests that scientists don't in fact gain much of their knowledge from patents, turning instead to other sources."); Wesley M. Cohen et al., *R&D Spillovers, Patents and the Incentives to Innovate in Japan and the United States*, 31 RSCH. POL'Y 1349, 1362-64 (2002).

I
THE PRESENT STUDY

The present study relies on forward citation data to track innovators' reactions to and interest in patented technologies.[66] The study uses forward citations as indicators of inventor interest and research intensity concerning technologies conceptually similar to the cited advances. Large numbers of forward citations indicate strong inventor interest in technologies like that in a cited patent. Large numbers of forward citations also confirm substantial invention follow-through in the technology neighborhoods of the cited patents. Because numbers of forward citations track inventor interest—and because inventors are under legal obligations to make these citations as part of their duties to provide full accounts of the background of their inventions—forward citations provide useful data on inventors' estimates of technology value and related shifts in technology development. Inventors convey their estimates of high technology value in their choices of innovation projects. They "follow the (perceived) money" and projected invention value in innovation targeting. Their aggregate value estimates are captured in forward citation counts reflecting crowdsourced information on projected invention value. Where a given advance attracts many forward citations, the cited advance reflects a technology domain with high estimated value in the minds of later innovators.

The following subsections describe the conceptual and methodological underpinnings of the present study. First, Subsection A explains why forward citations are useful metrics for evaluating inventor interest in particular technology domains (including descriptions of past studies using forward citations for this purpose). Second, Subsection B describes the data and methods used in the present study. Section II of this article presents the findings of the present study, including evidence of significant differences in the interest shown by subsequent inventors in owner-valued patents (that is, patents extended to their full term by their owners) as

[66] Forward citations are citations to a patent in later-issued patents. Inventors filing patent applications are required to describe the background of their inventions. One way to do this is to cite earlier patents that describe related inventions. These citations create "backward citations", so named because they cite patents that are *backward* in time from the citing patent. Once a patent issues, backward citations (along with additional citations added by patent examiners) appear in the patent and in databases recording the patent. Forward citations are backward citations looked at in the opposite direction; that is, a citation treated as a backward citation from the standpoint of a citing patent is treated as a forward citation from the standpoint of the cited patent. Forward citations are so labeled because the citing patents are issued later or *forward* in time from the cited patents. *See* Leonidas Aristodemou & Frank Tietze, *Citations as a Measure of Technological Impact: A Review of Forward Citation-Based Measures*, 53 WORLD PAT. INFO. 39, 40 (2018).

opposed to abandoned patents (that is, patents abandoned before their full term due to a failure to pay maintenance fees).

A. Forward Citations as Markers for Inventor Interest and Projected Invention Value

1. Forward Citations Reveal Technology Neighborhoods with High Inventor Interest and Projected Value

A citation in a patent application to an earlier patent suggests that the inventor filing the application was working in the technology vicinity or "neighborhood" of the advance in the cited patent. While a forward citation provides no guarantee of direct intellectual dependence (in the sense that the inventor of the citing advance was aware of and influenced by the cited advance), a forward citation does imply an intellectual proximity and conceptual relationship between the advances in the citing and cited patents.

Citations to earlier patents in an inventor's patent application are sometimes mistakenly taken as evidence that an inventor read the cited patents and derived his or her work from the cited patents' inventions.[67] This is probably incorrect in most cases and not the meaning of a forward citation relied on here. For the most part, inventors neither read earlier patents nor write their own patent applications.[68] Patent attorneys or agents write most patent applications, and these parties—along with patent searchers and patent examiners—account for patent citations in patent applications.

A more accurate interpretation of a patent citation is as a marker for similarity in technology between a cited and citing patent. A patent citation in a patent application indicates that the citing party felt that there was such a key similarity to the cited invention and that understanding the cited invention was important for evaluating the new features of the citing invention.[69] The cited invention then can be

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[67] The assumption that patent contents are inspected by subsequent innovators and have direct impacts on later technology development is implicit in citation analyses that use citation counts as measures of the varying technology development "influence" of different patents. *See, e.g.*, *id.*, ("Forward citations are commonly used to measure the technological impact of innovation.").

[68] *See* Lemley, *supra* note 65, at 22 n.16.

[69] Most patent citations are made by patent applicants, although some are added by patent examiners as they review patent applications. Patent applicants (and persons aiding in the drafting and submission of patent applications, such as patent attorneys) have a duty to disclose information that is materially related to the patentability of an invention, insofar as such information is known when a patent application is submitted to the USPTO. The required information includes past technology designs that bear upon whether an advance covered by a patent application is new and

considered as part of the background technology baseline or "prior art" against which the new (and not new) features of the advance described in a citing patent can be evaluated.[70]

Interpreted this way, citations suggest that the inventions in cited and citing patents share a single technology neighborhood defined by the common features of the advances.[71] A single citation confirms only that there are two advances in the relevant neighborhood (the cited and citing advances). But a large number of citations to a particular patent indicates that subsequent innovators produced numerous advances in the same technology neighborhood as the cited advance. Forward citations grouped around cited advances thereby measure the magnitude and intensity of inventive activity in the conceptual vicinity of the cited patent.[72] Large numbers of forward citations point to areas of strong innovator interest.

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sufficiently different from past technologies to qualify for a patent. The disclosed information serves as a starting point for reviews of patent applications by patent examiners. *See* U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE §§ 2001.05, 2001.06 (9th ed. 2020). Patent citations in a patent application are convenient ways to point to and disclose the contents of the cited patents to patent examiners. *See generally* Christopher A. Cotropia, Mark A. Lemley & Bhaven Sampat, *Do Applicant Patent Citations Matter?*, 42 RSCH. POL'Y 844 (2013) (describing patent examiners' consideration of cited patents as well as other prior art sources).

[70] Relevant prior art includes all types of publicly available information from which the novelty and nonobviousness of an advance covered by a patent application can be assessed. *See* U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE §§ 2001.05, 2001.06 (9th ed. 2020). Common sources of prior art information include publicly available knowledge, products, and patent documents. Patent records provide particularly important prior art sources both because they present recent technological knowledge in organized ways and because they are indexed and therefore easily retrieved via computer-enhanced searching. Some worldwide patent databases contain 130 million documents, collected and indexed over many years by patent offices in many countries. *See What Is Prior Art?*, EUR. PAT. OFF., https://www.epo.org/learning/materials/inventors-handbook/novelty/prior-art.html (last updated Nov. 3, 2021).

[71] This approach uses inventors' self-evaluations (or the evaluations of parties aiding inventors in filing patent applications) to identify patents that share similar technology design neighborhoods. A citation implies that the citing inventor feels his or her advance is conceptually close to the cited advance and in the same neighborhood. Other parties have recognized that technology similarity defines neighborhoods of patented advances but have attempted to define the relevant neighborhoods in terms of pre-existing technology classification systems and to measure the adjacency of advances based on these externally imposed schemes. *See* Madeline K. Kneeland, Melissa A. Schilling & Barak S. Aharonson, *Exploring Uncharted Territory: Knowledge Search Processes in the Origination of Outlier Innovation*, 31 ORG. SCI. 535 (2020).

[72] Manuel Trajtenberg previously recognized this implication of numerous forward citations:

Citation counts are crowdsourced indicators of technology "hot spots"—technology domains with intense innovation interest and high-volume productivity. These indicators reflect the views of talented innovators capable of generating patented advances since only the work of these innovators result in patent citations. Their interest, in turn, tracks the innovators' beliefs (and those of their research backers) in the economic potential of further inventions within the heavily pursued and extensively cited areas of innovation.[73]

> The very existence of [numerous citing] patents attests to the fact that the cited patents opened the way to a technologically successful line of innovation. Moreover, it presumably attests also to economic success (at least in expected value terms), since those subsequent patents are the result of costly innovational efforts undertaken mostly by profit-seeking agents . . . . [I]f citations keep coming, it must be that the innovation originating in the cited patent ha[s] indeed proven to be valuable.

A Penny for Your Quotes: Patent Citations and the Value of Innovations, 21 RAND J. ECON. 172, 174 (1990). According to this view, the meaning of later citations is that "a patent that has been revealed to be profitable will induce other firms to undertake research in technologically close but non-infringing areas, (probabilistically) resulting in citing patents." Bhaven N. Sampat & Arvids A. Ziedonis, *Patent Citations and the Economic Value of Patents: A Preliminary Assessment*, *in* HANDBOOK OF QUANTITATIVE SCIENCE AND TECHNOLOGY RESEARCH 277, 280-81 (Henk F. Moed et al. eds., 2004).

[73] *See* Trajtenberg, *supra* note 72, at 174. Recent empirical research suggests that numerous forward citations reflect strong market interest in (and perceived value of) technologies similar to those described in heavily cited patents. Based on studies of licensing of university patents (from Columbia University and the University of California) and related licensing revenues, Bhaven N. Sampat and Arvids A. Ziedonis concluded that high forward citation counts were good predictors that patents were licensed, but not good predictors of revenues gained once patents were licensed. Their preliminary interpretation of these results is that:

> [C]itations reflect market interest in areas in technological proximity to particular patents. Market interest induces innovative effort in particular technological areas, increasing the probability of later citations. At the same time market interest also increases the probability of licensing. However, as innovation and commercialisation are uncertain activities, the level of revenues ultimately earned by particular technologies may be influenced by factors other than market interest, including competition by competing technologies, licensees' commercialisation incentives, and R&D and marketing competencies.

Sampat & Ziedonis, *supra* note 72, at 295.

2. Past Studies Confirming Forward Citations' Links to Inventor Interest and Commercial Success

Past studies confirm that forward citations—particularly early-stage forward citations within three years of patent issuance (hereinafter "quick citations")—track innovator success in producing advances with high value. Researchers at the Massachusetts Institute of Technology (MIT) found that mean quick citations for different types of advances predicted approximately 64% of variations in value growth for diverse technologies.[74] They concluded that quick citations were markers for innovator interest, with areas of intense interest and active innovation efforts tending to produce the most commercially successful and valuable technologies.[75] Numerous early-stage citations point to attractive, fast-moving technology fields where many innovators (and supporting organizations drawn by the commercial potential of the fields) produce numerous advances with "immediate importance" in the further development of valuable technologies.[76]

Bronwyn H. Hall, Adam Jaffe, and Manuel Trajtenberg explained the link between forward citations and patent value as follows:

> There are reasons to believe that citations convey not just technological but also economically significant information: Patented innovations are for the most part the result of costly R&D conducted by profit-seeking organizations; if firms invest in further developing an innovation disclosed in a previous patent, then the resulting (citing) patents presumably signify that the cited innovation is economically valuable. Moreover, citations typically keep coming over the long run, giving plenty of time to dissipate the original uncertainty regarding both the technological viability and the commercial worth of the cited innovation. Thus, if we still observe citations years after the grant of

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[74] *See* Christopher L. Benson & Christopher L. Magee, *Quantitative Determination of Technological Improvement from Patent Data*, 11 PLOS ONE 1, 11 (2015).

[75] *See id.*

[76] While they did not provide detailed accounts of how advances achieved immediate importance in particular technology fields, the MIT researchers felt that immediate importance in technology development as measured by quick citations was consistent with the types of disruption and innovation redirection of technology fields noted by Clayton M. Christensen and the importance of technological discontinuities recognized by Philip Anderson and Michael L. Tushman. *See id.* (citing CLAYTON M. CHRISTENSEN, THE INNOVATOR'S DILEMMA: WHEN NEW TECHNOLOGIES CAUSE GREAT FIRMS TO FAIL (Harvard Bus. Review Press l997) and Philip Anderson & Michael L. Tushman, *Technological Discontinuities and Dominant Designs: A Cyclical Model of Technological Change*, 35 ADMIN. SCI. Q. 604, 604-33 (1990)).

> the cited patent, it must be that the latter had indeed proven to be valuable.[77]

They note that forward citation counts provide useful information on inventive project commitments and the values of firms that hold patent rights to highly cited inventions:

> We think of the knowledge-creation process as a continuum going from R&D to patents to citations, which involves the sequential revelation of information about the value to the firm of the innovations generated along the way. That is, R&D reveals the commitment of a firm's resources to innovation, patents catalog the success in generating codifiable new knowledge that the firm can in principle appropriate, and citations indicate the extent to which those innovations turn out to be "important" and hence presumably more valuable to the firm.[78]

Hall, Jaffe, and Trajtenberg concluded that the market value of companies holding patents tracked the frequency of forward citations to company patents, with "[t]he value of high citation intensity . . . disproportionately concentrated in highly cited patents[. F]irms having two to three times the median number of citations per patent display a 35% value premium, and those with 20 citations and more command a staggering 54% market-value premium."[79]

Other researchers have shown that forward citation variations track invention valuation differences.[80] For example, Dietmar Harhoff, Francis Narin, F. M. Scherer, and Katrin Vopel established private values for patents by asking German holders of United States patents to estimate the price at which they would have been willing to sell a patent three years after filing. They found that the estimated prices were correlated with forward citation counts, with the most highly cited patents having very high estimated values.[81] Manuel Trajtenberg examined links between forward citations and invention value as measured from estimates of the social surplus resulting from improvements in computed tomography (CT) scanners. He found that citation-weighted patent counts were highly correlated with differences in estimated

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[77] *Market Value and Patent Citations*, 36 RAND J. ECON. 16, 19 (2005).

[78] *Id.* at 24.

[79] *Id.* at 17.

[80] Sampat & Ziedonis, *supra* note 72, at 280 (noting that, in empirical studies of the economics of innovation, patent citation counts have been used as proxies for the private value of patents).

[81] *See Citation Frequency and the Value of Patented Inventions*, 81 REV. ECON. & STAT. 511, 512-13 (1999).

surplus value (even though patent counts alone showed no such correlation).[82] John R. Allison, Mark A. Lemley, Kimberly A. Moore, and R. Derek Trunkey used patents involved in litigation as a sample of valuable patents and found that these valuable patents were cited significantly more often than unlitigated patents.[83] Again focusing on litigated patents as a subset of all valuable patents, Jean O. Lanjouw and Mark A. Schankerman found that forward citations predicted patent litigation likelihood (and hence, patent value) when citations were made by competitors of the patent holders.[84] Francis Narin, Anthony Breitzman, and Patrick Thomas found a strong association between the quality of companies' patent portfolios, as measured by patent citation indicators, and the companies' stock market value in the short- and long-term.[85] Examining the licensing of patents by universities, Bhaven N. Sampat and Arvids A. Ziedonis concluded that high forward citation counts were good predictors that patents were licensed (suggesting that the highly-cited inventions were viewed as the most valuable by licensees) but found that forward citations did not explain variations in licensing revenues among licensed patents (suggesting that factors other than surrounding innovator interest influenced the differences in licensing revenues among licensed patents).[86]

B. Additional Analyses in the Present Study

1. Evaluating Differences in Inventor Interest Across Valuable and Abandoned Patents

The present research extends the studies just described by evaluating whether patent owners and subsequent innovators view patent value similarly. The study compares innovator interest in patented advances (as measured by forward citations after patent issuance) with patent owners' valuations of the same advances (as recorded in maintenance fee payments). Two major categories of patents are considered: valuable patents (defined as patents seen by owners as having sufficient value to warrant payment of all maintenance fees needed to keep the patents in force for their full terms) and relatively worthless patents (defined as patents that are

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[82] *See* Trajtenberg, *supra* note 72, at 172.

[83] *Valuable Patents*, 92 GEO. L.J. 435, 455 (2004) ("Patents that end up being litigated are much more likely to be cited as prior art by other issued U.S. patents than are non-litigated patents.").

[84] *See Characteristics of Patent Litigation: A Window on Competition*, 32 RAND J. ECON. 129 (2001).

[85] *Using Patent Citation Indicators to Manage a Stock Portfolio*, *in* HANDBOOK OF QUANTITATIVE SCIENCE & TECHNOLOGY RESEARCH 553, 553-54 (Henk F. Moed et al. eds., 2004).

[86] Sampat & Ziedonis, *supra* note 72, at 293.

abandoned by their owners due to non-payment of maintenance fees prior to the end of the patents' full terms).

Worthless patents are evaluated in three subgroups with varying ownership duration and valuation timing. The three subgroups include: (1) patents abandoned four years after issuance (reflecting relatively quick assessments of worthlessness); (2) patents abandoned eight years after issuance (reflecting more extended assessments of patent value before conclusions of worthlessness); and (3) patents abandoned twelve years after issuance (reflecting extensive fact finding and relatively late evaluations of patents still found to be worthless). One goal of this separation is to see if subsequent innovators show different interest in these subcategories of worthless patents. Citations to these three subcategories of patents illuminate whether inventors' interest in the different types track the diminishing uncertainties about invention value held by patent owners, reflected in delayed abandonment decisions.

Finally, for all four categories of patents (valuable patents and the three subcategories of worthless patents), additional comparisons are made of citation levels before and after patent abandonment (due to non-payment of maintenance fees) or expiration (due to completion of the full authorized patent term). The purpose here is to see if patent rights, while in force, are artificially suppressing innovation levels in the technological vicinity of the patented advances. If patent rights do suppress some innovation in this way, a jump upward in citation levels should occur upon the elimination of patent rights (whether through patent abandonment or through the natural expiration of a patent at the end of its full term).

2. The Data Used

The study examines patent abandonment decisions and inventors' forward citations concerning a random sample of 5,099 United States utility patents issued between January 1, 1995 and March 31, 1995. Information on these patents and related forward citations was obtained from two sources. Basic information on the patents, the advances they describe, and the inventors producing the patented advances was obtained from the AcclaimIP database service.[87] Additional information on patent characteristics and citations was obtained from PatentsView, a patent data project supported by the Office of the Chief Economist at the USPTO.[88]

[87] *See* ACCLAIMIP, http://www.acclaimip.com/ (last visited Jan. 2, 2022).
[88] *See* PATENTSVIEW, https://patentsview.org/ (last visited Jan. 2, 2022).

Diverse technologies were represented in the patent sample. The technology breakdown was as follows:[89]

Figure 1: 1995 Patent Sample by National Bureau of Economic Research (NBER) Technology Sub-Category

Category	Name	Sub-Category	Technology	N	Percent	Cum.
1	Chemical	11	Agriculture, food, textiles	33	0.65	0.65
		12	Coating	96	1.88	2.53
		13	Gas	18	0.35	2.88
		14	Organic compounds	170	3.33	6.22
		15	Resins	166	3.26	9.47
		19	Misc. (chem.)	490	9.61	19.08
2	Computers & Communications	21	Communications	256	5.02	24.10
		22	Computer hardware and software	212	4.16	28.26
		23	Computer peripherals	74	1.45	29.71
		24	Information storage	157	3.08	32.79
		25	Electronic business methods and software	24	0.47	33.26
3	Drugs & Medical	31	Drugs	234	4.59	37.85
		32	Surgery, medical instruments	226	4.43	42.28
		39	Misc. (drugs & med.)	23	0.45	42.73
4	Electrical & Electronic	41	Electrical devices	186	3.65	46.38
		42	Electrical lighting	108	2.12	48.50
		43	Measuring, testing	164	3.22	51.72
		44	Nuclear, X-rays	76	1.49	53.21
		45	Power systems	144	2.82	56.03
		46	Semiconductor devices	177	3.47	59.50
		49	Misc. (elec.)	165	3.24	62.74
5	Mechanical	51	Materials processing & handling	209	4.10	66.84
		52	Metal working	129	2.53	69.37
		53	Motors, engines, parts	165	3.24	72.60
		54	Optics	49	0.96	73.56
		55	Transporation	134	2.63	76.19
		59	Misc. (mech.)	224	4.39	80.58
6	Others	61	Agriculture, husbandry, food	88	1.73	82.31
		62	Amusement devices	63	1.24	83.55
		63	Apparel & textile	84	1.65	85.19
		64	Earth working & wells	56	1.10	86.29
		65	Furniture, house fixtures	112	2.20	88.49
		66	Heating	41	0.80	89.29
		67	Pipes & joints	41	0.80	90.10
		68	Receptacles	101	1.98	92.08
		69	Misc. (others)	404	7.92	100.00
		Total		5,099	100.00	

[89] *See* Bronwyn H. Hall, Adam B. Jaffe & Manuel Trajtenberg, *The NBER Patent Citations Data File* (Nat'l Bureau of Econ. Rsch., Working Paper No. 8498, 2001), https://www.nber.org/papers/w8498.pdf (describing the technology categories and sub-categories defined by the National Bureau of Economic Research in its technology classification system); Alan C. Marco et al., *The USPTO Historical Patent Data Files* 25 (U.S. Pat. & Trademark Off., Working Paper No. 2015-1, 2015) (Table 2), https://www.uspto.gov/sites/default/files/documents/USPTO_economic_WP_2015-01_v2.pdf.

Owners of patents in the sample perceived their patents as having widely varying values (as reflected in their decisions to keep or abandon the patents). Patent abandonment decisions governing the sample patents are summarized in the following figure. Patented advances identified as "Extended to Full Term" were viewed by their owners as sufficiently valuable to warrant payment of fees required for the extension of the relevant patents to their full terms, while those listed as abandoned were allowed to lapse by their owners at the indicated times due to the non-payment of required maintenance fees:

Figure 2: Patent Retention and Abandonment Breakdown

Retention/Abandonment	N	Percent	Cum.
Abandoned 4 Years After Issue	806	15.81	15.81
Abandoned 8 Years After Issue	1,024	20.08	35.89
Abandoned 12 Years After Issue	957	18.77	54.66
Extended to Full Term	2,312	45.34	100
Total	5,099	100	

These figures indicate that only a minority of the patents in the sample (about 45%) were kept in force for their full term. The remaining 55% lapsed at various points after patent issuance, suggesting that owners of these lapsed patents eventually felt that the patents were essentially worthless—worth less than the modest fees needed to keep the patents in force. While the full-term retention rate of about 45% for patents in the sample may seem low, it is consistent with the retention rate for all patents issued in the same period. According to calculations by Dennis Crouch for the Patently-O Blog, the rate of third maintenance fee payment in 2007 (the year when this fee would be due for patents issued in 1995) was about 45%.[90] Thus, the patent retention and abandonment decisions for the patents in the present sample were similar to those reached for all contemporaneous patents.

Patents in the sample were cited a total of 135,236 times (through August 20, 2019, the cutoff date for citations considered in this study). Individual patents were cited at widely varying levels. The mean citation count was 26.52 citations per patent. The distribution of total forward citations to patents in the sample was as follows:

[90] Crouch, *supra* note 3.

Figure 3: 1995 Patent Sample Forward Citation Breakdown

Forward Citations	N	Percent	Cum. Percent
0	149	2.92	2.92
1	219	4.29	7.22
2	255	5.00	12.22
3	251	4.92	17.14
4	251	4.92	22.06
5	243	4.77	26.83
6	224	4.39	31.22
7	199	3.90	35.12
8	178	3.49	38.62
9	177	3.47	42.09
10	184	3.61	45.70
11	148	2.90	48.60
12	135	2.65	51.25
13	117	2.29	53.54
14	131	2.57	56.11
15	120	2.35	58.46
16	115	2.26	60.72
17	109	2.14	62.86
18	99	1.94	64.80
19	73	1.43	66.23
20	68	1.33	67.56
21 or more	1,654	32.44	100.00
Total	5,099	100	

More than half of the patents in the sample had 12 or fewer forward citations during the more than 20 years covered by this study.[91] About 25% had 5 or fewer citations. Relatively few (only 149 or about 3% of the sample) had no citations. The top tiers of citations were as follows: top 10%—59 citations or more; top 5%—98 citations or more; and top 1%—248 citations or more.

[91] Citations were included in the study if made on or before August 20, 2019. Thus, the period for citations considered in the study extended from January to March 1995 (when the cited patents in the sample were issued) through August 20, 2019, or approximately 24 ½ years.

II
FINDINGS

A. Significant Differences in Citations Between Valuable and Worthless Patents

Innovators' interest in patents within the sample tracked the value assessments of patent owners. Patents seen as valuable by their owners were highly cited (reflecting strong interest in developing further advances similar to the cited innovations), while abandoned patents were cited much less frequently (reflecting relatively low interest in advances similar to the ones found valueless by patent owners). The breakdown of mean citation levels by patent abandonment categories was as follows:

Figure 4: Forward Citations Per Patent by Patent Retention Category

Retention/Abandonment	N	Mean Citations
Abandoned 4 Years After Issue	806	16.27
Abandoned 8 Years After Issue	1024	18.96
Abandoned 12 Years After Issue	957	21.95
Extended to Full Term	2312	35.34
Total	5099	26.52

All three of the mean citation figures for abandoned patents were significantly different (at the $p<.01$ level of statistical significance) from the 35.34 mean citations per patent received by valuable patents extended to their full term. This difference indicates that innovators (who made the innovation-targeting choices resulting in later patent citations) apparently saw the same value indicators (or lack of them) as patent owners making patent abandonment decisions.

Furthermore, the value assessments by innovators and patent owners correlated across the three subcategories of abandoned patents. Patents abandoned the soonest (4 years after issuance) were cited the least, presumably because these patents covered inventions that were the most clearly worthless. Similarly, patents abandoned at 8 years were cited somewhat more than patents abandoned at 4 years, while those abandoned at 12 years were cited a bit more than those abandoned at 8 years. Both patent owners and innovators appear to have taken some time to reach the conclusion that these patents covered worthless inventions, but eventually resolved their uncertainties in similar ways and with similar gradations in invention interest. For all of these subcategories of inventions ultimately found worthless, innovator interest (as reflected in mean citations) was far below the interest shown in inventions covered by valuable patents extended to their full term.

B. Citation Differences Controlling for Technology Types and Invention Sources

Some of the observed differences in citation levels for valuable and abandoned patents may reflect differences in the technology mixes for these two groups of patents and corresponding differences in citation patterns for different technologies. Similarly, factors such as research location and funding source may influence the analysis. To control for and remove differences caused by these variations, citation differences were evaluated using a negative binomial regression analysis.[92] In this analysis, the dependent variable was the total number of forward citations received by a patent and the independent variables were (1) a dummy variable recording whether a patent was a valuable patent (as perceived by its owner and indicated by a decision to pay maintenance fees necessary to extend the patent to its full term); (2) a series of dummy variables recording the NBER technology category of each patent (using the NBER technology category of mechanical advances as the base or "reference" category); (3) a dummy variable indicating whether a patent resulted from research conducted in the United States rather than overseas; and (4) an additional dummy variable indicating that a patented advance resulted from research conducted by an independent researcher (as opposed to a researcher supported by a corporation or university and resulting in an immediate assignment of the associated patent to the entity upon patent issuance). The regression results were as follows:

[92] Negative binomial regression analyses are appropriate for evaluating count data that is highly skewed toward numerous cases with low values. *See* Clay Ford, *Getting Started with Negative Binomial Regression Modeling*, U. VA. LIBR. (May 5, 2016), https://data.library.virginia.edu/getting-started-with-negative-binomial-regression-modeling/. In the present study, many of the patents had low citation counts.

Figure 5: Negative Binomial Regression Analysis of Forward Citation Odds

Variable	Odds Ratio	Standard Error	Z	P>Z
Valuable Patent	1.65	0.08	10.16	0.00
Chemical	1.11	0.10	1.24	0.21
Computers & Communications	2.14	0.15	10.78	0.00
Drugs & Medical	2.83	0.24	12.03	0.00
Electrical & Electronic	1.54	0.11	6.05	0.00
Other Technologies	1.18	0.08	2.46	0.01
US Source	1.71	0.08	11.04	0.00
Independent Inventor	0.95	0.06	-0.85	0.40
/lnalpha	0.16	0.03		
alpha	1.17	0.03		

The reported odds ratios estimate the odds of receiving a forward citation for a patent having the feature represented by each independent variable relative to the odds for a patent lacking the feature. For example, a patent from a United States source was 1.71 times or about 71% more likely to attract a forward citation than an otherwise similar patent resulting from foreign research (with research locations determined from the location of the lead inventor listed in each patent). The odds ratios for different technology types reflect odds relative to patents in the reference category of mechanical advances. Thus, a patent involving a computer or communication innovation was 2.14 times or over twice as likely to obtain a citation than a mechanical engineering patent that was similar in all other respects. All of the odds ratio values were statistically significant at the $p<.01$ level except those for chemical advances, other technology advances,[93] and advances from independent inventors.[94]

1. Significant Citation Variations with Patent Retention

These results confirm the significant relationship between valuable patents and citation levels across diverse technology types. The estimated odds ratio of 1.65 means that a valuable patent retained to its full term was about 65% more likely to

[93] The lack of statistically significant odds ratios for chemical advances and other technologies means that forward citations for advances of these types were not significantly more or less likely than citations for mechanical advances.

[94] The lack of a statistically significant odds ratio for independent inventors means that citations for advances produced by independent inventors were not more or less likely than citations for advances from other sources, all else being equal.

receive a forward citation than a comparable abandoned patent (controlling for differences due to technology and the other factors reflected in the independent variables used in the analysis). This statistically significant[95] odds ratio indicates that there was a positive relationship across technologies between patent owners' value assessments (as reflected in their decisions to extend patents to their full term and recorded in the "Valuable Patent" dummy variable) and innovator interest in the patented advances (as reflected in increased forward citations). Patents that were highly valued by patent owners were also likely to be interesting to innovators, leading to high citation counts. The high citation counts for these patents also indicate that innovators felt that further technologies in the vicinity of the cited patents had positive development potential (warranting the initiation of further research projects) and probable value.

2. Variations Across Technologies

The technology-specific odds ratios in these results suggest that research programs (and related citation processes) were particularly intense for some technologies. Substantial variations were present across technologies in likelihoods of forward citations. Patented advances covering computers and communications inventions as well as drugs and medical innovations were particularly likely to be cited, indicating strong interest in advances within these fields. Forward citations were also significantly more likely for electrical and electronic advances than for inventions in the reference category of mechanical innovations but were not significantly more likely (at the $p<.01$ level of statistical significance) for chemical advances and other technology inventions (suggesting that innovation interest and citation patterns in these fields were no more intense than for mechanical advances, all else being equal).

3. Domestic Versus Foreign Invention Sources

Advances from the United States were more likely to gain forward citations than comparable advances from foreign sources. The odds ratio of 1.71 for an advance from a United States source suggests that an advance from a domestic source was about 71% more likely to be cited than a counterpart from a foreign source, all else being equal. Whether this reflects a higher quality of United States advances leading to more citations, greater knowledge of United States advances by later innovators making citations, or greater interest in United States advances for other reasons (perhaps due to better targeting of these advances toward areas of high

[95] This odds ratio was statistically significant at the $p<.01$ level.

commercial potential) cannot be ascertained from the data examined in the present study.

4. Advances from Independent Inventors

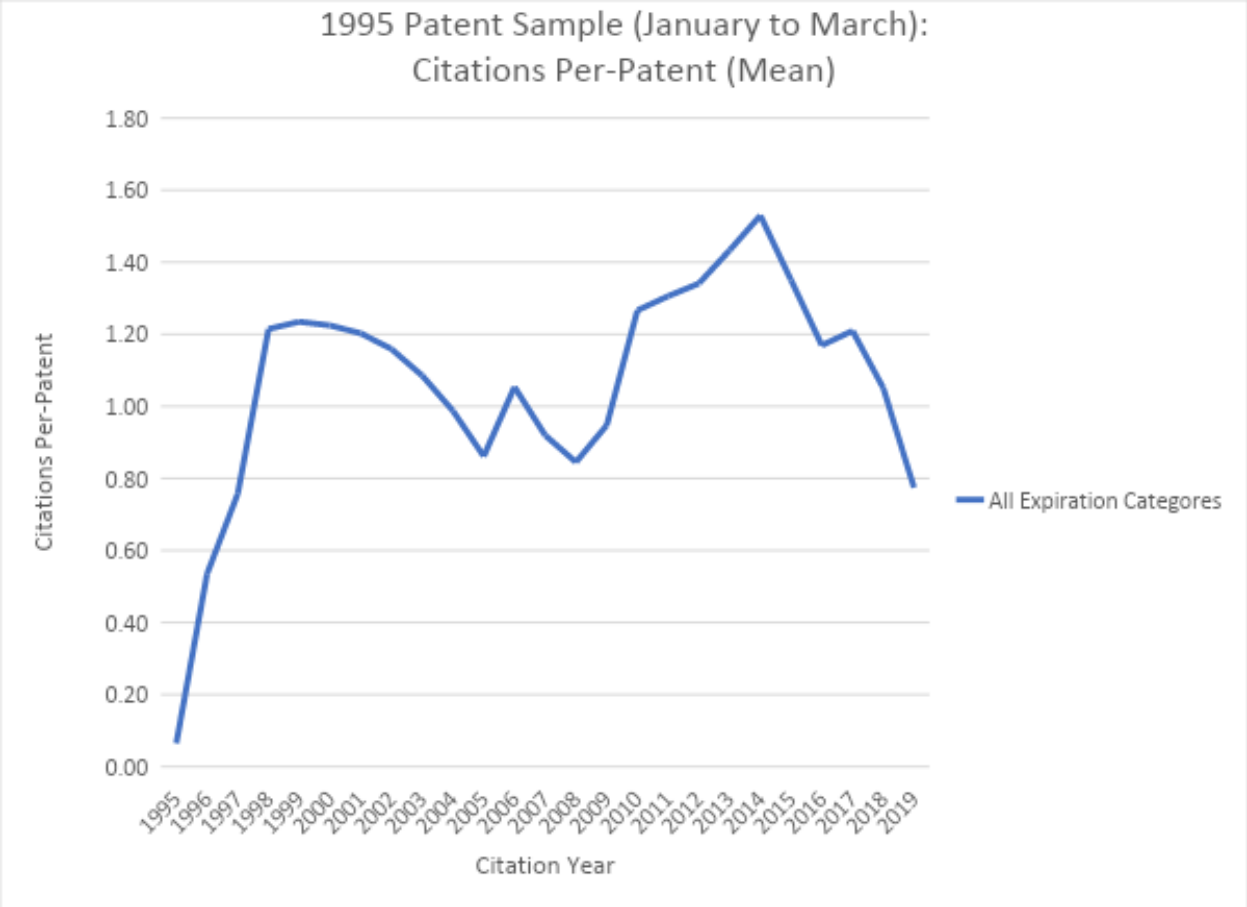
Interestingly, advances from independent inventors were no more or less likely to be cited than equivalent innovations from innovators working with institutional associations and support. The lack of a statistically significant odds ratio for citations to patents from independent inventors means that advances from independent inventors and similar advances from inventors working for organizations (such as corporations or universities) were equally likely to be of interest to later innovators and cited in later patents, all else being equal. This suggests that the content of patents drives innovator interest and later citations, not the institutional source of the patents. Patent citations are attracted by the technical content of a patent rather than the institutional associations of the party producing that content.

C. Citations Over Time

1. Variations in Citations Over the Life of Patents

Patents in the sample (all issued in early 1995) were cited at varying annual levels between 1995 and 2019. The following figure summarizes the per-patent citation means over this period. For each year, the reported figure reflects the mean number of citations in that year to the patents in the sample.

Figure 6



Two aspects of this graph probably reflect no more than anomalous artifacts resulting from data truncation. As more completely described below, the limited availability of the patents in the sample produced the sharp upward slope at the left side of the graph concerning citations in 1995 and 1996. Incomplete data gathering covering only part of 2019 accounted for the sharp downward slope for citations in that year.

i. Early Stage Data Anomalies

The upward slope at the left side of the graph probably reflects the first public availability of the sample patents upon their issuance and publication in early 1995.[96]

[96] Patents issued in 1995 were not subject to present rules on pre-issuance publication of patent applications, which provide that most patent applications are published 18 months after the applications are filed. The only exceptions are applications that the applying parties certify will not form the basis for counterpart patent applications in foreign patent systems. The latter type of patent applications can be maintained confidentially until patent issuance. These rules providing for pre-issuance publication of most applications only took effect in 2000, meaning that patents

Their earlier unavailability produced low citation levels in 1995 and for a few years after. Their initial unavailability until published in early 1995 may have suppressed initial citations for at least three reasons.

First, patents issued in late 1995 (which were the only 1995 patents capable of citing the patents in the sample) constituted only a fraction of the total year's set of citing patents (a fraction roughly corresponding to the portion of patents issued after January to March of 1995, or about 9 out of 12 months). Citations from only a partial year of citing patents would tend to produce unusually low per-patent citation counts for 1995.

Second, delays in the drafting of citing patent applications may explain the sorts of ramping up of per-patent citations seen in the years after 1995. Patent applications are typically drafted several years before the relevant patents are issued. Thus, patent applications drafted before 1995 (when the sample patents were not available for citing) may have resulted in many patents issued in later years. For example, a patent issued in 1997 may have stemmed from an application prepared in 1994, at which point the sample patents were still confidential.[97] A typical delay from patent application submission to patent issuance is about three years.[98] Assuming that most patent applications drafted in 1995 (when information about the sample patents was fully available) resulted in issued patents about three years later in 1998, one would expect normal levels of citations to the 1995 sample patents to begin only around 1998. This is precisely what is seen in the data. Citations to the 1995 patents in the sample level off after 1998. The sharp increases in patent citations between 1995 and 1998 may reflect the fact that not all patent applications took three years to examine. For example, if a few (but not most) patent applications

issued in 1995 (such as those in the sample) were only publicly available and capable of being cited as of their issuance in 1995. *See generally* U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 1120 (9th ed. 2020).

[97] Although it would be possible for a patent applicant filing an application in 1994 to amend the pending application in 1995 to include one of the recently published and publicly available patents in the sample, the patent applicant's legal obligation to make a full disclosure of relevant prior art applies only to the prior art known at the application's submission and would thus not include any obligation to make such an amendment. Indeed, a desire to avoid changes that might slow the consideration of an application by patent examiners might discourage such a legally optional amendment.

[98] *See How Long Does It Take to Get a Patent?*, ERICKSON LAW GROUP, http://www.ericksonlawgroup.com/law/patents/patentfaq/how-long-does-it-take-to-get-a-patent/ (last visited Jan. 2, 2022) ("The average time it takes to obtain a patent from the [USPTO] is about 32 months or a little under 3 years.").

drafted in 1996 and citing the 1995 patents emerged in 1997, this would have resulted in an intermediate level of per-patent citations for 1997, as seen in the data.

Third, the low but growing numbers of citations to the patents in the early years after their issuance in 1995 may reflect initially slow progress in further research concerning the distinctively new technologies described in the cited patents. If the distinctive originality of the advances patented in 1995 meant that researchers needed time to react to the new features and did not undertake many related research projects for a substantial period, the resulting delay in related research would produce a lag in the rise of citations. If related research was delayed, few initial citations to the 1995 advances would be made over the period of the delay. As related research increased with greater understanding and appreciation of the value of the advances patented in 1995, citations to the 1995 patents would slowly increase in parallel. Hence, learning about and reacting to the distinctively original advances described in the 1995 patents may explain delays in follow-on research and related delays in the rise of citations as seen in the data.

ii. Late Stage Data Anomalies

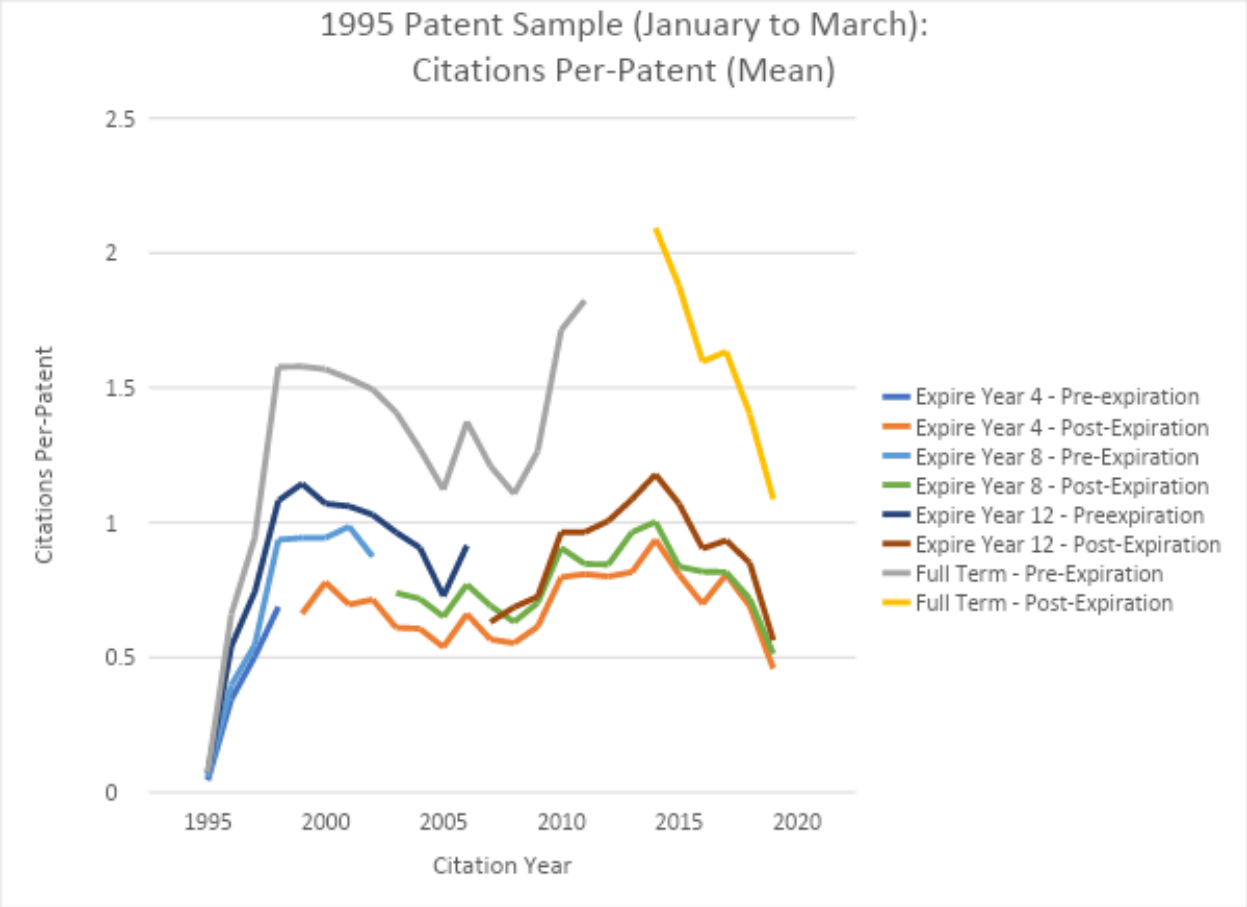
A different feature probably accounts for the low citation counts seen for 2019. The study considered citing patents issued through August 20, 2019. Since the data for 2019 only reflected a partial year of citing patents, the truncation of this data for 2019 produced an anomalously low per-patent citation figure in comparison with other years.

2. Citation Variations Over Time

i. Separating Citation Levels by Patent Value

The following figure summarizes the per-patent citations by year for the four types of patents considered in the study:

Figure 7



Each of the four categories of patents is represented by two lines—one reflecting per-patent citations before the patents in the category expired (due to either failure to pay maintenance fees or the completion of a full patent term) and a second line reflecting citations after the patent's expiration. For example, patents that were allowed to expire 4 years after patent issuance are represented by the dark blue line (for citations before expiration) and the dark orange line (for citations after expiration). Each pair of lines has a gap between them representing the year when the relevant patents ended and during which citation levels were anomalous (since the omitted years reflected partial periods split between patent enforceability and absence). For valuable patents extended to their full term, a two-year gap was included because the expiration dates of the patents included in the sample were spread over several years (resulting in several years of citation data influenced by both pre- and post-expiration patents).[99]

[99] The spreading of patent expirations over several years for full-term patents in the patent sample probably resulted from two patent law features. First, the full terms for patents in the

ii. Interpreting Citation Variations for Valuable and Worthless Patents

The results shown in Figure 7 reveal several interesting citation patterns. First, all four categories of patents exhibited changes in citations per patent that tracked overall differences in citation counts from year to year. This is apparent from the similar peaks and valleys in citation levels for all four categories of patents. For example, all four categories reflect a peak in per-patent citations in 2013-2014 corresponding to a surge in patent counts around this period (and a rise in related citations due to the increased number of citing patents).[100] These overall variations in total citation levels are evaluated more thoroughly in the next subsection of this article (where normalized assessments of per-patent citations are used to eliminate the effects of year-to-year changes in overall citations).[101]

Second, the ordering of citation levels from high citation levels for valuable patents downward to ever lower citation levels for the three categories of worthless patents is maintained throughout the terms of the cited patents. This ordering is present for every year from 1995 to 2019. Valuable patents are consistently the most frequently cited from early in their life, throughout their terms, and even after. Worthless patents are consistently cited at low levels early in their life, throughout their enforceability, and after lapsing. Apparently, innovators recognize valuable and worthless patents early and generally maintain their assessments throughout the life of the patents involved.

Innovators are arguably clearer eyed about patent value than patent owners. Patents that are ultimately but not initially abandoned by their owners (reflecting either denial by owners about the real worthlessness of their patents or initial gaps in information precluding owners from correctly identifying worthless patents) are seen by innovators very early in patent terms as having little research interest and

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sample were governed by two different legal standards. Some had durations limited to 17 years from patent issuance. Others benefitted from a change in the law that extended patent terms to 20 years from patent application filing (many patents already issued as of the change were given whichever of the new or old durations produced a longer patent term). This mixture of duration standards resulted in patent expirations of the sample patents distributed across multiple years. Second, additional patent term adjustments based on special circumstances—such as delays due to secrecy orders, interferences, or appellate review periods—meant that patent terms and expiration dates varied even further. *See generally Patent Term Calculator*, USPTO, https://www.uspto.gov/patent/laws-and-regulations/patent-term-calculator (last modified Dec. 30, 2021, 7:57 AM).

[100] United States utility patents jumped by about 33% between 2011 (108,622 issued) and 2014 (144,621 issued). *See U.S. Patent Statistics Chart: Calendar Years 1963 - 2020*, USPTO, https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (last updated May 2021).

[101] *See infra* Section II(C)(3).

are cited at relatively low levels accordingly. Innovators are willing (and perhaps compelled by resource limitations requiring them to make research choices carefully) to make patent value assessments promptly (and without the same attachment biases or other unwillingness to abandon costly innovations that may cause patent owners initially to overvalue their patented advances).

Of course, innovators are not perfect in recognizing worthless patents and moving their research to other areas. Some worthless patents are cited every year (both before and after patent lapsing). This indicates that innovators do not ignore abandoned patents altogether. Their citations to abandoned patents (roughly the same before and after patent expiration) probably reflect one or both of two processes.

First, these citations may result because worthless patents describe background elements of fields that still have research promise. The reasons why a specific patented advance is worthless and abandoned by its owner may leave some similar advances still worth pursuing (perhaps to correct the defects that rendered the abandoned innovation worthless). Hence, citations to abandoned patents may occur as some still promising research in related areas proceeds.

Second, citations to abandoned patents may result as patent applicants describe failed invention attempts to distinguish their later inventions and explain why these inventions are significantly different from the prior art in the relevant field of technology. The negative examples of worthless and abandoned inventions would provide a context and baseline for descriptive contrasts of inventions addressed in later patent documents. Used this way, citations of abandoned patents may characterize what has not worked and document how hard functionally meaningful innovation in the relevant field has been. Citations used for negative descriptive purposes may contribute to a "noise level" of citations to innovations that are known by the citing inventors to reflect unpromising but still descriptively relevant design directions.

The full reasons for the continuing noise level of citations to abandoned patents cannot be ascertained from this study. Further evaluations tracing the ways that citations to valuable and abandoned patents are relied on in citing patents (as well as whether the citations are predominantly made by patent applicants or by patent examiners) may reveal more about the role of abandoned patents in informing subsequent innovation and explain the lingering reasons for citations to patents recognized even by their owners as having little or no value for further technology development.

3. Normalized Citations Over Time

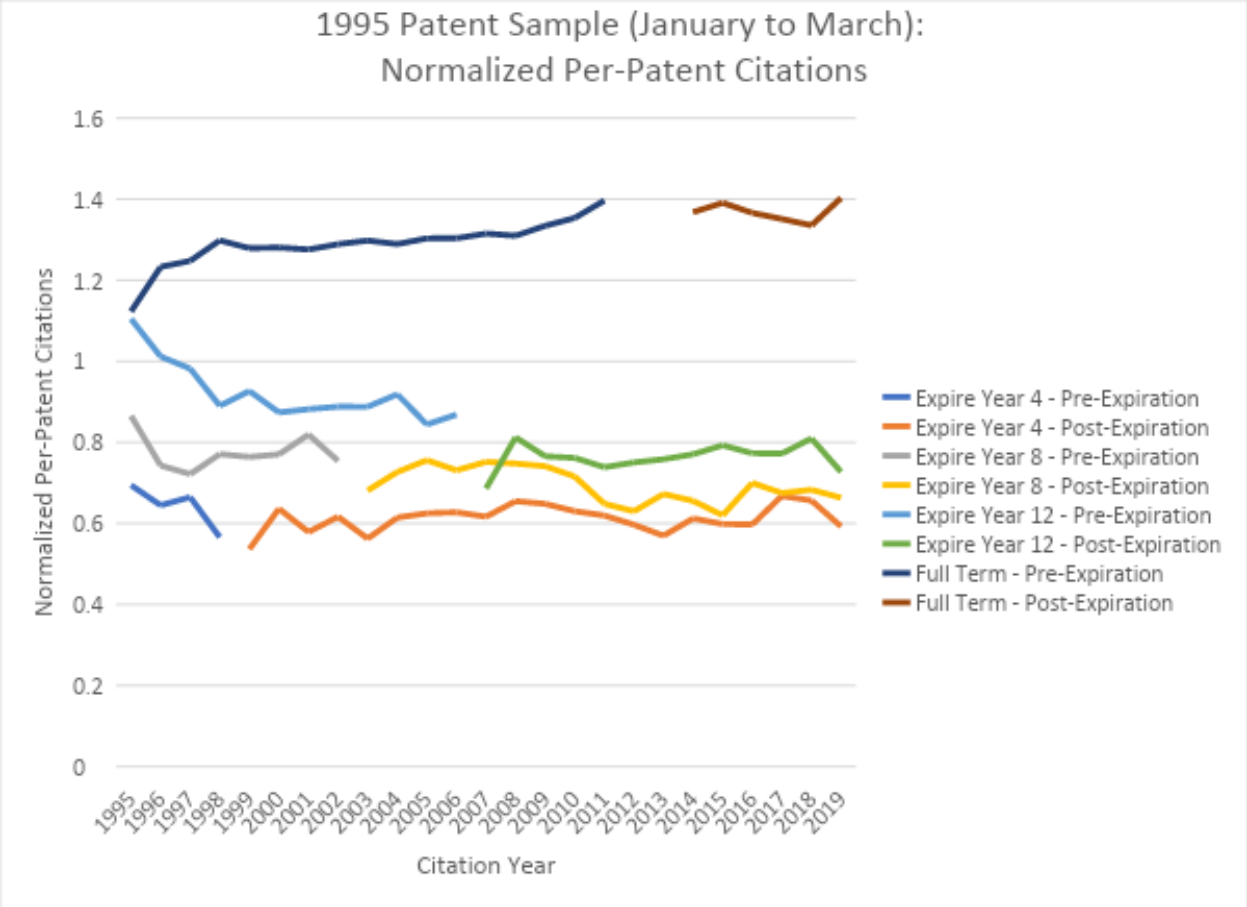
i. Computing Normalized Citation Counts

As previously mentioned, per-patent citation levels varied from year to year over the period of the study as the number of patents issued in various years changed. System-wide variations in per-patent citations—producing peaks and troughs in year-by-year citation figures—somewhat muddy the differences between patent value categories that are of interest in this study. It is difficult to know if the differences seen in the raw per-patent citation figures are due to changes in general citing levels or differences between citing levels for the four value categories.

To eliminate the effects of system-wide changes in citation volumes from year to year, normalized citation levels were computed to estimate citation levels for the four types of patents under study independent of overall changes in total citations. For each year and patent abandonment category, a normalized citation mean was computed that was equal to the mean per-patent citations for that year and category divided by the overall per-patent citations for the same year. The resulting normalized figures reflect the citations that would be expected for valuable and abandoned patents if the same number of citations per patent were made in every year considered in the study.

The resulting normalized per-patent citations are summarized in the following figure (as before, each of the four categories of valuable and abandoned patents is represented by two lines corresponding to citations in the category before and after patent expiration):

Figure 8



ii. Interpreting Normalized Citation Patterns

The normalized citation patterns—having removed the confounding effects of overall changes in citation levels—reveal the differences in citation patterns across patent value categories more clearly. This subsection interprets the citation patterns reflected in Figure 8.

a. Consistent Ordering Over Time

The relative ordering of citations—at high levels for valuable patents and ever lower levels for patents abandoned earlier and earlier—holds true in the normalized data throughout the period of the study. That order is present in citations for every year from 1995 to 2019. Innovators' assessments of interest (as reflected in citations) track owners' evaluations of patent value (as reflected in abandonment/retention decisions).

b. Learning Effects

Data on the latest abandoned patents (abandoned 12 years after patent issuance) provide insights into the parallel learning processes influencing valuation assessments of innovators making citations and patent owners. The initially high but rapidly diminishing interest of innovators in patented advances within this category (as reflected in the light blue line in Figure 8) indicates that innovators felt that advances in this group had promise but (as the diminishing line in later years indicates) were ultimately convinced otherwise. High initial interest by innovators in the latest abandoned patents produced initial citation levels that almost matched the high levels of citations for valuable patents. However, interest diminished year by year, ultimately reaching about the same low interest and low citation counts seen for other worthless patents abandoned at earlier points. This learning process, moving from initial promise to adverse findings, probably tracked the impressions of patent owners who maintained their belief in the value of their advances in this category for a long period (12 years) only to reach the long-delayed conclusion that their advances were worthless and should be abandoned. The reasons for this shift from apparent promise to identified worthlessness cannot be ascertained from the data in this study, but the learning path of innovators and patent owners about inventions covered by late-abandoned patents appears to have produced the same increasing disillusionment about innovation value.

c. Consistently Low Interest in Most Worthless Patents

Patents abandoned at 4 and 8 years after issuance—the patents most clearly and promptly ascertainable as worthless—described advances that were generally of low interest to innovators from the issuance of the patents. Citation levels for these patents started low and stayed there. There were few learning effects of the sort just discussed, and citation levels were consistently well below (approximately half) the levels seen for valuable patents. There was essentially no change in citation levels before and after patent expiration (due to the lapsing of patents at the 4- and 8-year points). This lack of change is consistent with the interpretation that innovators were just not interested in research in the vicinity of these patents and that, therefore, the enforceability of related patent rights had no impact. Such rights were not suppressing anything. Removing the rights made no difference.

d. Evidence of Patent Rights' Impacts on Later Research

In contrast to the absence of an increase in research levels upon the expiration of worthless patents, research levels and associated citation levels did increase for valuable patents after those patents expired. This suggests that some projects that would have incorporated the valuable patented technologies (and would have

involved actionable patent infringement accordingly) were suppressed during the period when patent rights applied but proceeded when those rights were relieved through patent expiration.

This provides further confirmation that innovators and patent owners evaluated invention value similarly before and after patent expiration, but innovators were further influenced (and forced to curtail some innovation projects) by the threat of, and value reduction implicit in, potential patent infringement litigation. The increase in research related to valuable patents after patent expiration (as evidenced by the corresponding jump in citation levels) is a confirmation of a basic feature of the patent bargain—that is, the release into the public domain of the valuable elements of a patented advance upon patent expiration makes those elements freely available for new research and product development. The citation pattern seen here suggests that there is a meaningful enhancement of research following patent expiration, at least for valuable patents recognized as such by their owners and retained to their full patent term. These patents release the most valuable and interesting technologies for further use upon patent expiration and consequently spur the largest increase in research once their patent rights disappear.

4. Quantifying Patent Rights' Impacts

To estimate the size of the impact of altered patent rights on citation levels, per-patent citation means with and without patent rights were compared through several regression analyses. For each year and patent abandonment category, a per-patent citation mean was computed.[102] These annual per-patent citation means were combined to create a set of panel data. In the panel data, each panel corresponded to one of the four patent abandonment categories, and the year a citation was made was the timing variable.[103] The regression analyses used mean per-patent citations as the dependent variable, and a dummy variable corresponding to patent expiration (or lapsing) as the independent predictor variable. The panel regressions employed a random effects model that controlled for factors not otherwise included in the regression analysis (including year-to-year variations in total volumes of citations). An initial panel regression analysis was performed using all of the data. This analysis

[102] The resulting annual citation figures were the same as those plotted in Figure 7.

[103] Two portions of yearly citation data were excluded from the regression analyses because they reflected abnormal and unrepresentative citation processes. First, data on citations in the years 1995 and 1996 were excluded because the patents in the sample (issued in early 1995) may not have been publicly available when most patent applications resulting in patents issued in 1995 and 1996 were drafted (thereby precluding citations to patents in the sample). Second, data from 2019 was excluded because citations from only a portion of that year were considered in this study (the cutoff date for citations considered in this study was August 20, 2019).

was supplemented with four further panel regression analyses addressing changes in portions of the citation data upon patent expiration—one study using just the data for valuable patents (those extended to their full term) and three more using data on the three subcategories of abandoned patents.

i. Overall Impacts of Patent Expiration on Citations

Relying on data covering all 100 yearly citation means (25 for each of the four categories of patents), a panel regression analysis estimated the overall impact of removing patent rights on related citations. The results were as follows:

Figure 9: Overall Impact of Patent Expiration on Citations Per Patent

Mean Citations Per Patent	Coef.	Std. Err.	z	P>z	[95% Conf.	Interval]
Expiration Impact	0.1659	0.0620	2.68	0.0070	0.0444	0.2874
Constant	0.8290	0.1670	4.96	0.0000	0.5017	1.1562
/sigma_u	0.3214	0.1177			0.1568	0.6588
/sigma_e	0.2770	0.0200			0.2405	0.3192
rho	0.5737	0.1828			0.2333	0.8643
Likelihood-ratiotest of sigma_u=0: chibar2(01) = 61.55; Prob>=chibar2 = 0.000						
LR chi2(1) = 6.84						
Log likelihood = -20.627651; Prob > chi2 = 0.0089						

The statistically significant coefficient for the dummy variable corresponding to the ending of patent rights (due to completion of full patent terms or patent lapsing following non-payment of maintenance fees) indicates that the release of patent rights tended to produce a corresponding increase in per-patent citations. This is consistent with the view that patent rights, while in force, were a constraint on some research projects that proceeded in greater numbers once those rights were terminated. It is logical to infer that similar levels of projects in these technology vicinities would have proceeded in the period of active patent rights if those rights were not present and constraining research.

The amount of constraint from patent rights is suggested by comparing the estimated per-patent citations with and without patent rights. The citations with such rights—corresponding to the mean citation level in the period before patent expiration—are estimated by the constant in Figure 9. This indicates that the estimated or typical annual citation count per patent before patent expiration was about .8290 annual citations per patent or just above 1 citation every 14 months.

After patent expiration, this increased by about .1659 (the coefficient for the dummy variable representing patent expiration) to about .9949. This represents about a 20% increase over the pre-expiration citation level.

Assessing the overall impact of patent expiration in this way masks the possible differences between impacts of valuable and worthless patents. As already explained, removals of patent rights due to expirations of valuable patents were expected to have greater impacts on research than expirations of rights related to abandoned patents. Research interest in technologies like those covered by valuable patents was much greater (and therefore much more likely to be restricted by active patent rights generated by valuable patents) than the lesser levels (if any) of research interest related to abandoned patents. Conversely, research related to abandoned patents was expected to change little in the presence or absence of patent rights. To see if this was the case, separate assessments of valuable and abandoned patent expirations were needed.

ii. Patent Expiration Impacts by Patent Categories

To reveal these differences, a set of four regression analyses was performed, each using the data on just one of the four patent expiration categories under scrutiny (valuable patents extended to their full term plus the three subcategories of abandoned patents). The results were as follows:

Figure 10: Impacts of Patent Expiration on Yearly Per-Patent Citation Means

Patent Category	Expiration Impact	Standard Error	z	P>z	[95% Conf.	Interval]
Expire Year 4	0.1159	0.0769	1.51	0.132	-0.0348	0.2667
Expire Year 8	-0.0740	0.0565	-1.31	0.190	-0.1847	0.0367
Expire Year 12	-0.0366	0.0600	-0.61	0.542	-0.1543	0.0810
Full Term	0.3431	0.1218	2.82	0.005	0.1044	0.5817

These results confirm the substantial differences in the impacts of patent expiration on the citations made to valuable and worthless patents. For valuable patents extended to their full term, the impact of terminating patent rights appears substantial. The removal of patent rights in this category resulted in a statistically significant rise in per-patent citations.[104] The regression coefficient reported in Figure 10 indicates that the annual per-patent citations for valuable patents went up from a mean of about 1.4301 citations before patent expiration to about 1.7732

[104] This impact was statistically significant at the $p<.01$ level.

citations after patent expiration.[105] For the 2,312 valuable patents included in the patent sample, this jump in citations reflects about 793 additional citing advances each year following patent expiration in comparison to the citations to the same patents in the period before patent expiration.

In contrast, there was no significant impact from terminating patent rights on citation levels for any of the three categories of worthless patents. None of the regression coefficients for these three categories of abandoned patents were significantly different than 1.0, meaning that there was no meaningful difference found in per-patent citation means before and after patent expiration. Patent rights appear to have had little impact before they expired; once they were gone due to patent expiration, they continued to not have an impact. Rights constraining unwanted activities have the same practical impacts as no rights at all.

Applying this last insight at a higher policy level, the constant (and generally low) citation levels for worthless and ultimately abandoned patents suggests that a large fraction of issued patents probably have few impacts on continuing research choices and directions. Even while worthless and ultimately abandoned patents are in force, innovators make roughly the same decisions about research directions as they do in later periods when rights related to the patents are not a factor. The decisions before and after patent expiration are as if these patents did not exist. This insight about minimal patent impacts—applicable to a majority of issued patents in recent years since a majority of patents are regularly abandoned—casts doubt on frequently voiced concerns about the extensive limitations on research resulting from the vast numbers of patents issued in the United States.[106]

By contrast, valuable patents—those extended to their full terms by their owners—do appear to constrain related research choices, but these patents represent less than half of the United States patents. Policy discussions and possible reforms should focus on this minority of patents with meaningful research impacts and not be distracted and misdirected by a concern over the vast numbers of worthless and abandoned patents with little or no innovation consequences.

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[105] These before and after figures were both estimated by the regression analyses of yearly citation means—the figure for pre-expiration means reflects the estimate recorded in the constant of the analysis, and the post-expiration figure reflects the constant plus the estimated coefficient of the dummy variable corresponding to patent expiration.

[106] These arguments are sometimes posed as complaints about the "thickets" that issued patents are asserted to place in the way of productive research. *See, e.g.*, *Too Many Patents*, PAT. PROGRESS, https://www.patentprogress.org/systemic-problems/too-many-patents/ (last visited on Jan. 2, 2022).

CONCLUSION

Patent owners' assessments of the value of their patented inventions (as reflected in decisions to either abandon patents or extend the patents to their full patent terms) track later interest by technology developers. Patents with high perceived private value (as determined by their owners) are interesting to numerous later innovators (as evidenced by high levels of citations to the valuable patents).

High patent values perceived by patent owners and strong interest shown by subsequent innovators point to distinct technology subfields with intense development and rapid advancement. Such subfields—exemplified by the highly-cited innovations at their core—are the heartlands of valuable technology development.

Conversely, patents perceived by owners as having little commercial promise (and abandoned accordingly) describe technology with little interest to innovators as they decide where to focus further technology development. The technologies addressed in abandoned patents are often "dead ends" in technology progress that are rarely explored by later technologists (resulting in few later citations).

Patents that are abandoned and rarely cited describe technology development hinterlands—subfields with little interest for further technology development. They describe technology explorations and findings with little if any influence on later technology and product development. While the inventions described in these abandoned patents are functionally complete, distinctive in some design features, and capable of producing minimally useful results—all features needed to gain a patent—patented but abandoned inventions may have few technological offspring. Rather, these abandoned patents may be most useful in technology development as pointers to technological "negative space"[107]—that is, technology-development attempts that failed to contribute advantageous functionality to innovation users and that are accordingly of little interest to subsequent innovators.

[107] In art, "negative space" is an empty void that carries a message due to its shape or other characteristics. *See* Sara Barnes, *How Artists Use Negative Space to Say A Lot with Nothing*, MY MOD. MET (June 21, 2019), https://mymodernmet.com/negative-space-definition/.

NEW YORK UNIVERSITY

JOURNAL OF INTELLECTUAL PROPERTY AND ENTERTAINMENT LAW

VOLUME 11 FALL 2021 NUMBER 2

TRADEMARKS, TRADE DRESS, AND THE PATIENT COSTS OF PHARMACEUTICAL BRANDING

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While the high cost of prescription drugs is often attributed to strong patent protections and special forms of market exclusivity granted to new small molecule drugs and biologics, there is another factor that explains high prices: the law of trademark and trade dress. Prescription drugs are not just introduced into the market after regulatory approval; they are released with special shapes, colors, packaging, logos, and comprehensive promotional campaigns. After their patent and exclusivity terms end, generic manufacturers, which may produce the medicines at 95% or less of the original retail price, may sell generic versions of the therapeutic compounds but may not sell them with the same appearance as the original medicines. The result is patient confusion, higher costs, and less adherence to drug regimens for the nearly two-thirds of U.S. adults who need prescription drugs. This Article analyzes the effect of trademark and trade dress law on prescription drug prices and recommends both regulatory and judicial approaches that may reduce the threat current law poses to individual and public health.

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INTRODUCTION

On July 9, 2021, U.S. President Joe Biden signed an executive order directing the U.S. Food and Drug Administration (FDA) to facilitate the approval for, and importation of, cheaper prescription drugs, but this order did not address one of the most important sources of high drug prices: appearance.[1] "More than 131 million people — 66 percent of all adults in the United States — use prescription drugs."[2] For millions of elderly individuals and those suffering from chronic conditions, they are an essential aspect of maintaining health. Access to those medications is affected by cost, and in that respect, conversations about prescription drugs frequently involve the role of patents as part of the reason prescription drug prices in the United States are so high.[3] This Article places the law of trademark and

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[1] Exec. Order No. 14,036, 86 Fed. Reg. 36987, 36997 (July 9, 2021), https://www.federalregister.gov/d/2021-15069 ("[T]o lower the prices of and improve access to prescription drugs and biologics, continue to promote generic drug and biosimilar competition, as contemplated by the Drug Competition Action Plan of 2017 and Biosimilar Action Plan of 2018 of the Food and Drug Administration . . . .").

[2] Emily Ihara, *Prescription Drugs*, GEO. HEALTH POL'Y INST., https://hpi.georgetown.edu/rxdrugs/ (last visited Jan. 20, 2022).

[3] *See, e.g.*, ERIN H. WARD, KEVIN J. HICKEY & KEVIN T. RICHARDS, CONG. RSCH. SERV., R46679, DRUG PRICES: THE ROLE OF PATENTS AND REGULATORY EXCLUSIVITIES (2021). *See generally* Chandra Nath Saha & Sanjib Bhattacharya, *Intellectual Property Rights: An Overview*

trade dress on equal footing with patents and regulatory market exclusivities in the broader conversation on prescription drug prices so that policymakers, physicians, pharmacists, and other stakeholders will address the law of medicine appearance as well as other forms of market protection.[4] The recommendations contained below would stand even in the face of, or complementary to, other market exclusivity reforms.

Consider an elderly patient who is prescribed a drug regimen that begins with a bright green pill that is protected by patents, market exclusivity, as well as careful product design by its original manufacturer. After the patent and market exclusivity terms end, state law requires that the medicine be substituted by a cheaper generic version. The elderly patient, used to seeing the bright green pill, now sees a pill that is smaller and has a blue tinge. Believing that there is a mistake—perhaps the wrong medicine was put into the bottle—the patient stops taking the medication until she can speak with her doctor. After several weeks, the patient is convinced the change will not harm her health. Assume then, two weeks later, the pharmacy switches to a different generic supplier, whose pills again appear different. The medicine, dosage, strength, frequency, and all other relevant medical factors are unchanged, but the patient now believes, again, that there is a systematic error in the medical supply chain and stops taking the medicine again. All of this occurs because trademark and trade dress law prohibit the generic manufacturers from using the same pill appearance.

This scenario is routine, not exceptional. In one study, about half of patients (51%) reported receiving a prescription refill in which their pills' appearance changed in the last year and, of those patients, about half (53%) reported that it happened two or more times.[5] The relationship between patients and their medicines is deeply affected by how they appear (inside and outside packaging): their color, shape, hue, imprints, size, texture, and coating.[6] Patients taking generic versions of

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and Implications in Pharmaceutical Industry, 2 J. ADVANCED PHARM. TECH. RSCH. 88, 88-89 (2011).

[4] Indeed, as early as 1977, the Federal Trade Commission concluded that "the trademark, like the patent, might be given a limited life" due to the costs that trademarks impose on medicines. FED. TRADE COMM'N, STAFF REPORT ON SALES, PROMOTION, AND PRODUCT DIFFERENTIATION IN TWO PRESCRIPTION DRUG MARKETS 80 (Feb. 1977).

[5] Rachel E. Barenie, Aaron S. Kesselheim, Joshua J. Gagne, Zhigang Lu, Eric G. Campbell, Sarah K. Dutcher, Wenlei Jiang & Ameet Sarpatwari, *Preferences for and Experiences With Pill Appearance Changes: National Surveys of Patients and Pharmacists*, 26 AM. J. MANAGED CARE 340 (2020).

[6] Jeremy A. Greene & Aaron S. Kesselheim, *Why Do the Same Drugs Look Different? Pills, Trade Dress, and Public Health*, 365 N. ENG. J. MED. 83 (2011).

the same medication receive pills of different sizes, shapes, and colors routinely because of trade dress protections, and those changes, alterations, and adjustments, in turn, often adversely affect their adherence to their prescription schedules and trust in the medicines they need.[7]

The importance of drug products' appearance is well recognized in the industry: pharmaceutical firms invest as much or more in color, name, shape, and related branding and marketing features as they do in the development of the active pharmaceutical ingredients that actually treat disease and illness.[8] For the most part, those investments *are not* protected by patents. They are protected by the law of trademark and trade dress. And those laws, in turn, do more than just raise the cost of prescription drugs. They shape patient adherence to prescription drug regimens; cause or ameliorate the possibility of medication error; and play a complex role in the division of responsibility between licensing authorities, primarily the FDA and the U.S. Patent and Trademark Office (USPTO).[9]

Medicines may be protected by a patent as to the small molecule structure of the active compound, while the color, shape, and appearance of a capsule that contains the medicine may be protected by trademarks. Information accompanying the product may be protected by copyright.[10] Other aspects of production and

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[7] Jennifer L. Lenahan, Danielle M. McCarthy, Terry C. Davis, Laura M. Curtis, Marina Serper & Michael S. Wolf, *A Drug by Any Other Name: Patients' Ability to Identify Medication Regimens and Its Association with Adherence and Health Outcomes*, 18 J. HEALTH COMM. 31, 32 (Supp. 2013).

[8] Rebecca Farley, *Do Pharmaceutical Companies Spend More on Marketing than Research and Development?*, PHARMACYCHECKER, https://www.pharmacychecker.com/askpc/pharma-marketing-research-development/#! (last updated Apr. 28, 2021).

[9] *Compare* Ameet Sarpatwari, Joshua J. Gagne, Zhigang Lu, Eric G. Campbell, Wendy J. Carman, Cheryl L. Enger, Sarah K. Dutcher, Wenlei Jiang & Aaron S. Kesselheim, *A Survey of Patients' Perceptions of Pill Appearance and Responses to Changes in Appearance for Four Chronic Disease Medications*, 34 J. GEN. INTERNAL MED. 420 (2019) (examining patient adherence based on appearance), *with* Robert D. Litowitz & Lynn M. Jordan, *Procedures and Strategies for Pharmaceutical Brands: United States*, WORLD TRADEMARK REV. (Sept. 6, 2016), https://www.worldtrademarkreview.com/procedures-and-strategies-pharmaceutical-brands-united-states (discussing branding strategies that navigate the interplay between FDA and UPSTO requirements).

[10] Roseann B. Termini & Amy Miele, *Copyright and Trademark Issues in the Pharmaceutical Industry–Generic Compliance or Brand Drug Imitating–"Copycat or Compliance,"* PENN. BAR ASS'N Q., Jan. 2013, at 34; *see also* Thomas J. Daly & Alek Emery, *Branding Pharmaceuticals: Drug Naming and Non-Traditional Trademarks*, WORLD TRADEMARK REV. (July 17, 2019), https://www.worldtrademarkreview.com/brand-management/branding-pharmaceuticals-drug-naming-and-non-traditional-trademarks.

advertising may be protected by trade secrets.[11] All of these intellectual property protections affect cost most straightforwardly, but other aspects of patient welfare and provider knowledge as well.

This Article sheds light upon the substantial costs that trademark and trade dress impose on patients and emphasizes that, in the broader context of scrutinizing the relationship between intellectual property and high drug prices, patents and regulatory exclusivities are only a piece of a more complicated puzzle.[12] In highlighting trademark and trade dress, this Article endeavors to single out that form of intellectual property protection for special scrutiny by legislators, regulators, and judges.

Intellectual property, generally, is controversial.[13] On the one hand, each of the traditional forms of protection—copyrights, patents, and trademarks—involve giving an individual or a firm the right to exclude others and, in many cases, charge high prices for products.[14] Especially in the context of copyright and trademark, the intellectual property right burdens the use of words, information, and data that may be important for communication, learning, and expression.[15] On the other hand, those intellectual property rights provide incentives to create and invent.

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[11] Kristan Lansberry, *Protecting Trade Secrets in the Medical Product Approval Process*, FDLI (Apr. 2018), https://www.fdli.org/2018/04/update-protecting-trade-secrets-medical-product-approval-process/.

[12] *E.g.*, *id.*; Termini & Miele, *supra* note 10; WARD ET AL., *supra* note 3.

[13] *See generally* SAM F. HALABI, INTELLECTUAL PROPERTY AND THE NEW INTERNATIONAL ECONOMIC ORDER: OLIGOPOLY, REGULATION, AND WEALTH REDISTRIBUTION IN THE GLOBAL KNOWLEDGE ECONOMY (2018) (re-evaluating conventional wisdom of the distributive consequences of intellectual property rights).

[14] Shyamkrishna Balganesh, *Demystifying the Right to Exclude: Of Property, Inviolability, and Automatic Injunctions*, 31 HARV. J.L. & PUB. POL'Y 593, 628-29 (2008); Christine Greenhalgh & Mark Rogers, *The Value of Intellectual Property Rights to Firms and Society*, 23 OXFORD REV. ECON. POL'Y 541 (2007); Henry E. Smith, *Intellectual Property as Property: Delineating Entitlements in Information*, 116 YALE L.J. 1742, 1800 (2007) (observing how copyright law tends to place less reliance on exclusion than patent law and is thus less "property-like"); Fox Film Corp. v. Doyal, 286 U.S. 123, 127 (1932) ("The owner of the copyright, if he pleases, may refrain from vending or licensing and content himself with simply exercising the right to exclude others from using his property.").

[15] Annette Kur, *Fundamental Concerns in the Harmonization of (European) Trademark Law*, *in* TRADEMARK LAW AND THEORY: A HANDBOOK OF CONTEMPORARY RESEARCH 151 (Graeme B. Dinwoodie & Mark D. Janis eds., 2008); TRADE MARKS AT THE LIMIT 163-64 (Jeremy Phillips ed., 2006).

These controversies play out vividly in the context of medicines[16] and remain the subject of heated debate.[17] Broadly speaking, disputes over the intellectual property protections afforded to pharmaceutical companies tend to focus on patents and market exclusivities given pursuant to the generation of data used to support regulatory approval.[18] These incentives, the companies argue, encourage continuous innovation.[19] Critics argue that the incentives do precisely the opposite: they encourage investment in incremental changes that just barely qualify for costly patent protection, keeping drug prices high and imposing significant barriers to entry for other manufacturers.[20]

Leaving to one side the acrimonious debate over the incentives that the regulatory state might extend to promote the optimal investment in the right number and variety of biomedical innovations, the reality is that trademark and trade dress

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[16] Levon Khachigian, *Pharmaceutical Patents: Reconciling the Human Right to Health with the Incentive to Invent*, 25 DRUG DISCOVERY TODAY 1135, 1146 (2020) ("This can be easily understood in the context of modern pharmaceutical innovation involving high development, testing and regulatory costs. An important part of any patent system is to ensure the public benefits from access to innovation. However, it is crucial to effectively facilitate public access to medicines that result from this innovation. As access to essential medicines is a core minimum obligation for states to realize the human right to health, this objective has great weight."); Aakash Shah, Jonathan Warsh & Aaron Kesselheim, *The Ethics of Intellectual Property Rights in an Era of Globalization*, 41 J.L. MED. & ETHICS 841 (2013); Frederick M. Abbott, *Falsified and Substandard Medicines: Current Challenges and Long Term Solutions: A Public Health Perspective*, IBSA (Oct. 15, 2010), http://www.law.nyu.edu/sites/default/files/ECM_PRO_074747.pdf ("The pharmaceutical industry, like most industries, is highly competitive. The actors with the power to do so fairly consistently demonstrate the willingness to use IPRs [intellectual property rights] to obtain commercial advantage beyond the 'legitimate scope' of their rights.").

[17] Ana Swanson, *Big Pharmaceutical Companies Are Spending Far More on Marketing than Research*, WASH. POST (Feb. 11, 2015), https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/.

[18] Erin Fox, *How Pharma Companies Game the System to Keep Drugs Expensive*, HARV. BUS. REV. (Apr. 6, 2017), https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive.

[19] Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 507 (2009).

[20] KEVIN T. RICHARDS, KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES (2020) ("[P]atenting practices are used to keep drug prices high, without any benefit for consumers or innovation."); Sy Mukherjee, *Protect at All Costs: How the Maker of the World's Bestselling Drug Keeps Prices Sky-High*, FORTUNE (July 18, 2019, 6:30 AM), https://fortune.com/longform/abbvie-humira-drug-costs-innovation; Sam F. Halabi, *The Drug Repurposing Ecosystem: Intellectual Property Incentives, Market Exclusivity, and the Future of "New" Medicines*, 20 YALE J.L. & TECH. 1 (2018).

are unique.[21] The product distinguishing rationale that purportedly justifies trademark and trade dress law arguably does precisely the opposite in the prescription drug context.[22]

This Article analyzes the protections that trademark and trade dress afford pharmaceutical companies outside of patents and regulatory exclusivities, which are generally placed at the center of pharmaceutical pricing and policy debates.[23] Quite apart from price, patients and their supporters use color, shape, logo, hue, size, and appearance—the classic areas of trademark and trade dress protection—to ensure that they are taking the correct medications, in the prescribed amounts, and at the right times to maintain their health, treat disease, and avoid adverse interactions between medications if they are taking more than one.[24] The Article identifies the specific individual and public health problems posed by trademark and trade dress protection and recommends changes in current law that may contribute toward the difficult question of balance that pervades all scholarship on the advantages and disadvantages of using intellectual property protection to promote innovation.[25] In the context of pharmaceutical trademarks and trade dress, this means understanding when allowing pharmaceutical firms to protect trademarks and trade dress is too costly relative to the value in having patients adhere to their prescribed medical

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[21] Megan Brewster & Pallab Singh, *Intellectual Property Protection for Biologics*, *in* ACAD. ENTREPRENEURSHIP FOR MED. & HEALTH SCIENTISTS (Nalaka Gooneratne, Rachel McGarrigle & Flaura Winston eds., 2019), https://repository.upenn.edu/ace/vol1/iss3/11; J.W. Kenagy & G.C. Stein, *Naming, Labeling, and Packaging of Pharmaceuticals*, 58 AM. J. HEALTH-SYST. PHARM. 2033, 2033 (2001).

[22] Kelley Clements Keller, *Free Riders at the Drugstore: Generics, Consumer Confusion, and the Public Good*, 12 CHI.-KENT J. INTELL. PROP. 184, 186 (2013) ("The difficulty lies in striking a balance between the competing interests of national brands to trademark protection for source identifiers on their products and the rights of generic labels to bring publicly accepted substitute drugs to market that earn the public's trust and confidence. Absent a stable and reliable body of law, both branded and generic manufacturers may be left with inadequate security or guidance for effective business planning with respect to advertising and branding schemes, a situation that will inevitably result in costly litigation and contribute to the rising cost of drugs.").

[23] Rebecca Tushnet, *Trademark Law as Commercial Speech Regulations*, 58 S.C. L. REV. 737-56 (2007).

[24] Barenie et al., *supra* note 5.

[25] Dan L. Burk & Brett McDonnell, *The Goldilocks Hypothesis: Balancing Intellectual Property Rights at the Boundary of the Firm*, 2007 U. ILL. L. REV. 575, 577 (2007) ("Thus, we posit a 'Goldilocks hypothesis' for intellectual property rights and the firm: like the size of a chair, the temperature of a porridge, or the firmness of a mattress, the provision of intellectual property rights should not vary too far to one extreme or another, but must be calibrated so that it is 'just right.'").

regimens, avoid medication error, and place trust in their providers and their medicines.

Part I situates trademark and trade dress protections for pharmaceuticals in the broader context of intellectual property protections, which (the Articles argues) overemphasize patents and regulatory exclusivities and underemphasize trademark and trade dress. Part II analyzes the specific costs that current trademark and trade dress law impose on patients as they attempt to adhere to their prescription drug regimens, as well as the costs imposed on physicians as they attempt to help their patients do so. Part III details the legislative, regulatory, and judicial possibilities for addressing the costs that trademark and trade dress impose on patient and physician populations. The Article then provides a brief conclusion.

I
PATENT, COPYRIGHT, AND TRADEMARK PROTECTION FOR PHARMACEUTICAL INNOVATIONS

From the manufacturer's perspective, planning the intellectual property protections for pharmaceuticals entails careful analysis of product features, the probability of inadvertent or uncontrollable disclosure, and the chemical or biochemical character. Although patents are generally regarded as the foundational and most important protection, they are of limited duration, may be costly to enforce, and are expensive to obtain *ex ante*.[26] Trademark protections, by contrast, are potentially indefinite and may guard significant aspects of a drug's value even after a patent term expires.

This Part describes the varying forms of intellectual property that explain the high costs of prescription drugs in the United States. It concludes with the specific kinds of protection that trademark and trade dress afford, and how those protections are indefinite so that even when other forms of intellectual property expire, trademark and trade dress still keep generic manufacturers from providing prescription drugs with all the precise attributes of the original medicine.

[26] Aaron S. Kesselheim, Michael S. Sinha & Jerry Avorn, *Determinants of Market Exclusivity for Prescription Drugs in the United States*, 177 JAMA INTERNAL MED. 1658 (2017), http://dx.doi.org/10.1001/jamainternmed.2017.4329.

A. Patent and Regulatory Exclusivity

For small molecule drugs, patent protections cover a 20-year period, generally shortened by the time of disclosure to the time of regulatory approval.[27] By international treaty, the 20-year patent term is largely universal, but conditions for granting patents vary by country, and individual countries may allow non-patent forms of regulatory exclusivity.[28] For example, in the United States, regulatory exclusivities may generally offer 6-month, 3-, 5-, 7-, and (for biologics) 12-year protections, depending on approval channel and characterization.[29] These exclusivity periods allow pharmaceutical manufacturers to market drugs without competition.[30] At the expiration of the patent and regulatory exclusivity terms, generic drug manufacturers may enter the marketplace more efficiently and at a lower price by complying with formula and manufacturing specifications already approved by the FDA (or the equivalent national regulatory authority).[31] Under U.S. law, generic entrants are also encouraged with less stringent regulatory pathways and the possibility of 180 days of exclusivity if they are the first to the market.[32] In 2017, generic drugs constituted around 70% of total prescription drugs dispensed but only made up 16% of total drug spending.[33] Despite the development of an extensive regulatory framework, drug pricing still faces considerable scrutiny from Congress.[34]

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[27] Termini & Miele, *supra* note 10; Subhasis Saha, *Patent Law and TRIPS: Compulsory Licensing of Patents and Pharmaceuticals*, 91 J. PAT. & TRADEMARK OFF. SOC'Y 364, 366-67 (2009).

[28] *See* Roberto Romandini, *Flexibilities Under TRIPS: An Analysis of the Proposal for Reforming Brazilian Patent Law*, 15 J. MARSHALL REV. INTELL. PROP. L. 150, 183 (2016); Matthias Lamping et al., *Declaration on Patent Protection—Regulatory Sovereignty Under TRIPS*, 45 INT'L REV. INTELL. PROP. & COMPETITION L. 679, 681 (2014).

[29] Halabi, supra note 20, at 27.

[30] *Id.* at 20.

[31] *Id.* at 25; SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharm., Inc., 211 F.3d 21, 26 (2d Cir. 2000).

[32] Ravi Gupta, Nilay D. Shah, & Joseph S. Ross, *Generic Drugs in the United States: Policies to Address Pricing and Competition*, 105 CLINICAL PHARM. & THERAPEUTICS 329, 330 (2019).

[33] Aaron S. Kesselheim, Alexander S. Misono, William H. Shrank, Jeremy A. Greene, Michael Doherty, Jerry Avorn & Niteesh K. Choudhry, *Variations in Pill Appearance of Antiepileptic Drugs and the Risk of Nonadherence*, 173 JAMA INTERNAL MED. 202, 202 (2013).

[34] *See, e.g.*, *Drug Pricing in America: A Prescription for Change, Part I: Hearing Before the S. Comm. on Finance*, 116th Cong. 116 (2019); *The Cost of Rising Prescription Drug Prices: Hearing Before the H. Ways and Means Comm.*, 116th Cong. (2019); *Examining the Actions of Drug Companies in Raising Prescription Drug Prices: Hearing Before the H. Comm. on Oversight and Reform*, 116th Cong. (2019); Ryan Davis, *Breaking Down 3 New Senate Bills Targeting Drug Prices*, LAW360 (Apr. 18, 2019, 7:36 PM), https://www.law360.com/articles/1150045/breaking-down-3-new-senate-bills-targeting-drug-prices.

There are good reasons that patents and regulatory exclusivities are not the only intellectual property protection deployed as part of firms' strategies to maximize revenue. When challenged, small molecule drugs especially may fail tests for novelty and non-obviousness essential for patent validity.[35] Under U.S. federal law, generic manufacturers are encouraged to challenge the validity of patent claims before the technical expiry of the patent. By filing a so-called "paragraph IV" certification (named after its location in the Code of Federal Regulations), generic applicants, as part of their submissions, submit claims that one or more drug patents are "invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the [generic] application is submitted."[36] In order to do so, the generic manufacturer must notify the patent holder of the patent challenge.[37] The patent holder must then file an infringement suit within 45 days to avoid immediate approval of the generic application.[38] If an infringement suit is filed within 45 days, then a 30-month stay is granted by the FDA to allow the parties to resolve the dispute.[39] If a generic manufacturer successfully challenges the validity

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[35] Roin, *supra* note 19, at 504-05 ("Amid this general optimism about the effectiveness of patents in promoting pharmaceutical innovation, scholars have overlooked a critical flaw in the system: socially valuable drugs often cannot be patented even though they are unlikely to be developed for public use without that protection. If the idea for a drug is not novel or is obvious—perhaps because it was disclosed in an earlier publication or made to look obvious by recent scientific advances—then it cannot be patented. Yet the mere idea for a drug alone is generally of little value to the public. Without clinical trials proving the drug's safety and efficacy—a prerequisite for approval by the Food and Drug Administration (FDA) and acceptance by the medical community—that drug is unlikely to benefit the public.").

[36] 21 C.F.R § 314.94(a)(12)(i)(A)(4) (2020); *Patent Certifications and Suitability Petitions*, FDA, https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions (last updated Jan. 12, 2022).

[37] *In re* Lipitor Antitrust Litig., 868 F.3d 231 (3d Cir. 2017) ("On December 10, 2002, Teva obtained ANDA first-filer status for a generic version of Effexor XR. Teva's ANDA included paragraph IV certifications, asserting that Teva's sale, marketing, or use of generic Effexor would not infringe Wyeth's patents or that those patents were invalid or unenforceable . . . . Within the 45-day period prescribed by the Hatch-Waxman Act, Wyeth brought suit against Teva for patent infringement in the District of New Jersey."); Edward Hore, *A Comparison of United States and Canadian Laws as They Affect Generic Pharmaceutical Market Entry*, 55 FOOD & DRUG L.J. 373, 385 (2000).

[38] 35 U.S.C. § 271(e)(5).

[39] Liam Bendicksen, Jonathan J. Darrow & Aaron S. Kesselheim, *Challenging Patents to Promote Timely Generic Drug Entry: The Second Look Act and Other Options*, HEALTH AFF. BLOG (Aug. 31, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200827.532806/full/ ("A better option would be to continue to require that most patents be listed in the Orange Book, but reduce the 30-month stay to a shorter period, such as 18 months. Lawmakers could also limit the stay to a narrower set of patents or eliminate the stay entirely, though this could lead to delayed litigation (and thus delayed generic entry) by removing the incentive for brand-name

of a patent, then it is granted 180 days of generic market exclusivity upon approval.[40] If the patent is found to be invalid, the generic manufacturer still has to wait for the expiration of the exclusivity period granted by the FDA upon approval of the new drug product.[41]

After this process or expiration of the patent or regulatory exclusivity period, manufacturers rely upon alternative forms of intellectual property protection, some of which have stirred controversy.[42] Strategies including "evergreening," "authorized generics," "citizen petitions," and "pay for delay" allow firms to increase the length of market exclusivity and limit competition in ways related to, but technically outside of, the intellectual property sphere.[43] "Evergreening" means the patenting of peripheral features of drugs, like their coating or normal metabolites, that allow claims for longer exclusivity even though those patents do not relate to the active pharmaceutical ingredient.[44] "Evergreening" allows manufacturers to protect "new" drugs with patents following the expiration of the old patent.[45] These

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manufacturers to bring patent challenges within 45 days."); Elizabeth H. Dickinson, *FDA's Role in Making Exclusivity Determinations*, 54 FOOD & DRUG L.J. 195, 198 (1999).

[40] Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product-Hopping*, 62 FLA. L. REV. 1009, 1014 (2010) ("[T]he Act provided 180 days of marketing exclusivity to the first generic firm to certify that the brand firm's patent was not valid or that the generic's drug did not infringe the patent. Such exclusivity was reserved for the first generic firm-known as a "Paragraph IV filer"-that sought to enter during the patent term. During the period, which begins after the first commercial marketing of the drug, the FDA cannot approve other ANDAs for the same product.").

[41] *See* 21 C.F.R. § 314.108 (2016); 21 C.F.R. § 316.31 (2013); 21 C.F.R. § 316.34 (2013).

[42] RICHARDS ET AL., *supra* note 20.

[43] *Id.*; *see also* Andrew Hitchings, Emma Baker & Teck Khong, *Making Medicines Evergreen*, 345 BMJ 1 (2012).

[44] James Love & Tim Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, 82 CHI-KENT L. REV. 1519, 1542 (2007).

[45] Roger Collier, *Drug Patents: The Evergreening Problem*, 185 CMAJ E385, E385 (2013) ("As any would-be inventor knows, coming up with something the world has never seen before can be tough. Tweaking something old and calling it new, on the other hand, is considerably easier. In the pharmaceutical trade, when brand-name companies patent 'new inventions' that are really just slight modifications of old drugs, it's called 'evergreening.' And it's a practice that, according to some who have looked into it, isn't doing a whole lot to improve people's health. 'Typically, when you evergreen something, you are not looking at any significant therapeutic advantage. You are looking at a company's economic advantage,' says Dr. Joel Lexchin, a professor in the School of Health Policy and Management at York University in Toronto, Ontario. 'The response from the brand side is that they are trying to protect their markets so they can further invest in R&D [research and development]. And even if they make a modification to a drug, doctors are still quite able to prescribe the generic version of the older product. Having said that, the brand-name

follow-on products are initially cheaper, which encourages prescribers to adopt their use, and by leveraging the trademark, trade dress, and brand of the follow-on product, drug manufacturers can maintain a significant share of the market.[46]

Under "pay for delay" agreements, brand-name pharmaceutical firms offer to pay generic manufacturers to delay the release of a generic drug.[47] These receive heavy criticism because they cost U.S. consumers more than $3.5 billion annually due to increased drug costs.[48] "Citizen petitions" also delay generic approval because firms may submit these to the FDA for priority review to have the FDA review the generic applications for possible changes.[49] Brand-name manufacturers can also release their own "authorized generics" as patent or exclusivity expiration nears.[50] If the "authorized generic" is the first generic on the market, it can obtain 180 days of generic exclusivity.[51] Lastly, brand-name manufacturers may limit generic manufacturers' ability to do bioequivalence testing by refusing or delaying access to the brand-name drug.[52]

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companies put an awful lot of money into marketing the newer version, and that marketing is designed to affect what doctors do.'").

[46] *Id.* In one example, in Switzerland, a co-payment incentive program combined with an increase in generic drug competition contributed to the replacement of brand-name drugs and the reduced prices of brand-name drugs. However, this loss of profit from brand-name drugs was fully offset by successful marketing of follow-on drugs through evergreening strategies. Nathalie Vernaz, Guy Haller, Francois Girardin, Benedikt Huttner, Christophe Combeqcure, Pierre Dayer, Daniel Muscionico, Jean-Luc Salomon & Pascal Bonnabry, *Patented Drug Extension Strategies on Healthcare Spending: A Cost-Evaluation Analysis*, 10 PLOS MED. 1, 6 (2013).

[47] *See, e.g.*, Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136, 355 (2013).

[48] *Pay-for-Delay: When Drug Companies Agree Not to Compete*, FED. TRADE COMM'N, https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay (last visited Jan. 20, 2022).

[49] *See In re* Flonase Antitrust Litig., 795 F. Supp. 2d 300, 309 (E.D. Pa. 2011) (denying summary judgment of whether defendant's conduct constituted "sham" petitioning); La. Wholesale Drug Co. v Sanofi-Aventis, No. 07 Civ. 7343 (HB) 1, 2 (S.D. N.Y. Aug. 28, 2009) (denying judgment as a matter of law following verdict that defendant's conduct did not constitute "sham" petitioning); *In re* DDAVP Direct Purchaser Antitrust Litig., 585 F.3d 677, 686 (2d Cir. 2009) (reversing dismissal for failure to state a claim of sham petitioning); *In re* Wellbutrin XL Antitrust Litig., 260 F.R.D. 143, 160 (E.D. Pa. 2009) (addressing standing for bringing complaint based on sham petitions).

[50] *See* Jay Hancock and Sydney Lupkin, *Drugmakers Master Rolling Out Their Own Generics to Stifle Competition*, KAISER HEALTH NEWS (Aug. 5. 2019), https://khn.org/news/drugmakers-now-masters-at-rolling-out-their-own-generics-to-stifle-competition/.

[51] *Id.*

[52] *Id.*

Aside from these strategies, monetary and injunctive relief is available for brand-name manufacturers for claims related to copyright, trademark, trade dress, and trade secrets.[53]

B. Copyright

Copyright protects expressions of ideas, although not the ideas themselves.[54] As soon as an idea is expressed in a fixed, tangible medium, copyright protection generally attaches.[55] Copyrights can be held by individuals or corporations. For individuals, the copyright lifespan is for the life of the author plus an additional 70 years.[56] For firms (technically works for hire), the copyright lifespan is the first of 120 years from creation or 95 years after publication.[57]

Copyright protection for pharmaceutical manufacturers typically protects the packing material, the design and appearance of the package, and the labeling from being infringed, copied, or duplicated and from unauthorized use.[58] However, this does not protect medical literature; it only protects the "unique form of designing or explaining" the manufacturer's products.[59]

In the United States, copying a drug label is not generally copyright infringement if the FDA deems it necessary for approval of generic drugs, and if it does not interfere with existing principles of copyright law.[60] Because the U.S. Food, Drug, and Cosmetics Act requires compliance with the labeling guidelines to reassure bioequivalence of generic drugs, the FDA may require *verbatim* compliance

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[53] *Id.*; Abbott, *supra* note 16, at 1; Termini & Miele, *supra* note 10, at 35.

[54] Termini & Miele, *supra* note 10, at 35.

[55] 17 U.S.C. § 102(a); Christopher Buccafusco, *A Theory of Copyright Authorship*, 102 VA. L. REV. 1229, 1231-32 (2016) ("The Supreme Court has offered some guidance. In order to be copyrightable, a work must be original, at least minimally creative, and fixed in a tangible medium of expression. Original, in this sense, means that the work was not copied from another source. It is a binary distinction. Creativity is a scalar concept involving more or less novelty or cleverness. The Court has explained, however, that the threshold for creativity in copyright law is very low. And to constitute a fixed writing, a work must be made 'sufficiently permanent or stable to permit it to be perceived, reproduced, or otherwise communicated for a period of more than transitory duration.'").

[56] 17 U.S.C. § 302(a).

[57] 17 U.S.C. § 302(c).

[58] Javed Hasan, *Position of Design & Copyright Protection in Pharmaceutical Industry*, MEDICARE NEWS (June 30, 2018) https://medicarepharmabusiness.com/position-of-design-copyright-protection-in-pharmaceutical-industry/.

[59] Abbott, *supra* note 16, at 7.

[60] SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharm., Inc., 211 F.3d 21, 23 (2d Cir. 2000).

with previously approved drug labeling.[61] Therefore, labeling may only be protected by copyright if the manufacturer adds creative parts to the labeling or adds labeling beyond the FDA's requirements.[62]

In some countries, copyright claims can arise in the pharmaceutical industry regarding product monographs.[63] A product monograph is a publicly available document containing information regarding the safety and efficacy of a particular drug.[64] In those cases, although the monographs are public scientific data, copyright infringement claims may be asserted if one or more competitors substantially reproduces a manufacturer's product monograph.[65]

While copyright may serve a relatively limited function in protecting drug-related information from legitimate competitors, it plays a special role in the context of counterfeit, falsified, and substandard drugs.[66] "Unfortunately, there are currently no accurate estimates of the global burden of falsified and substandard drugs precisely because activity occurs in global black and gray markets."[67] Evidence suggests, however, that the problem is most severe in low- and middle-income countries, so copyright plays a particularly important role in the customs context, where authorities examine imports for copyright infringement specifically.[68] Imitation drugs mimic other drugs or substances in appearance, whereas counterfeit drugs copy another drug's label, container, and/or identifying marks.[69] In that respect, copyright and trademark share important features with respect to

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[61] 21 U.S.C. § 355(j)(2)(A)(v).

[62] Termini & Miele, *supra* note 10, at 36. As with patents, copyright protections have achieved some uniformity through international treaty, but the conditions required for the assertion of copyright to protect drug information varies by the law in each country. Saha & Bhattacharya, *supra* note 3, at 89.

[63] Ryan Steeves, *"I Shouldn't Copy, Right?" Why Pharmaceutical Companies Should Care About Copyright*, MONDAQ (June 26, 2014), https://www.mondaq.com/canada/copyright/323120/i-shouldnt-copy-right-why-pharmaceutical-companies-should-care-about-copyright.

[64] *Id.*

[65] *Id.*

[66] Termini & Miele, *supra* note 10, at 38.

[67] Sam F. Halabi & Lawrence O. Gostin, *Falsified and Substandard Medicines in Globalized Pharmaceutical Supply Chains: Toward Actionable Solutions*, *in* FOOD AND DRUG REGULATION IN AN ERA OF GLOBALIZED MARKETS 51, 54 (Sam F. Halabi ed., 2015).

[68] *See* Sachiko Ozawa, Daniel R. Evans, Sophia Bessias, Deson G. Haynie, Tatenda T. Yemeke, Sarah K. Laing & James E. Herrington, *Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low- and Middle-Income Countries: A Systematic Review and Meta-Analysis*, JAMA NETWORK OPEN (Aug. 10, 2018), http://dx.doi.org/10.1001/jamanetworkopen.2018.1662.

[69] United States v. Articles of Drug, 601 F. Supp. 392, 395 (D. Neb. 1984).

pharmaceutical firms' intellectual property strategies. As with trademark protection, which will occupy the remainder of this Article, rights holders are often accused of over-enforcing their claims (for example, asserting copyright infringement at the border when the extent to which that protection applies may be in doubt).[70] Nevertheless, copyright, patent, and trademark play important roles in a comprehensive intellectual property strategy.[71]

C. Trademark and Trade Dress

While patents protect products and copyrights protect the expression of ideas fixed in a tangible medium, trademarks protect "any mark, name, or logo under which trade is conducted for any product or service and by which the manufacturer or the service provider is identified."[72] Trademark protection may also extend to sounds, scents, flavors, textures, and product appearance.[73] In the case of pharmaceuticals, other non-traditional marks (such as shape) can be protected as "trade dress" if the appearance of the drug has acquired distinctiveness.[74]

Within limits, trademark protection provides an incentive for firms to invest in the quality of goods and services and, relatedly, to reduce the costs to consumers of identifying products with desirable quality and price in the same class of products ("search costs").[75] Without laws prohibiting trademark infringement or misappropriation, imitators would be enabled to free ride on those investments and dupe consumers.[76] Where the product supplied is not only inferior but hazardous—medicines are an important example—the concern about quality is magnified.[77]

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[70] *See* Nokia Corp. v. Revenue & Customs Comm'rs, [2009] EWHC 1903 (Ch). (Eng.).

[71] Termini & Miele, *supra* note 10, at 35.

[72] Saha & Bhattacharya, *supra* note 3, at 89; *see also* 15 U.S.C. § 1127. *See generally* Sam F. Halabi, *Reconciling International Obligations to Protect Health and Trademarks: A Defense of Trademarks as Property*, *in* INTERNATIONAL INTELLECTUAL PROPERTY: A HANDBOOK OF CONTEMPORARY RESEARCH 389, 389-406 (Daniel J. Gervais ed., Edward Elgar Publ'g Ltd. 2015).

[73] John T. Cross, *Trademark Issues Relating to Digitalized Flavor*, 19 YALE J.L & TECH. 339, 363 (2017) ("Trademark protection in the United States is not limited to words, logos, and other classic trade symbols. It also can extend to non-verbal, non-pictorial features of the product itself, including overall shape, color, decoration, sound, and even scent. At least in theory, the flavor of a product could also serve as a trademark for that product.") (footnotes omitted).

[74] Daly & Emery, *supra* note 10.

[75] William M. Landes & Richard A. Posner, *Trademark Law: An Economic Perspective*, 30 J.L. & ECON. 265, 275-80 (1987).

[76] Robert G. Bone, *Hunting Goodwill: A History of the Concept of Goodwill in Trademark Law*, 86 B.U. L. REV. 547, 555-56 (2006).

[77] Charles Clift, *Combating Counterfeit, Falsified and Substandard Medicines: Defining the Way Forward?* (Nov. 2010) (Briefing Paper, Chatham House), The Royal Institute of International Affairs.

When well-functioning, trademark protection thus promises a mutual benefit to firms and consumers.[78]

1. Trademark

In the United States, the Lanham Act created a system of federal trademark registration and federal claims of relief for trademark infringement.[79] To be registered as a trademark, the mark must be distinctive.[80] In the context of trademark registration, the most distinctive marks have "inherent distinctiveness" if they are arbitrary, fanciful, or suggestive.[81]

Trademarks are one of the most important forms of intellectual property protection available to pharmaceutical firms.[82] The pharmaceutical industry invests at least $27 billion annually on marketing brand awareness to U.S. doctors and patients.[83] Like other forms of intellectual property protection, trademarks can provide a significant market advantage; however, the basis of that advantage differs. Patents and regulatory exclusivities prevent others from mimicking physical product features.[84] In that respect, trademarks appear less protective—other products with similar physical features may still be sold if their appearance is distinguished. But, unlike patent and regulatory exclusivity protection (or even copyright), trademark

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[78] Halabi, *supra* note 72, at 392-93.

[79] 15 U.S.C. 1051 *et seq*.

[80] Landes & Posner, *supra* note 75, at 287-88 ("Trademark protection is available only for a word or other signifier that identifies the underlying good (or service) and distinguishes it from that of other producers. Lack of distinctiveness would make the mark incapable of identifying the good . . . .").

[81] Abercrombie & Fitch Co. v. Hunting World, Inc., 537 F.2d 4, 9 (2d Cir. 1976). *But see* Alexandra J. Roberts, *Trademark Failure to Function*, 104 IOWA L. REV. 1977, 2020 (2019) ("When it comes to trademark protectability . . . empirical data reveals that the current regime's over-emphasis on inherent distinctiveness and under-emphasis on use as a mark does not adequately predict or reflect the perceptions of real consumers."); Thomas R. Lee, Eric D. DeRosia & Glenn L. Christensen, *An Empirical and Consumer Psychology Analysis of Trademark Distinctiveness*, 41 ARIZ. ST. L.J. 1033, 1039-54 (2009) (finding that "context" corresponding to common indicators of trademark use had greater influence on consumer perception of distinctiveness than the *Abercrombie* taxonomy).

[82] KEVIN J. HICKEY, ERIN H. WARD & WEN S. SHEN, CONG. RSCH. SERV., R45666, DRUG PRICING AND INTELLECTUAL PROPERTY LAW: A LEGAL OVERVIEW FOR THE 116TH CONGRESS 3 n.20 (2019), https://fas.org/sgp/crs/misc/R45666.pdf.

[83] *Persuading the Prescribers: Pharmaceutical Industry Marketing and Its Influence on Physicians and Patients*, PEW CHARITABLE TR. (Nov. 11, 2013), http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients.

[84] Halabi, *supra* note 20.

protection is potentially perpetual when taking a few relatively inexpensive measures.[85]

More importantly, the drug's appearance may be, and frequently is, the most important market advantage: when trademarks protect brands with substantial value, the brand itself becomes a product characteristic that consumers value, even cherish, but competitors may not copy.[86] Moreover, because of what trademark is designed to achieve—trustworthiness in the view of the consumer—patients may refuse to switch to lower cost alternatives because doing so is costly—what is generally known as "search costs"—in that they must research the alternative's origin, price, and reputation.[87] There is substantial evidence that name brands of previously patent-protected medicines can maintain a premium price over newly available generic versions of the same medicines.[88] AstraZeneca's prescription drugs Prilosec

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[85] Deborah R. Gerhardt, *Beware the Trademark Echo Chamber: Why Federal Courts Should Not Defer to USPTO Decisions*, 33 BERKELEY TECH. L.J. 643, 645 (2018) ("[T]rademark rights can change dramatically over time. Most forms of intellectual property, like patents, copyrights, and rights of publicity, have set linear terms of protection and then move into the public domain. Trademarks are different. They can move in and out of protectable status as market uses and language evolve. A trademark, if carefully curated as a source identifying symbol, can last forever."); Jonathan Hyman, Charlene Azema & Loni Morrow, *If the IP Fits, Wear It: IP Protection for Footwear—A U.S. Perspective*, 108 TRADEMARK REP. 645, 661 (2018) ("There is no limit on the duration of trademark protection . . . . A federal trademark registration must be renewed every ten years and can be renewed indefinitely so long as the registrant attests to continued use of the registered mark in the United States with a supporting specimen as evidence of use."); *see also* Robert G. Bone, *Trademark Functionality Reexamined*, 7 J. LEGAL ANALYSIS 11 n.25 (2015) ("To be sure, some courts argued that granting a perpetual common law monopoly in features that were never patented or extending the patent monopoly beyond the patent term would conflict with the patent statute.").

[86] Sam Foster Halabi, *International Trademark Protection and Global Public Health: A Just-Compensation Regime for Expropriations and Regulatory Takings*, 61 CATH. U. L. REV. 325, 338 (2012) ("In some industry sectors, such as soda and tobacco, a trademark's value may comprise the majority of a company's worth precisely because of indivisibility of advertising, promotion, and marketing costs from consumer preference for the trademark. These investments yield even greater gains in states with high rates of illiteracy because symbols or diagrams are more important in product selection than written words.") (footnotes omitted); Shawn K. Baldwin, *"To Promote the Progress of Science and Useful Arts": A Role for Federal Regulation of Intellectual Property as Collateral*, 143 U. PA. L. REV. 1707, 1704 (1995) ("[T]rademarks may represent as much as eighty percent of a company's value.").

[87] *See generally* Mark P. McKenna, *A Consumer Decision-Making Theory of Trademark Law*, 98 VA. L. REV. 67 (2013) (discussing consumer search costs theory and its domination of the discussion of trademark law for the last several decades).

[88] Mark A. Hurwitz and Richard E. Caves, *Persuasion or Information? Promotion and the Shares of Brand Name and Generic Pharmaceuticals*, 31 J.L. & ECON. 299, 314 (1988).

and Nexium are both known in the marketplace as the "Purple Pill." Pfizer also succeeded in registering the blue diamond shape of its tablets as a trademark for its prescription drug Viagra. In short, in a world where information is costly, it is rational for patients to pay more for what they know rather than spend time researching potentially equivalent products.[89]

Brand names of drugs are protected by trademark, but this does not include the name of the drug itself.[90] Prozac, for example, is also called Erocap, Lorien, Lovan, and Zactin outside the United States, although the name of the compound is fluoxetine.[91] For a proprietary name to become a registered trademark, it must be reviewed by both the medicine's regulatory authority (in the United States, the FDA) as well as the trademark review authority (in the United States, the USPTO).[92]

The standards of review are different and reflect the mandates of those authorities. The FDA is primarily concerned with proposed trademark names that may induce medication error (for example, a name that may be confused when a physician writes the prescription, a pharmacy fills it, or a patient ingests it). Names

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[89] C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?*, 36 PHARMACY & THERAPEUTICS 669, 682 (2011) ("Another common complaint is that manufacturers often use [direct-to-consumer pharmaceutical advertising] to promote expensive 'me-too' or 'copycat' drugs that might not offer any significant benefits over older and cheaper medications. For example, two heavily promoted diabetes treatments, rosiglitazone (Avandia, GlaxoSmithKline) and pioglitazone (Actos, Takeda), were found to be no more effective—or safe—than older drugs, even though they were much more expensive. In another study, older drugs for the treatment of schizophrenia were found to be equally effective and to cost as much as $600 per month less than olanzapine (Zyprexa, Eli Lilly), quetiapine (Seroquel, AstraZeneca), or risperidone (Risperdal, Janssen).") (footnotes omitted).

[90] Alfred B. Engelberg, *Have Prescription Drug Brand Names Become Generic?*, AM. J. MANAGED CARE (Nov. 18, 2014), https://www.ajmc.com/view/have-prescription-drug-brand-names-become-generic ("Bayer has maintained a large share of the aspirin market for decades by using the Bayer name to identify the original version of aspirin. The use of a corporate name in association with a generic name for a medicine would create a clear brand identity shared by the medicine and its original producer, which would permanently distinguish the original product from later generic versions. That would enable patients to choose between competing bioequivalent medicines, all of which have the same name and appearance, on price and real or perceived differences in quality just as they now do when purchasing over-the-counter medicines.").

[91] Ameet Sarpatwari & Aaron S. Kesselheim, *The Case for Reforming Drug Naming: Should Brand Name Trademark Protections Expire upon Generic Entry?*, PLOS MEDICINE (Feb. 9, 2016), https://doi.org/10.1371/journal.pmed.1001955.

[92] Katherine P. Califa, *Ready to Release a New Pharmaceutical? What to Think About When Selecting Your Drug Name*, NAT'L L. REV. (Nov. 8, 2017), https://www.natlawreview.com/article/ready-to-release-new-pharmaceutical-what-to-think-about-when-selecting-your-drug.

proposed for trademark protection are reviewed for visual and auditory similarities to other drugs.[93] To protect patients from misidentifying medications, drugs must avoid looking and sounding alike.[94] As Katherine P. Califa explains:

> The FDA considers spelling similarities such as whether two names share identical prefixes, suffixes, or infixes, and whether the names are a similar length. The FDA also considers the overall "shape" of the words. Do both names have similar looking letters in similar positions in the names – including "tall" letters ("l" "t" "f"), "round" letters ("o" "a" "c" "e" "u"), cross-stroke letters ("T" "Z" "F" "J" "I"), or down-stroke letters ("v" "r" "n" "u")? The FDA will balance these factors, along with an analysis of the phonetic similarities, to determine the overall similarity between two drug names.[95]

"The FDA views medication errors as preventable and has essentially adopted a zero-risk tolerance policy. [Overall], the FDA rejects proprietary names at a rate of 40% or more . . . ."[96]

The USPTO, on the other hand, reviews drug names to determine whether the new trademark is capable of registration, whether the new trademark conflicts with a prior trademark application or registration, and whether the trademark application complies with the USPTO's rules.[97] The USPTO's primary considerations when evaluating whether to grant registration include whether the mark is sufficiently distinctive and whether there is a likelihood of confusion with respect to other registered marks.[98] "The 'likelihood of confusion' test considers factors such as similarities in marks, the relatedness of goods and services, the relatedness of trade

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[93] *Id.*

[94] *See id.*; *see also Medication Errors Related to CDER-Regulated Drug Products*, FDA, https://www.fda.gov/drugs/drug-safety-and-availability/medication-errors-related-cder-regulated-drug-products (last updated Sept. 8, 2021).

[95] Califa, *supra* note 92.

[96] Nicholas de la Torre & Jennifer Theis, *United States*, *in* PHARMACEUTICAL TRADEMARKS 2013/2014: A GLOBAL GUIDE 82, 83 (4th ed. 2013), https://www.brinksgilson.com/files/pharma_2013_article.pdf.

[97] Califa, *supra* note 92; Termini & Miele, *supra* note 10, at 39; Hannah Brennan, *The Cost of Confusion: The Paradox of Trademarked Pharmaceuticals*, 22 MICH. TELECOMM. & TECH. L. REV. 1, 6 (2015).

[98] 15 U.S.C. § 1052(d), (f).

channels, market conditions[,] and the number and nature of similar marks in use for similar goods."[99]

Trademark and trade dress protections are used to signal to consumers the source of a product; trademark generally addresses the name, logo, or symbol of a product whereas trade dress addresses the visual appearance of a product or its packaging. The standard for claiming trademark infringement has increased over the years as courts have shifted the burden to the party claiming trademark infringement to prove a "likelihood of irreparable harm" to obtain injunctive relief.[100] For many years, trademark infringement claims were granted a "presumption of irreparable harm," allowing for injunctive relief.[101] However, following the Supreme Court's rulings in *eBay v. MercExchange* and *Winter v. NRDC*, the standard changed from a "presumption of irreparable harm" to a burden upon the party claiming a "likelihood of irreparable harm."[102] Under current U.S. law, a plaintiff claiming trademark infringement must satisfy the elements in place for all types of injunctive relief. A plaintiff "must establish that [they are] likely to succeed on the merits, that [they are] likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [their] favor, and that an injunction is in the public interest."[103]

2. Trade Dress

Within the protections legally offered by trademark, "trade dress" may apply to a product, giving additional claims against competitors.[104] Trade dress is generally

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[99] de la Torre & Theis, *supra* note 96, at 82; *see, e.g.*, Polaroid Corp. v. Polarad Elecs. Corp., 287 F.2d 492, 495 (2d Cir. 1961); AMF, Inc. v. Sleekcraft Boats, 599 F.2d 341, 348-49 (9th Cir. 1979).

[100] Anne Gilson LaLonde & Jerome Gilson, *Adios! To the Irreparable Harm Presumption in Trademark Law*, 107 TRADEMARK REP. 913, 924-26 (2017).

[101] *Id.* at 916, 918-19.

[102] *Id.* at 922-24; eBay Inc. v. MercExchange, LLC, 547 U.S. 388, 394 (2006) ("Because we conclude that neither court below correctly applied the traditional four-factor framework that governs the award of injunctive relief, we vacate the judgment of the Court of Appeals, so that the District Court may apply that framework in the first instance.").

[103] Ferring Pharm., Inc. v. Watson Pharm., Inc., 765 F.3d 205, 210 (3d Cir. 2014) (quoting Winter v. NDRC, Inc., 555 U.S. 7, 20 (2008)).

[104] Indeed, scholars have challenged the close association between trademark law and trade dress protection. *See, e.g.*, Glynn S. Lunney, Jr., *The Trade Dress Emperor's New Clothes: Why Trade Dress Does Not Belong on the Principal Register*, 51 HASTINGS L.J. 1131, 1162-63 (2000) ("In addition to relying on perceived congressional intent, courts have also proffered superficial policy analyses as justifications for recognizing trade dress as principal register subject matter. In this vein, courts have typically asserted, first, that trade dress can act like a traditional trademark, helping consumers identify and distinguish products, and second, that so long as the functionality doctrine excludes protection for those features that represent 'the best or one of a few

a more fragile form of intellectual property protection than trademark, but in the context of medicines, it wields enormous influence in the control of entry by competing products.[105]

> To qualify as trade dress an attribute must meet three criteria: it must be nonfunctional, it must lead to confusion (or deception) if imitated, and it must have a secondary association with the product for the consumer. A product's functional attributes are essential to the use or purpose of the product or must affect the cost or quality of the product. Functionality is key in pharmaceutical-related trade dress, because if a company with a brand-name drug owned exclusive rights over a functional attribute of that drug, a competitor could not offer a truly equivalent generic version.[106]

Under U.S. law, trade dress is generally divided into two types: product design and product packaging.[107] If the identifying dress serves a function, trade dress protection is unavailable.[108] Typical functional attributes of drugs are safety and efficacy, although courts have found features like chocolate flavoring or a "pleasing" pink color to serve a functional purpose.[109] To claim trade dress infringement, firms

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superior designs available,' trade dress protection will generate no anticompetitive consequences. However, this analysis fails to justify recognition of trade dress as principal register subject matter for two reasons. First, the Court has repeatedly warned against 'simplistically . . . assuming that *whatever* furthers the statute's primary objective must be the law.' Second, the policy analysis that courts have offered both overstates the benefits that such recognition achieves and understates its true cost. A more careful analysis of the policies implicated by trademark protection fully justifies distinguishing between the protection of words and symbols as trademarks and the protection of trade dress under principles of unfair competition.") (footnotes omitted).

[105] Greene & Kesselheim, *supra* note 6. On trade dress fragility, see Homeland Housewares, LLC v. Euro-Pro Operating LLC, No. CV 14-03954 DDP (MANx), 2014 U.S. Dist. LEXIS 156675 at *7-9 (C.D. Cal. Nov. 5, 2014); Mike Vaughn Custom Sports, Inc. v. Piku, 15 F. Supp. 3d 735, 744-49 (E.D. Mich. 2014).

[106] Green & Kesselheim, *supra* note 6, at 83.

[107] Sabrina Rodrigues, *Say "Yes" to the [Trade] Dress: A Comment on Trade Dress Protection for the "Look and Feel" of Lifestyle Blogs*, 53 WAKE FOREST L. REV. 1005, 1021 (2018).

[108] *Id.* at 1024; *see, e.g.*, Shire U.S. Inc. v. Barr Labs., Inc., 329 F.3d 348 (3d Cir. 2003); Ives Labs., Inc. v. Darby Drug Co., 601 F.2d 631 (2d Cir. 1979).

[109] William R. Warner & Co. v. Eli Lilly & Co., 265 U.S. 526 (1924); Norwich Pharmacal Co. v. Sterling Drug, Inc., 271 F.2d 569, 572 (2d Cir. 1959); *see also In re* Ferris Corp., 59 U.S.P.Q.2d (BL) 1587 (T.T.A.B. 2000) (finding that the applied-for color "pink" is functional for wound dressings).

endeavor to avoid disclosing or advertising utilitarian advantages of features that may serve as the basis of trade dress protection.[110]

Section 43(a) of the Lanham Act, which codifies the federal unfair competition act, includes trade dress protection from infringement if the criteria above are satisfied.[111] Courts' interpretations of the criteria for trade dress protection under the Lanham Act are consistent for the first two elements. However, the third element (secondary association) has divided authorities. Some courts require trade dress to have "acquired secondary meaning" while other courts require a showing of either "secondary meaning" or that the product is "inherently distinctive."[112]

In the pharmaceutical context, "secondary meaning" suggests that the protected mark leads a patient or consumer to associate that dress or mark with the drug.[113] "Secondary meaning" is the traditional rule that results from consumer

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[110] Daly & Emery, *supra* note 10; *In re* Change Wind Corp., 123 U.S.P.Q.2d (BL) 1453 (T.T.A.B. 2017); John L. Welch, *Precedential No. 19: TTAB Affirms Section 2(e)(5) Functionality Refusal of Wind Turbine Configuration*, TTABLOG (July 24, 2017), http://thettablog.blogspot.com/2017/07/precedential-no-19-ttab-affirms-2e5.html ("The TTAB affirmed a Section 2(e)(5) refusal to register the product configuration shown below, for 'Wind turbines; Windpowered electricity generators,' finding the design to be functional because 'it is essential to the use or purpose of the product.' [Applicant] Change Wind's own utility patent took the wind out of its sails.").

[111] William F. Gaske, *Trade Dress Protection: Inherent Distinctiveness as an Alternative to Secondary Meaning*, 57 FORDHAM L. REV. 1123, 1125-26 (1989) ("Section 43(a) of the Lanham Act codifies the federal unfair competition law, which includes the protection of trade dress from infringement. A successful claim for trade dress infringement under section 43(a) requires proof of three elements. First, the trade dress must be nonfunctional. Second, the trade dress of the competitor's product must be so similar to the trade dress of plaintiff's product that confusion as to the product's source is likely. Courts agree on these first two elements but are split on the third requirement. A number of courts require that the trade dress have acquired 'secondary meaning,' while other courts require that the trade dress either have 'secondary meaning' or be 'inherently distinctive.'") (footnotes omitted).

[112] *Id.*

[113] *Ives Labs.*, 601 F.2d at 643 ("One would not initially suppose the color of a capsule to be functional. Unlike the chocolate in the Warner case . . . the blue and blue-and-red coatings of Ives' capsules do not contribute to their efficacy; any other colors would do as well. The argument that, like functional elements, color ought to be automatically denied protection because of the risk of creating monopolies through tying up all available colors does not seem persuasive; the evidence showed that, in addition to the other primary colors, an endless number of color combinations was available to the defendants. The case for functionality thus depends on the evidence proffered by defendants that copying whatever colors Ives had chosen served a number of utilitarian purposes, essential to effective competition. At this stage of the case we need not go beyond saying that the judge was warranted in considering this to be fairly arguable. With respect to secondary meaning we cannot say that Ives would necessarily be unable to establish that consumers had come

association of a product with a single source or manufacturer rather than the product generally.[114] "Inherent distinctiveness" requires a product to have distinguishing characteristics that are an indication of the source or manufacturer.[115] "Secondary meaning" is acquired over time, while "inherent distinctiveness" is immediate.[116] To meet the "inherent distinctiveness" standard, a product will likely have to be considered "arbitrary," "fanciful," or "suggestive" as a trademark.[117]

In the pharmaceutical context, manufacturers have asserted trademark rights regarding the shape and color of drug capsules.[118] In *In re American Home Products Corp.*, the drug manufacturer attempted to register a "tri-colored three dimension circular shaped design."[119] There, the Patent and Trademark Office determined that the drug met the qualifications for trademark registration.[120] The tri-coloration and shape were not considered "inherently distinctive."[121] However, the extensive marketing for more than 20 years that was directed at identifying the drug based on its coloring scheme was "clearly and unambiguously" used to promote trademark recognition and "secondary meaning."[122]

Generic manufacturers have generally asserted that brand-name manufacturers may not legitimately assert trade dress protection because the aesthetics of drugs are "functional."[123] A mark is "functional" if a manufacturer's competitors would need the mark to communicate information about their products to consumers.[124] The issue has divided courts interpreting and applying trade dress

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to associate the blue and blue-and-red colors with the trademark Cyclospasmol.") (citations omitted); Daly & Emery, *supra* note 10.

[114] Wal-Mart Stores, Inc. v. Samara Bros., Inc., 529 U.S. 205, 211 (2000).

[115] Michele A. Shpetner, *Determining a Proper Test for Inherent Distinctiveness in Trade Dress*, 8 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 947, 973-74 (1998).

[116] *Id.* at 972-74.

[117] *Id.* at 959-61.

[118] Lenahan et al., *supra* note 7, at 32.

[119] *In re* Am. Home Prods. Corp., 226 U.S.P.Q. (BL) 327, 328 (T.T.A.B. 1985).

[120] *Id.* at 330-31.

[121] *Id.* at 329.

[122] *Id.* at 330.

[123] *See, e.g.*, Johnson & Johnson v. Actavis Grp., 87 U.S.P.Q.2d (BL) 1125 (S.D.N.Y. 2008); Shire U.S. Inc. v. Barr Labs., Inc., 329 F.3d 348 (3d Cir. 2003); Ives Labs., Inc. v. Darby Drug Co., 488 F. Supp. 394 (E.D.N.Y. 1980), *rev'd*, 638 F.2d 538 (2d Cir. 1981), *rev'd sub nom.* Inwood Labs., Inc. v. Ives Labs., Inc. 456 U.S. 844 (1982), *aff'd*, 697 F.2d 291 (2d Cir. 1982).

[124] *Johnson & Johnson*, 87 U.S.P.Q.2d (BL) at 1128.

law.[125] Two cases demonstrating differing applications of trade dress law to aesthetic properties of drug products are relevant for the recommendation made in Part III.

In general, the functionality doctrine allows for the protection of color, for example, if the color is not "essential to the use or purpose of the article" and does not "affect[] the cost or quality of the article."[126] Courts have upheld functionality arguments barring trade dress in some pharmaceutical contexts when patients associate product features with therapeutic care.[127] In *Ives Lab., Inc. v. Darby Drug Co.*, Ives sued generic manufacturers for utilizing a similar color scheme for varying doses of cyclandelate, a medicine taken mostly by elderly patients with vascular diseases, which Ives sold under the trademark Cyclospasmol.[128] A functionality defense was successful after first being reversed, and then subsequently upheld after multiple appeals.[129]

Ives manufactured cyclandelate, marketing it as Cyclospasmol in 200mg doses contained in pale blue capsules imprinted with "Ives 4124," and 400mg doses in red and blue capsules imprinted with "Ives 4148." The generic manufacturers purchased bulk cyclandelate powder and colored capsules to assemble their products in the same color-coded dosage scheme. The court held that the capsule colors were functional and that "secondary meaning" of the colors as a means of identifying source, rather than chemical ingredient, function, or dose, was not shown.[130]

> The court finds that the colors are functional in several respects. First, many elderly patients associate the appearance of their medication with its therapeutic effect. There was testimony that some patients refuse to take equivalent drugs of a different color despite explanation of the equivalence by their doctors. Other patients eventually accept equivalent drugs of a different appearance if their physician assures them that the prescription was filled correctly but are caused considerable anxiety and confusion by the change. When

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[125] J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 7:69, Westlaw (coverage through Dec. 2021).

[126] TRADEMARK MANUAL OF EXAMINING PROCEDURE §1202.02(a) (July 2021).

[127] *See, e.g.*, *Shire*, 329 F.3d at 350 ("Shire's product literature, promotional materials, and mailings, which its sales staff distributed to physicians, feature color pictures of the Adderall tablets and sometimes direct patients to examine the tablets to ensure that they have received exactly the drug prescribed. Shire does not advertise its products in general consumer publications, but pictures of Adderall tablets appear in the Physician's Desk Reference and in certain consumer books.").

[128] *Ives*, 488 F. Supp. at 396.

[129] Inwood Labs., Inc. v. Ives Labs., Inc. 456 U.S. 844, 844 (1982).

[130] *Ives*, 488 F. Supp. at 398.

> patients associate the drug with its therapeutic effect in this manner, to insist that defendants use a different color would unjustifiably put them at a competitive disadvantage. Thus color is an important ingredient in the commercial success of the product.
>
> Second, some patients co-mingle their drugs in a single container and then rely on the appearance of the drug to follow their doctors' instructions. One doctor testified that he prepares a chart using the color and shape of the medication to help disoriented and forgetful patients avoid confusion between several drugs. While this practice is not universal, clearly some doctors use the appearance of a drug in communicating with their patients and in assisting them to take the correct medications at the appropriate times.[131]

Subsequent cases have recognized that "competitors might be free to copy the color of a medical pill where the color serves to identify the kind of medicine . . . ."[132] Therefore, under some circumstances, the color and shape of drugs carry utilitarian functions and thus are ineligible for trade dress protection.

However, the extent of the freedom to copy colors for identification purposes may be limited. In *Johnson & Johnson v. Actavis Group*, the U.S. District Court for the Southern District of New York concluded that even if a yellow-gold color was generally associated with over-the-counter antibiotic ointments, the particular use of that color on packaging of Johnson & Johnson's Neosporin, an antibiotic ointment, was not essential to its use by consumers and awarded summary judgment against a functionality defense.[133]

Neosporin is packaged in a tube that Johnson & Johnson (J&J) argued was distinguished by a yellow-gold background, a green color and particular typeface for the brand name, and a curving arrow in the gold/yellow color. Actavis, the generic manufacturer, sold the antibiotic ointment in a tube with the same yellow-gold feature, but none of the other features asserted to have trademark and trade dress protection.[134]

J&J sued Actavis for violation of its trademark and trade dress. Actavis argued that the yellow-gold color was functional, allowing consumers to identify that the product contained an antibiotic. Actavis provided evidence of consumer association

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[131] *Id.* at 398-99.
[132] *Shire*, 329 F.3d at 358 (quoting *Inwood*, 456 U.S. at 853).
[133] Johnson & Johnson v. Actavis Grp., 87 U.S.P.Q.2d (BL) 1125, 1128-29 (S.D.N.Y. 2008).
[134] *Id.* at 1126-27.

between shades of yellow and antibiotics, and it pointed out that the gold-colored drop on packaging for J&J's Band-Aids signified the presence of an antibiotic ointment (that itself was manufactured by Actavis for inclusion in J&J's Band-Aids). However, J&J provided evidence that other antibiotic ointments were sold in other colors of packaging.[135]

Although the separate issue of "secondary meaning" was held to be a disputed issue of fact, the court granted summary judgment for J&J on the issue of functionality, holding that protecting the color would not significantly hinder competition.[136] Thus, while evidence of an association with therapeutic effect that was "not universal" in *Ives* was sufficient to demonstrate functionality, similar evidence of an association between yellow-gold and antibiotic function was not enough to allow a functionality defense to reach a jury in *Johnson & Johnson*, demonstrating that the functionality of aesthetic properties of drugs is fact-specific and subject to significant uncertainty.[137]

To summarize, in litigation, trademark and trade dress protections are handled similarly, with some additional burdens placed upon the latter class of plaintiffs.[138] Trademark protections involve a mark placed on the product or its packaging, whereas trade dress protections involve the aesthetic of the product or its packaging.[139] Because trade dress is a subset of trademark protection, claims must conform to the same standards as trademark protections.[140] However, courts seem uncertain as to whether a "secondary meaning" standard or an "inherent distinctiveness" standard is optimal for determining if a manufacturer should be granted trade dress protections.[141] Finally, in the pharmaceutical context specifically, a product's appearance (like its color or shape) may have functionality (allowing patient identification of therapeutic effect) and be barred from trade dress

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[135] *Id.* at 1127-28.

[136] *Id.*

[137] *Compare* Ives Labs., Inc. v. Darby Drug Co., 488 F. Supp. 394, 398-99 (E.D.N.Y. 1980) ("One doctor testified that he prepares a chart using the color and shape of the medication to help disoriented and forgetful patients avoid confusion between several drugs. While this practice is not universal, clearly some doctors use the appearance of a drug in communicating with their patients and in assisting them to take the correct medications at the appropriate times."), *with Johnson & Johnson*, 87 U.S.P.Q.2d (BL) at 1128 ("The fact that one brand of bandages uses a color to depict a drop of ointment that is similar to the Gold Mark used as a background color on the NEOSPORIN(r) packaging is insufficient for a jury to conclude that the Gold Mark is functional when used to sell antibiotic ointment.").

[138] Ann Bartow, *Counterfeits, Copying and Class*, 48 HOUS. L. REV. 707, 710-11 (2011).

[139] Qualitex Co. v. Jacobson Prods. Co., 514 U.S. 159, 170 (1995).

[140] Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763, 770 (1992).

[141] Gaske, *supra* note 111, at 1126.

protection.[142] However, significant uncertainty arises due to the fact-intensive inquiry involved in a functionality defense.[143]

As will be more fully discussed below, in the context of prescription drugs, trade dress protections (or at least the uncertainty and expense of overcoming purported protections) have large impacts on patient health outcomes. Patients are often unable to recognize medications after generic substitution of functionally equivalent (but aesthetically different) medications. The changes reduce patient adherence or the successful continuation of treatment regimens. This causes a negative perception of generic medications because patients associate a loss of safety and efficacy with the change in appearance.[144]

II
THE UNIQUE COSTS TRADEMARK AND TRADE DRESS IMPOSE UPON PATIENTS

Whatever the effect of trademark and trade dress protections elsewhere in the economy, their effect on patients deserves special scrutiny. More than 131 million people—66% of all adults in the United States—use prescription drugs. Utilization is particularly high for older people and those with chronic conditions.[145] Women are generally more likely than men to use prescription drugs; approximately 40% of men and 66% of women age 18 to 34 use prescription drugs, although those populations converge as they reach 80.[146]

This Part explains why trademark and trade dress law cause medication adherence problems, raise barriers to efforts to lower prescription drug costs, and increase the risk of medication error. Trademark and trade dress law force generic manufacturers to adapt the color, appearance, and shape of the medicines they sell, and there is not uniformity as to how generic firms approach drug appearance—only that they not infringe on the appearance of trademark and trade dress protected features. Because pharmacies switch generic supplier firms with some regularity, this means that patients may receive different looking medications more than once or twice per year. Thus, trademark and trade dress law keep prices high, cause patient confusion, and result in medication error and patient nonadherence.

Patient adherence to prescription drug regimens is essential for maintaining health and avoiding severe illness and premature death. Patients are considered

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[142] *E.g.*, *Qualitex*, 514 U.S. at 170.

[143] *Cf.* Johnson & Johnson v. Actavis Grp., 87 U.S.P.Q.2d (BL) 1125, 1128-29 (S.D.N.Y. 2008).

[144] *See infra* Part II.

[145] Ihara, *supra* note 2.

[146] *Id.*

adherent to medications when they take prescribed agents at doses and times recommended by a healthcare provider and agreed to by the patient.[147] Patient adherence to prescription drug regimens is affected by many factors of unequal weight, but a substantial body of evidence suggests that, in aggregate, cost and potential confusion are important factors. In a survey of 14,464 Medicare beneficiaries, patients who did not fill at least one prescription reported the following reasons: "thought it would cost too much" (55.5%), "medicine not covered by insurance" (20.2%), "didn't think medicine was necessary for the condition" (18.0%), and "was afraid of medicine reactions/contraindications" (11.8%).[148]

The relationship between adherence and cost is more emphasized among the socioeconomically marginalized, including racial and ethnic minorities. Specific factors that have been identified as barriers to medication adherence among inner-city patients with low socioeconomic status include high medication costs, lack of transportation, poor understanding of medication instructions, and long wait times at the pharmacy.[149] "Patient *nonadherence* to prescribed medications is associated with poor therapeutic outcomes, progression of disease, and an estimated burden of billions per year in avoidable direct health care costs."[150]

Over 90% of prescription drugs dispensed are generic drugs, both because they are less expensive and because state mandatory substitution laws require that pharmacies in most states fill prescriptions with generic versions where available.[151] For approval by the FDA, generic drugs must be the bioequivalent of the brand-name version, meaning it must have the same "dosage form, safety, strength, route

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[147] Lars Osterberg & Terrence Blaschke, *Adherence to Medication*, 353 NEW ENG. J. MED. 487, 487 (2005) ("Adherence to (or compliance with) a medication regimen is generally defined as the extent to which patients take medications as prescribed by their health care providers. The word 'adherence' is preferred by many health care providers, because 'compliance' suggests that the patient is passively following the doctor's orders and that the treatment plan is not based on a therapeutic alliance or contract established between the patient and the physician.").

[148] Jae Kennedy, Iulia Tuleu & Katherine Mackay, *Unfilled Prescriptions of Medicare Beneficiaries: Prevalence, Reasons, and Types of Medicines Prescribed*, 14 J. MANAGED CARE PHARMACY 553, 553 (2008).

[149] Sunil Kripalani, Laura E. Henderson, Terry A. Jacobson & Viola Vaccarino, *Medication Use Among Inner-City Patients After Hospital Discharge: Patient-Reported Barriers and Solutions*, 83 MAYO CLINIC PROC. 529 (2008).

[150] Aurel O. Iuga & Maura J. McGuire, *Adherence and Health Care Costs*, 7 RISK MGMT. & HEALTHCARE POL'Y 35, 35 (2014) (emphasis added).

[151] ASS'N FOR ACCESSIBLE MEDS., 2020 GENERIC DRUG & BIOSIMILARS ACCESS & SAVINGS IN THE U.S. REPORT 16 (2020), https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf; *see also* Kesselheim et al., *supra* note 26.

of administration, quality, performance characteristics and intended use."[152] Unlike drug names, the FDA does not regulate the physical appearance of drugs, although it has issued guidance with respect to size and shape of tablets and capsules as well as some aspects of packaging.[153] Because of this, pharmaceutical companies may protect the physical attributes of their drugs through trademark and trade dress.[154]

The essential question with respect to trademark and trade dress protection in the pharmaceutical context, then, is: does the benefit to patients from identification of brand-name prescription medications (the trademark rationale) outweigh the cost to patients in the form of reduced adherence attributable to more expensive medicines *and* the cost imposed when trade dress confuses rather than clarifies (the "IP cost" and the "confusion cost")? This Article argues that the answer is "no" and makes specific recommendations to incorporate that answer into law.

A. Trade Dress and Demand-Side Measures to Increase Drug Affordability

Physicians and public authorities (who often pay for treatment for some or all of their populations) have emphasized supply-side measures to ensure access to medicines at an affordable cost—to individuals when they are required to pay and by the public treasury for populations covered by universal health insurance systems.[155] Supply-side measures include investment in generic manufacturing capability; regulatory and intellectual property incentives for generic manufacturers to enter markets; and state substitution laws that allow or require that pharmacies fill prescriptions with lower cost generic drugs that are therapeutically equivalent.[156] For example, streamlining the generic drug approval process in the United States by prioritizing applications from manufacturers who introduce a generic drug with limited competition would decrease prices and similarly limit the number of

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[152] Abdulrazaq S. Al-Jazairi, Sakra Blhareth, Iyad S. Eqtefan, & Saleh A. Al-Suwayeh, *Brand and Generic Medications: Are They Interchangeable?*, 28 ANNALS SAUDI MED. 33, 33 (2008).

[153] Kesselheim et al., *supra* note 33, at 202-03.

[154] *Id.*

[155] Fritz von der Schulenburg, Sotiris Vandoros & Panos Kanavos, *The Effects of Drug Market Regulation on Pharmaceutical Prices in Europe: Overview and Evidence from the Market of ACE Inhibitors*, 1 HEALTH ECON. REV. 18, 18 (2011) ("We find that although some measures are effective in reducing originator prices, others appear to have an insignificant effect. Results suggest that supply side measures such as mandatory generic substitution, regressive pharmacy mark-ups and claw-backs are effective in reducing pharmaceuticals prices.").

[156] Jesse C. Vivian, *Generic-Substitution Laws*, 33 U.S. PHARMACIST 30 (2008).

competing products with disparate visual schemes.[157] Supply- and demand-side policies help to encourage the use of generic drugs over brand-name drugs.[158]

Demand-side policies are necessary to improve prescribing physicians' and patients' perceptions of generic drugs to encourage more prescriptions.[159] Demand-side policy proposals include charging fees to increase resources for more efficient reviewal processes; addressing anticompetitive strategies; and providing financial incentives to physicians and pharmacists.[160] Some European countries have implemented financial incentives to physicians and pharmacists to encourage the use of generic drugs, and similar measures could be taken by states with respect to disease categories where patient confusion is widespread or severe.[161] State substitution laws already use the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) as the measure for substitutability, so at the very least, it would be possible to incorporate a notice system for pharmacies to use when substituting therapeutically equivalent drugs.[162]

Generic drugs are relatively inexpensive when compared to brand-name drugs because of the less strict regulatory pathway to obtaining approval and the already-existing competitive market for the drug.[163] To maintain competitive and sustainable pricing, drug manufacturers must be ensured that a high volume of generic drugs will enter the market and be used through supply- and demand-side policies.[164] Regulations have generally addressed supply-side policies and decreased the average cost of generic drugs by 10-80% of the cost of brand-name drugs while

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[157] *See* Olivier J. Wouters, Panos G. Kanavos & Martin McKee, *Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending*, 95 MILBANK Q. 554, 570 (2017).

[158] Pieter Dylst, Arnold Vulto & Steven Simoens, *Demand-Side Policies to Encourage the Use of Generic Medicines: An Overview*, 13 EXPERT REV. PHARMACOECONOMICS OUTCOMES RSCH. 59 (2013).

[159] *Id.*

[160] *Id.* at 61-65.

[161] *Id.* at 64.

[162] *Id.*

[163] Wouters et al., *supra* note 157, at 556.

[164] OECD, ROUNDTABLE ON GENERIC PHARMACEUTICALS 22 (2010), https://www.oecd.org/competition/abuse/46138891.pdf ("These policy developments in France, and particularly the agreement with physicians, were an important part of the sudden growth in the use of generics: rates of generic substitution increased from 18% of drugs for which there were generic versions in 2000 to 48.2% by 2002. However, by 2006, generics accounted for only 17% by volume of all reimbursed medicines, compared with 65% in the UK. These numbers in France increased following the implementation of a reference price scheme covering off-patent drugs in 2003.") (citations omitted).

improving access to the market.[165] However, demand-side policies are needed to incentivize prescriptions of generic medications by physicians and substitutions to generic drugs by pharmacists, and to improve patients' perceptions of the safety and efficacy of generic drugs.[166]

Demand-side measures should include laws, regulations, and judicial interpretations that acknowledge the special costs that trademark and trade dress impose in the prescription drug context.[167] Although sometimes it may be necessary to prescribe brand-name medications (for example, if a patient has an allergy to the generic alternative), the majority of the time, generic drugs are avoided due to misconceptions or habits by physicians.[168] Several successful policies exist addressing generic drug misconceptions in European countries and the United States.[169] Studies have shown that low health literacy action plans can also encourage adherence to generic drugs because the physician and/or pharmacist will be more involved with counseling patients regarding therapy, which may include discussing the visual differences between brand and generic forms of the prescription drug.[170]

B. Trade Dress and Nonadherence

As analyzed above, trade dress allows pharmaceutical firms to apply identifiable physical attributes to their products if they do not change the functional attributes of the medications—indeed, functionality would render those features ineligible for trade dress protection.[171] Health scholars have long criticized the protections given to medications under trade dress doctrine for at least two reasons. As a purely legal matter, patient adherence can be shown to depend upon drug appearance, rendering all aspects of drug appearance "functional."[172] For example,

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[165] Dylst, *supra* note 158, at 59.

[166] *Id.*

[167] Wouters et al., *supra* note 157, at 573.

[168] *Id.*

[169] *Id.* at 555.

[170] H. Shonna Yin, Ruchi S. Gupta, Suzy Tomopoulos, Alan L. Mendelsohn, Maureen Egan, Linda van Schaick, Michael S. Wolf, Dayana C. Sanchez, Christopher Warren, Karen Encalada & Bernard P. Dreyer, *A Low-Literacy Asthma Action Plan to Improve Provider Asthma Counseling: A Randomized Study*, 137 PEDIATRICS 1, 8 (2016).

[171] Aaron S. Kesselheim, Katsiaryna Bykov, Jerry Avorn, Angela Tong, Michael Doherty & Niteesh K. Choudhry, *Burden of Changes in Pill Appearance for Patients Receiving Generic Cardiovascular Medications After Myocardial Infarction*, 161 ANNALS INTERNAL MED. 96, 101 (2014).

[172] *But see* Marc P. Misthal, *Looks Can be Deceiving—Protectable Elements of a Pill's Appearance*, GOTTLEIB, RACKMAN & REISMAN, P.C., https://grr.com/publications/looks-can-deceiving-protectable-elements-pills-appearance/ (last visited Jan. 20, 2022) (discussing the

patients who take multiple medications are often 80 years of age or older with higher rates of visual or other impairment, increasing the risk of errors.[173] As a result, the legal framework introduces deadweight loss by incentivizing pharmaceutical firms to make design decisions for the purpose of preserving monopoly power rather than patient benefit.

Studies have shown an increase in patient harm because of nonadherence due to reliance on the physical appearance of drugs.[174] Patients receiving generic versions of the same medication receive pills of different sizes, shapes, and colors routinely because of trade dress protections.[175] In a study testing medication nonadherence for those with uncontrolled blood pressure, the ability of a patient to identify their medication based on its appearance was directly correlated to a diagnosis of uncontrolled blood pressure and an increase in hospital visits over the course of a year.[176] Patients who relied solely on the appearance of medication were 1.26 times more likely to report uncontrolled hypertension and 1.35 times more likely to report hospitalization in the past year.[177] These patients self-reported an increased nonadherence to generic medications.[178]

Similar outcomes have been reported in other studies. For example, in a study of 11,472 patients who had failed to fill a prescription for anti-epileptic drugs (in 4

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implications of Shire U.S. Inc. v. Barr Labs., Inc., 329 F.3d 348 (3d Cir. 2003), on protections for the appearance of Pfizer's Viagra).

[173] Juan Cardenas-Valladolid, Carmen Martin-Madrazo, Miguel A. Salinero-Fort, Enrique Carrillo de-Santa Pau, Juan C. Abanades-Herranz & Carmen de Burgos-Lunar, *Prevalence of Adherence to Treatment in Homebound Elderly People in Primary Health Care: A Descriptive, Cross-Sectional, Multicentre Study*, 27 DRUGS & AGING 641 (2010); Brian R. Levinthal, Daniel G. Morrow, Wanzhu Tu, Jingwei Wu & Michael D. Murray, *Cognition and Health Literacy in Patients with Hypertension*, 23 J. GEN. INTERNAL MED. 1172 (2008).

[174] Lenahan et al., *supra* note 7, at 32 (finding that patients who were unable to identify their hypertension medications either by name or by appearance were more likely to miss taking a medication in the past week compared with those who were able to identify by name or appearance); Kesselheim et al., *supra* note 171, at 101 ("The odds of nonpersistence in case patients increased by 34% after a change in pill color."); Anton J.M. de Craen, Pieter J. Roos, A. Leonard de Vries & Jos Kleijnen, *Effect of Colour of Drugs: Systematic Review of Perceived Effect of Drugs and of Their Effectiveness*, 313 BRITISH MED. J. 1624, 1625 (1996) ("Most colours have universal meanings in a wide variety of cultures, red generally being considered strong and active, and blue and green to be associated with good. The colour of drug formulations might cause different expectations in patients, and could therefore produce different therapeutic effects.") (footnotes omitted).

[175] *See* Lenahan et al., *supra* note 7, at 32.

[176] *Id.* at 35.

[177] *Id.*

[178] *Id.*

shapes and 37 colors) within 5 days of the elapsed days were approximately 30% more likely to have had the color of their pill changed before that failure relative to a control group of 50,050 patients who did not so fail.[179] Gaps in filling medication were 27% greater following a color discordance in anti-epileptic drugs when compared to a control.[180] For patients suffering from a seizure disorder, there was a 53% increase in prescription filling gaps when a color discordance occurred prior to filling.[181] Color appeared to be more relevant than shape.[182] Likewise, with prescription drugs dispensed to patients following myocardial infarctions, a 30% increase in nonadherence was observed in patients who received a medication with a different shape or color.[183]

An international study tested members of the United States, China, and Colombia to determine the psychological effects of different colors and shapes of medication.[184] The study revealed that patients associate certain characteristics with different shapes and colors.[185] For example, a pink-colored drug may be viewed as sweet compared to a white-colored drug that may be perceived as salty, or a round-shaped drug may be perceived as more easily swallowed compared to a drug with edges.[186] This study suggests that people around the world may have similar perceptions regarding the physical appearance of drugs, and that these perceptions may have adverse effects on a patient's adherence to a treatment plan.[187]

The evidence linking objective measures of prescription drug appearance is even more important given that health literacy plays such an influential role in a patient's independent ability to adhere to prescription drug regimens.[188] Health literacy is correlated to nonadherence to medication or to nonadherence to a dependent's treatment plan with medication.[189] In the aforementioned study for uncontrolled blood pressure, patients who were unable to identify their medication by name or appearance were more likely to miss taking a medication compared to

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[179] *See* Kesselheim et al., *supra* note 33, at 203-04.
[180] *Id.* at 204-05.
[181] *Id.*
[182] *See id.* at 205.
[183] *See* Kesselheim et al., *supra* note 171, at 100-01.
[184] Xiaoang Wan et al., *Assessing the Expectations Associated with Pharmaceutical Pill Colour and Shape*, 45 FOOD QUALITY & PREFERENCE 171, 171 (2015).
[185] *Id.* at 179.
[186] *Id.*
[187] *Id.* at 180.
[188] Lenahan et al., *supra* note 7, at 35.
[189] *Id.*; *see also* Yin et al., *supra* note 170, at 2.

those who could identify all of their medications by name or appearance.[190] However, this difference was not significant when compared to those who relied solely on identifying medication based on its physical appearance.[191]

Moreover, there is some evidence that the need to closely align prescription drug appearance with adherence will disproportionately affect children. "Low health literacy . . . is likely to contribute to poor management of child asthma."[192] Physicians who have utilized low literacy written asthma action plans (WAAP) with parents or guardians have seen greater medication adherence by child patients.[193] The low-literacy WAAP involved clear communication that included a presentation of medication instructions and inhaler colors, spacer use, a statement including the need for everyday use and the importance of the "yellow zone" on Flovent and Singulair, and explicit words used to present symptoms of exacerbation.[194] The low-literacy WAAP showed self-reported increased adherence to treatment and an increased understanding of the medication, as well as an increased satisfaction amongst the physicians utilizing the plan.[195]

Thus, substituting generics with differing look-and-feel subject to trade dress protections implicates poorer health outcomes. Nonadherence to medication is shown to be related to a patient's ability to identify the medication based on the color of the pill and health literacy.[196] Due to the number of generic medications on the market and the prevalence of generic substitutions by physicians and pharmacists, patients are exposed to medications of bioequivalence that differ in physical appearance.[197] The difference in appearance casts doubt on a patient's perception of efficacy, which contributes to nonadherence and potential adverse outcomes.[198]

These studies suggest that modifying the current FDA regulations to prohibit or limit drug manufacturers from claiming trade dress protection on the appearance of drugs could lead to more consistent adherence to drug therapies by improving patient confidence in the safety and efficacy of prescription drugs.

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[190] Lenahan et al., *supra* note 7, at 35.
[191] *Id.*
[192] Yin et al., *supra* note 170, at 2.
[193] *Id.*
[194] *Id.* at 3.
[195] *Id.* at 7.
[196] Leslie R. Martin, Summer L. Williams, Kelly B. Haskard & M. Robin Dimatteo, *The Challenge of Patient Adherence*, 1 THERAPEUTICS & CLINICAL RISK MGMT. 189 (2005); Kesselheim et al., *supra* note 171, at 96.
[197] Kesselheim et al., *supra* note 171, at 96.
[198] Kesselheim et al., *supra* note 26, at 206.

C. Trade Dress and Medication Error

Regulatory authorities, including the FDA, have long known that aspects of prescription drugs (including pill shape and packaging) potentially impact rates of medication error, defined as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer."[199] In guidance released in 2013, the FDA acknowledged that packaging trade dress could make it difficult for healthcare professionals, caregivers, and/or patients to readily locate and understand critical safety information.[200] The guidance encouraged pharmaceutical firms to avoid or minimize the use of corporate trade dress that could make it difficult for end users to distinguish between different medications or different strengths of the same medication.[201]

> For example, the FDA recommends that the container label size should not be too small and should feature text sizes that are easy to read. The Guidance goes so far as to almost dictate a 12-point sans serif font size (such as Arial) to improve readability of pharmaceutical labels. In addition, the FDA seeks to define an acceptable color contrast between the text and the container label background color to afford adequate legibility of the text. Most importantly, the FDA intends to actively discourage the use of logos, bars, stripes, watermark graphics, lines, and symbols on container labels and / or carton labeling because they can distract the reader from important information and add to label clutter. Instead, the Guidance recommends placement of images of tablets and / or capsules on the packaging so patients or caregivers can verify the contents of the container and supposedly reduce medication errors.[202]

Similarly, in 2015, the FDA released guidance on the size, shape, and other physical attributes of tablets and capsules, acknowledging that "differences in

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[199] *Working to Reduce Medication Errors*, FDA, https://www.fda.gov/drugs/information-consumers-and-patients-drugs/working-reduce-medication-errors (last updated Aug. 23, 2019).

[200] U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: SAFETY CONSIDERATIONS FOR CONTAINER LABELS AND CARTON LABELING DESIGN TO MINIMIZE MEDICATION ERRORS: DRAFT GUIDANCE (2013), https://www.fda.gov/media/85879/download.

[201] *Id.*

[202] Hanna Blake, *The FDA's Guidance on Labels and Cartons: Yet Another Attack on Pharmaceutical Trade Dress?*, PHARMAPHORUM (Nov. 11, 2013), https://pharmaphorum.com/views-and-analysis/the-fda-s-guidance-on-labels-and-cartons-yet-another-attack-on-pharmaceutical-trade-dress/.

physical characteristics (e.g., size and shape of the tablet or capsule) may affect patient compliance and acceptability of medication regimens or could lead to medication errors."[203] In both its 2013 and 2015 guidance, the FDA was explicit that the findings were non-binding and have had a correspondingly minimal effect on firm behavior.[204] In other words, the FDA has expressed clear awareness that the size, shape, and color of medications matter (or are arguably "functional") for purposes of patient understanding and avoidance of medication error. That awareness should serve as a basis for judicial interpretations of the law when adjudicating trademark and trade dress claims in the prescription drug context.

III
LEGISLATIVE, REGULATORY, AND JUDICIAL SOLUTIONS TO TRADEMARK AND TRADE DRESS COSTS

This Part addresses legislative, regulatory, and judicial measures that may be taken with respect to trademark and trade dress barriers to producing generic medicines that appear as original drugs, cause less patient confusion, result in less medication error, and allow generics to occupy a larger share of the market, thereby lowering costs. While legislative solutions are always more burdensome, some of the measures below may require changes in the federal Food, Drug & Cosmetics Act. But others may be implemented through existing FDA authorities and the adoption by federal courts of reasoning applied in the Third Circuit's *Shire* decision.

The legislative and regulatory solutions to many of the problems outlined above are available through existing FDA findings and guidance, statutory text, and judicial opinions that address the reach and limits of trademark and trade dress. Legislatively, Jeremy Greene and Aaron Kesselheim have argued that the FDA

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[203] U.S. FOOD & DRUG ADMIN., SIZE, SHAPE, AND OTHER PHYSICAL ATTRIBUTES OF GENERIC TABLETS AND CAPSULES: GUIDANCE FOR INDUSTRY 1 (2015), https://www.fda.gov/media/87344/download.

[204] Katharyn Grant, *FDA Releases Final Guidance for Size, Shape and Other Physical Attributes of Generic Drugs*, NORTON ROSE FULBRIGHT (July 8, 2015), https://www.thebrandprotectionblog.com/fda-releases-final-guidance-for-size-shape-and-other-physical-attributes-of-generic-drugs/ ("Although the FDA had announced in October 2014 that it was concerned that differences in color between brand and generic products could cause patient confusion and decrease drug regimen adherence, the newly released guidance includes no recommendation that generic tablets or capsules should be the same color as the RLD [reference listed (brand) drug]. The FDA's guidance is not binding, and by its own terms, it applies only to new generic drug products submitted to the Office of Generic Drugs via an abbreviated new drug application (ANDA) . . . . [G]eneric drug companies should be careful that their efforts to adhere to FDA guidance do not expose them to trade dress infringement claims.").

could address problems caused by trademark and trade dress by using their existing authority over drug names and applying it to other aspects of drug appearance:

> A first step toward reform would be to include FDA certification of pharmaceutical size, shape, and color in the drug-approval process. For example, a pill's attributes could be proposed by the manufacturer during the original New Drug Application. Currently, such a process occurs for the brand name of the medication; extending it to pill appearance should not require additional legislation. This would create a clear path for generic manufacturers to declare during the ANDA process that their products have similar appearances. Where these drugs do differ (e.g., as in dyes, fillers, or excipients), physicians or pharmacists could still locate manufacturer data from unique identifier codes embossed on pills. Further public health benefits could emerge if the reduction in trade dress helps to combat the physician's persistent use of, and the patient's preference for, costly brands when generic equivalents are available.[205]

For products already on the market, legislation could address the highest priority drug classes where confusion results in nonadherence and impose a color-based scheme, as has already been piloted for inhalers and ophthalmologic products in the United Kingdom and the United States respectively.[206]

Judicially, reform is even more straightforward. There is already federal appellate precedent for acknowledging that the color, size, and shape of drugs affect adherence.[207] Indeed, in *Ives*, analyzed above, the U.S. Supreme Court granted review of the case and, while reaching its conclusion on a different basis, acknowledged that the generic producer had offered a legitimate basis for its imitation of pill appearance.[208] Acknowledging that these aspects of drugs are functional and clarifying the evidentiary burden to reduce uncertainty would disqualify them from trademark and trade dress protection while not obviously rendering them susceptible of other intellectual property protections like patents that would cause higher prices.

These proposals, of course, address only a specific aspect of the nonadherence problem. Legislation at the state and federal levels could do more to address health illiteracy, which has generally accompanied studies of prescription drugs' visual

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[205] Greene & Kesselheim, *supra* note 6, at 87.
[206] *Id.*
[207] Shire U.S. Inc. v. Barr Labs., Inc., 329 F.3d 348, 355-59 (3d Cir. 2003).
[208] Inwood Labs., Inc. v. Ives Labs., Inc. 456 U.S. 844, 857-58 (1982).

effect.[209] Greater communication from healthcare providers to patients using health literacy action plans has shown to improve nonadherence to generic medications. Demand-side policies should be enacted by governments to improve physicians' and patients' perceptions of generic drugs, including discussing the color schemes and appearance of alternatives.

CONCLUSION

Trademark and trade dress impose more costs on patients than the benefit they impart through their purported function of helping patients distinguish different kinds of drugs. This Article has analyzed how current use of trademark and trade dress fuel patient nonadherence to prescription drug regimens, cause medication error, and raises prices. Partial and even complete solutions to some of these problems may be found in existing legal authorities. The FDA has already explicitly acknowledged the confusion that may arise through drug names otherwise protected by trademark and has aggressively used its authority to reject 40% or more of names that may result in nonadherence, patient confusion, and medication errors by both providers and patients. It has further implicitly acknowledged in guidance related problems that pill shape, color, and size may raise with respect to the same patients.

What is more, it appears that the new generation of blockbuster drugs—biologic drugs that treat numerous autoimmune conditions—may be similarly affected by trademark and trade dress. As Michael S. Sinha has carefully analyzed, companies are pairing these injectable and inhalable medicines with devices and delivery systems over which they are also patenting functional and non-functional features.[210] If the law is not clarified, then these next generation drugs may be just as costly as the last generation of small molecule drugs.

To address these problems, the FDA may expand the reach of its authority with respect to manufacturing to certify pharmaceutical size, shape, and color. Federal judges, who almost exclusively review the issues raised by allegedly trademark infringing drugs, could apply persuasive appellate and U.S. Supreme Court authority to find that most features of drugs are functional.

These measures, of course, are limited to the effects of trademark and trade dress protection on patients. In this context, as in many others, there is a great need

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[209] *See, e.g.*, Sandra Vamos, Orkan Okan, Tetine Sentell & Irving Rootman, *Making a Case for "Education for Health Literacy": An International Perspective*, 17 INT'L J. ENV'T RSCH. PUB. HEALTH 1436 (2020), https://doi.org/10.3390/ijerph17041436.

[210] Michael S. Sinha, *Costly Gadgets: Barriers to Market Entry and Price Competition for Generic Drug-Device Combinations in the United States*, 23 MINN. J.L. SCI. & TECH. (forthcoming).

for publicly supported programs that expand health literacy, especially in contexts for which there is already a great deal of evidence as to sources of confusion and nonadherence. But the role of trademark and trade dress protection is relatively straightforward and should be addressed in ways more consistent with better individual and public health outcomes.

NEW YORK UNIVERSITY

JOURNAL OF INTELLECTUAL PROPERTY AND ENTERTAINMENT LAW

VOLUME 11 FALL 2021 NUMBER 2

ANTI-SUIT INJUNCTIONS AND JURISDICTIONAL COMPETITION IN GLOBAL FRAND LITIGATION: THE CASE FOR JUDICIAL RESTRAINT

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The proliferation of international jurisdictional conflicts and competing "anti-suit injunctions" in litigation over the licensing of standards-essential patents has raised concerns among policymakers in the United States, Europe, and China. This Essay recommends that while international bodies develop a more comprehensive, efficient, and transparent methodology for assessing global "fair, reasonable and nondiscriminatory" ("FRAND") royalty rates, national courts voluntarily "stand down" from assessing global FRAND rates and instead limit their assessments to FRAND royalty rates applicable to patents within their own jurisdictions.

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INTRODUCTION

Thanks to the decades-long efforts of international standards development organizations ("SDOs"), today's electronic devices seamlessly communicate and interconnect via widely adopted protocols like 3G/4G/5G, Wi-Fi, Bluetooth, and USB. Because of these standards, markets and supply chains for computers, networking equipment, and communication devices have largely become global. Global product markets, however, also mean global litigation, and disputes over patents covering some of these standards (so-called "standards-essential patents" or "SEPs") are routinely fought in a half-dozen or more jurisdictions around the world.

The crux of many of these disputes is whether the holder of a SEP has honored the commitment that it has made to an SDO to license that SEP to manufacturers of standardized products (often called "implementers") on terms that are "fair, reasonable and nondiscriminatory" ("FRAND"). Because there is no generally accepted definition of FRAND, and SDOs offer little guidance regarding its details, disputes have arisen regarding the royalty rates and other terms that SEP holders must offer to potential licensees in order to comply with their FRAND commitments.[1]

I
NATIONAL VERSUS GLOBAL FRAND RATES

Courts adjudicating FRAND disputes face a dilemma. On the one hand, patents are issued under national law and, by definition, have legal effect only in the issuing jurisdiction. On the other hand, the parties to FRAND disputes are often multinational corporations with operations (and patents) in jurisdictions around the world. Moreover, many of these parties privately negotiate worldwide license agreements to cover their global operations without regard for the particular patents issued in any given country. In resolving a dispute over FRAND royalty rates, a court must thus decide whether to focus only on the patents issued and asserted in its own jurisdiction or to consider the global business relationship between the parties. Even though a national court typically lacks the authority to adjudicate damages with respect to the *infringement* of foreign patents, the fact that FRAND disputes are essentially contractual disputes gives a national court the jurisdictional

[1] *See generally* Jorge L. Contreras, *Global Rate Setting: A Solution for Standards-Essential Patents?*, 94 WASH. L. REV. 701, 713-26 (2019) (describing a range of disputed issues relating to FRAND).

authority to determine a global rate for the portfolio licensed under the agreement in question (as opposed to infringement *damages* for patents in other jurisdictions).[2]

In some cases, courts have limited their assessment of FRAND royalties to the national patents that have been asserted. These cases include *Microsoft v. Motorola*,[3] *In re Innovatio*,[4] *Ericsson v. D-Link*,[5] and *Optis v. Huawei*.[6] In each of these cases, a U.S. district judge or jury determined a FRAND royalty rate and awarded damages to the SEP holder based on valid and infringed U.S. patents.

However, in 2017, the U.K. High Court for Patents ruled in *Unwired Planet v. Huawei*[7] that it was authorized to set the terms of a global FRAND license between the parties, covering not only the SEP holder's U.K. patents, but also foreign patents covered by its FRAND commitment. In that case, the SEP holder, Unwired Planet, had offered a smartphone manufacturer, Huawei, a worldwide license under the asserted SEPs. Huawei argued that it only wished to obtain a license under the U.K. patents that Unwired Planet had asserted, and that Unwired Planet's insistence on a worldwide license was unreasonable.[8] In evaluating the reasonableness of the license offer, the court first observed that the "vast majority" of SEP licenses are granted on a worldwide basis with occasional exclusions.[9] It then observed that both parties were global companies: Unwired Planet held patents in 42 countries, while Huawei had operations in 58 countries.[10] As a result, it concluded that "a licensor and licensee acting reasonably and on a willing basis would agree on a worldwide licence."[11] In contrast, the court reasoned, country-by-country licensing in such a situation would be highly inefficient.[12] Accordingly, the court determined the royalty rates across the globe that would enable Unwired Planet to comply with its FRAND

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[2] For a discussion of the differences between adjudication of patent damages and FRAND royalty rates, see Jorge L. Contreras et al., *The Effect of FRAND Commitments on Patent Remedies*, *in* PATENT REMEDIES AND COMPLEX PRODUCTS: TOWARD A GLOBAL CONSENSUS 160, 161-63 (C. Bradford Biddle et al. eds., 2019).

[3] Microsoft v. Motorola, 2013 U.S. Dist. LEXIS 60233 (W.D. Wash. 2013), *aff'd* 795 F.3d 1024 (9th Cir. 2015) (recognizing the existence of non-U.S. patents but focusing its analysis only on U.S. patents).

[4] *In re* Innovatio IP Ventures, LLC, 2013 U.S. DIST. Lexis 144061 (N.D. Ill. 2013).

[5] Ericsson, Inc. v. D-Link Sys., Inc., 773 F.3d 1201, 1225-29 (Fed. Cir. 2014).

[6] Optis v. Huawei, No. 2:17-cv-123-JRG-RSP, 2018 WL 476054 (E.D. Tex. Jan. 18, 2018).

[7] Unwired Planet Int'l Ltd. v. Huawei Techs. Co. [2017] EWHC (Pat) 711 (Eng.), *aff'd* [2020] UKSC 37.

[8] *Id.* at ¶ 524.

[9] *Id.* at ¶ 534.

[10] *Id.* at ¶ 538.

[11] *Id.* at ¶ 543.

[12] *Id.* at ¶ 543-44 (referring to such a prospect as "madness").

obligation and ruled that Huawei accept a license on these terms or suffer an injunction against the sale of infringing products in the United Kingdom.[13]

A similar approach was taken by the U.S. District Court for the Central District of California in *TCL v. Ericsson*,[14] though that court's global FRAND determination was made with the consent of both parties. Most recently, courts in China have proven willing to assess FRAND royalty rates on a global basis (see below).

The ability of one national court to determine FRAND rates applicable to patents around the world can lead to two forms of a legal "race." First is a "race to the bottom" among jurisdictions—a well-documented phenomenon in which jurisdictions intentionally adapt their rules, procedures, and substantive outlook to attract litigants.[15] Second, differences among jurisdictions are likely to encourage parties to initiate litigation in the jurisdiction most favorable to their positions as quickly as possible, often to foreclose a later suit in a less favorable jurisdiction. This situation is referred to as a "race to judgment" or a "race to the courthouse," which may prematurely drive parties to litigation rather than negotiation or settlement.[16]

II
ANTI-SUIT INJUNCTIONS

An anti-suit injunction ("ASI") is an interlocutory *in personam* remedy issued by a court in one jurisdiction to prohibit a litigant from initiating or continuing parallel litigation in another jurisdiction. While an ASI can bind a party to litigation, it has no binding effect on a foreign court.

ASIs have been issued for centuries in a wide range of commercial, antitrust, and bankruptcy actions.[17] In recent years, however, the most significant use of ASIs has been in connection with global FRAND disputes. For example, a court reviewing

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[13] *Id.* at ¶ 537.

[14] TCL Commc'n Tech. Holdings, Ltd. v. Telefonaktiebolaget LM Ericsson, No. CV 15-2370 JVS(DFMx), 2018 WL 4488286 at *50-52 (C.D. Cal. 2018), *rev'd in part*, *vacated in part*, *and remanded* 943 F.3d 1360 (Fed. Cir. 2019).

[15] *See* Jorge L. Contreras, *The New Extraterritoriality: FRAND Royalties, Anti-Suit Injunctions and the Global Race to the Bottom in Disputes over Standards-Essential Patents*, 25 B.U. J. SCI. & TECH. L. 251, 280-83 (2019).

[16] *See id.* at 283-86.

[17] For an overview and history of the U.S. approach to anti-suit injunctions, see Trevor C. Hartley, *Comity and the Use of Antisuit Injunctions in International Litigation*, 35 AM. J. COMP. L. 487, 489-90 (1987); George A. Bermann, *The Use of Anti-Suit Injunctions in International Litigation*, 28 COLUM. J. TRANSNAT'L. L. 589, 593-94 (1990); S.I. Strong, *Anti-Suit Injunctions in Judicial and Arbitral Procedures in the United States*, 66 AM. J. COMP. L. 153, 155-56 (2018).

a SEP holder's compliance with a FRAND licensing commitment may issue an ASI to prevent the SEP holder from pursuing foreign FRAND rate determination or infringement claims until the first court has completed its adjudication of the licensing terms.

In the United States, courts considering issuing ASIs follow some variant of the three-part framework developed by the Ninth Circuit in *E. & J. Gallo Winery v. Andina Licores*.[18] Under the *Gallo* framework, a court must first determine whether the parties and the issues in the action in which the ASI is sought ("the local action") are functionally equivalent to those in the action sought to be enjoined ("the foreign action"). If so, the court must determine whether resolution of the local action would be dispositive of the foreign action. The court must then assess whether any of the four factors identified by the Fifth Circuit in *In re Unterweser Reederei*[19] are present. These factors include whether the foreign litigation would (1) frustrate a policy of the issuing forum; (2) be vexatious or oppressive; (3) threaten the issuing court's jurisdiction; or (4) prejudice other equitable considerations. If at least one of the *Unterweser* factors is present, the court must ask whether the injunction will have a significant impact on international comity.[20] If not, then the ASI may be issued.

III
ASIs IN FRAND CASES

The first notable ASI in a FRAND case was issued by the U.S. District Court for the Western District of Washington in *Microsoft v. Motorola*,[21] the facts of which are fairly typical. In that case, Microsoft alleged that Motorola breached its commitment to offer Microsoft a FRAND license as required under the rules of two SDOs.[22] As a result, Microsoft sued Motorola for breach of contract in the Western

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[18] E. & J. Gallo Winery v. Andina Licores S.A., 446 F.3d 984, 991 (9th Cir. 2006). *See generally* Strong, *supra* note 17, at 159-64.

[19] *In re* Unterweser Reederei, GmbH, 428 F.2d 888, 890 (5th Cir. 1970), *aff'd on reh'g*, 446 F.2d 907 (5th Cir. 1971), *rev'd on other grounds sub nom.* M/S Bremen v. Zapata Off-Shore Co., 407 U.S. 1 (1972).

[20] Gallo, 446 F.3d at 994 ("Comity is 'the recognition which one nation allows within its territory to the legislative, executive or judicial acts of another nation, having due regard both to international duty and convenience, and to the rights of its own citizens, or of other persons who are under the protection of its laws.'") (quoting Hilton v. Guyot, 159 U.S. 113, 164 (1895)).

[21] Microsoft Corp. v. Motorola, Inc., 871 F. Supp. 2d 1089, 1097 (W.D. Wash. 2012), *aff'd*, 696 F.3d 872 (9th Cir. 2012).

[22] The SDOs in question are the Institute of Electrical and Electronics Engineers Standards Association ("IEEE-SA"), which publishes the 802.11 "Wi-Fi" wireless networking standard, and the International Organization for Standardization ("ISO"), which publishes the H.264 video compression standard.

District of Washington. Six months later, Motorola sued Microsoft for patent infringement in Germany. The German court found infringement and enjoined Microsoft from selling infringing products in Germany. In response, Microsoft sought an ASI from the U.S. court to prevent Motorola from enforcing the German injunction until the resolution of the U.S. action. Finding that the resolution of the U.S. matter would dispose of the German matter (i.e., if Motorola were found to have breached its FRAND obligations, then Motorola would not be entitled to seek injunctive relief against Microsoft in any jurisdiction, including Germany), the U.S. court entered the ASI against Motorola. On appeal, the Ninth Circuit affirmed.

Several other ASI actions followed in U.S. FRAND cases, including *Vringo v. ZTE*,[23] *TCL v. Ericsson*,[24] *Apple v. Qualcomm*,[25] *Optis v. Huawei*,[26] and *Huawei v. Samsung*.[27] The courts granted ASIs in about half of these cases (see Table 1).[28]

A. Anti-Anti-Suit Injunctions

By 2018, international litigants and courts began to resist the imposition of ASIs by U.S. courts through anti-anti-suit injunctions ("AASIs"). Like an ASI, an AASI operates *in personam*, prohibiting a litigant from taking a particular action (seeking or enforcing an ASI), rather than purporting to restrain the authority of a foreign court.[29]

In *IPCom v. Lenovo*,[30] a U.S. district court granted an ASI preventing IPCom from pursuing parallel infringement litigation against Lenovo outside the United States. In response, IPCom brought an action in France seeking to prevent Lenovo from enforcing the U.S. ASI. The French court granted the AASI, holding that, except under certain circumstances, ASIs are contrary to French *ordre public* and

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[23] Vringo, Inc. v. ZTE Corp., No. 14-cv-4988 (LAK), 2015 WL 3498634, at *1 (S.D.N.Y. June 3, 2015).

[24] TCL Commc'n Tech. Holdings v. Telefonaktienbolaget LM Ericsson, No. 8:14-cv-00341-JVS-AN, 2015 U.S. Dist. LEXIS 191512, at *10 (C.D. Cal. Jun. 29, 2015).

[25] Order Denying Anti-Suit Injunction, at 5-6, Apple Inc. v. Qualcomm Inc., No. 3:17-cv-00108-GPC-MDD (S.D. Cal. Sep. 7, 2017).

[26] Order, Optis Wireless Tech., LLC v. Huawei Techs. Co., No. 2:17-Cv-00123-JRG-RSP (E.D. Tex. May 14, 2018).

[27] Order Granting Samsung's Motion for Antisuit Injunction, Huawei Techs. Co. v. Samsung Elecs. Co., No 3:16-cv-02787-WHO (N.D. Cal. Apr. 13, 2018).

[28] For a summary of the facts and holdings of these cases, see Contreras, *supra* note 15, at 265-78.

[29] The leading U.S. case regarding AASIs is Laker Airways Ltd. v. Sabena, Belgian World Airlines, 731 F.2d 909 (D.C. Cir. 1984). *See* Alexander Shaknes, *Anti-Suit and Anti-Anti-Suit Injunctions in Multi-Jurisdictional Proceedings*, 21 NYSBA INT'L L. PRACTICUM 96, 100 (2008).

[30] Lenovo (U.S.) Inc. v. IPCom GmbH & Co., No. 19-1389 (N.D. Cal. Mar. 19, 2019).

"seeking an anti-suit injunction—such as the one pursued by Lenovo in California—would infringe upon IPCom's fundamental rights pursuant to French laws . . . ."[31] A U.K. court also issued an AASI in favor of IPCom, reasoning that "it would be vexatious and oppressive to IPCom if it were deprived entirely of its right to litigate infringement and validity of [its U.K. patent]."[32]

A German court responded similarly in *Continental v. Avanci*,[33] issuing an AASI to prevent the enforcement of a U.S. ASI that sought to prevent a number of SEP holders from pursuing litigation in Germany. The German court found that the requested ASI would have been incompatible with German law.[34]

B. China Takes Center Stage

Though Chinese judicial actions have been the targets of ASI motions in U.S. cases since at least 2015, it wasn't until 2020 that Chinese courts began to issue ASIs of their own. Then, during the course of 2020 alone, Chinese courts issued an unprecedented four ASIs in major FRAND cases.

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[31] Tribunal de grande instance [TGI] [Paris Court of First Instance] Paris, Nov. 8, 2019, 19/59311, *aff'd* Cour d'appel [CA] [Court of Appeal of Paris] Paris, Mar. 3, 2020, 19/21426. An English translation is available at http://caselaw.4ipcouncil.com/french-court-decisions/ipcom-v-lenovo-court-appeal-paris-rg-1921426; *see also* Enrico Bonadio & Luke McDonagh, *Paris Court Grants a SEP Anti-Anti-Suit Injunction in IPCom v Lenovo: A Worrying Decision in Uncertain Times?*, J. INTELL. PROP. L. & PRAC. (forthcoming).

[32] IPCom GmbH & Co. v. Lenovo Tech. (U.K.) Ltd. [2019] EWHC 3030 (Pat) 52 (Eng.).

[33] Cont'l Auto. Sys., Inc. v. Avanci LLC, No. 19-cv-2520 (N.D. Cal. Jun. 12, 2019).

[34] Landgericht München I, Oct. 11, 2019, 21 O 9333/19, https://www.gesetze-bayern.de/Content/Document/Y-300-Z-BECKRS-B-2019-N-25536?hl=true; Landgericht München I, Dec. 12, 2019, 21 O 9512/19, https://www.gesetze-bayern.de/Content/Document/Y-300-Z-BECKRS-B-2019-N-%2033196?hl=true&AspxAutoDetectCookieSupport=1.

Three of these cases—*Conversant v. Huawei*,[35] *InterDigital v. Xiaomi*,[36] and *OPPO v. Sharp*[37]—involved a non-Chinese company's assertion of SEPs against a Chinese manufacturer. In each case, a Chinese court granted an ASI requested by the Chinese manufacturer, enjoining parallel actions in Germany (*Conversant*), Germany and India (*InterDigital*), and Germany, Japan, and Taiwan (*OPPO*).[38] In all three cases, the Chinese court imposed a penalty of 1 million yuan (approximately US$150,000) per day for any violation of the ASI.[39] In response to these Chinese ASIs, courts in Germany[40] and India[41] issued AASIs.

Unlike the other three Chinese cases, *Ericsson v. Samsung*[42] did not involve a Chinese party (Ericsson is Swedish, and Samsung is South Korean). The case related to an existing SEP cross-license between Samsung and Ericsson that was due to expire at the end of 2020. On December 7, Samsung sought a FRAND royalty rate

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[35] Huawei Techs. Corp. v. Conversant Wireless Licensing S.A.R.L. (2019) Zui Gao Fa Zhi Min Zhong No. 732, 733, 734 Part I (Sup. People's Ct. Aug. 28, 2020). An unofficial English translation is available at https://patentlyo.com/media/2020/10/Huawei-V.-Conversant-judgment-translated-10-17-2020.pdf. For a more detailed discussion, see Yang Yu & Jorge L. Contreras, *Will China's New Anti-Suit Injunctions Shift the Balance of Global FRAND Litigation?*, PATENTLY-O BLOG (Oct. 22, 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3725921.

[36] Xiaomi Commc'n Tech. Co. v. InterDigital Inc. (2020) E 01 Zhi Min Chu 169 (Wuhan Interm. People's Ct. Sept. 23, 2020). An unofficial English translation is available at https://patentlyo.com/media/2020/10/Xiaomi-v.-InterDigital-decision-trans-10-17-2020.pdf. For a more detailed discussion, see Yu & Contreras, *supra* note 35.

[37] Guangdong OPPO Mobile Telecomm. Corp. v. Sharp Corp. (2020) Yue 03 Min Chu No.689-1 (Shenzhen Intermed. People's Ct. Dec. 3, 2020). The Supreme People's Court upheld the Shenzhen ruling on Sept. 2, 2021. *See* Bing Zhao, *Chinese Judges Can Set Global SEP Rates and Licence Terms, Supreme People's Court Confirms*, IAM (Sep. 2, 2021), https://www.iam-media.com/frandseps/chinese-courts-can-set-global-sep-rate-and-licensing-terms-spc-confirms.

[38] *See* Zeyu Huang, *The Latest Development on Anti-Suit Injunction Wielded by Chinese Courts to Restrain Foreign Parallel Proceedings*, CONFLICT LAWS.NET (July 9, 2021), https://conflictoflaws.net/2021/the-latest-development-on-anti-suit-injunction-wielded-by-chinese-courts-to-restrain-foreign-parallel-proceedings/ (discussing the ASIs in *Conversant* and *OPPO*); Gregory Glass, *Delhi High Court Confirms India's First Anti-Anti-Suit Injunction*, ASIA IP (May 13, 2021), https://asiaiplaw.com/article/delhi-high-court-confirms-indias-first-anti-anti-suit-injunction (discussing the ASI in *InterDigital*).

[39] *See* Huang, *supra* note 38; Glass, *supra* note 38.

[40] *See* Huang, *supra* note 38; Mathieu Klos, *Munich Court Confirms AAAASI in SEP Battle Between InterDigital and Xiaomi*, JUVE PAT. (Feb. 26, 2021), https://www.juve-patent.com/news-and-stories/cases/munich-court-confirms-aaaasi-in-sep-battle-between-interdigital-and-xiaomi/.

[41] *See* Glass, *supra* note 38.

[42] Samsung Elecs. Co. v. Telefonaktiebolaget LM Ericsson (2020) E 01 Zhi Min Chu No. 743 (Wuhan Interm. People's Ct. Dec. 25, 2020) (China).

determination for Ericsson's SEPs in the Wuhan Intermediate People's Court. On December 11, Ericsson sued Samsung for infringement in the Eastern District of Texas. In response, Samsung asked the Wuhan court for an ASI preventing Ericsson from seeking relief in the United States. On December 25, the Wuhan court issued the ASI, which also prohibited Ericsson from seeking to negate the ASI in Texas (i.e., an "AAASI"). The Texas court quickly issued a temporary restraining order and then a preliminary injunction, prohibiting Samsung's enforcement of the Wuhan ASI and requiring Samsung to indemnify Ericsson against any penalties imposed by the Wuhan court.[43] *Ericsson v. Samsung* is a particularly salient example of forum shopping in FRAND cases, as both parties sought to litigate in jurisdictions other than their "home" jurisdictions, presumably due to the advantages that they perceived in the laws and procedures of those jurisdictions.

In response to the growing popularity of ASIs in China, courts in Europe have begun issuing pre-emptive AASIs to prevent litigants from seeking and enforcing ASIs issued by Chinese courts. In two recent cases, *IPBridge v. Huawei* and *Philips, General Electric and Mitsubishi Electric v. Xiamoi*, German courts in Düsseldorf and Munich have granted pre-emptive AASIs prohibiting Chinese parties from seeking ASIs in China before any such ASIs have been sought.[44]

The remarkably rapid actions and counter-actions in all of these cases exemplify the "race to the courthouse" discussed above.

[43] Memorandum Opinion and Preliminary Injunction, Ericsson Inc. v. Samsung Elecs. Co., No. 2:20-CV-00380-JRG, 2021 WL 89980 (E.D. Tex. Jan. 11, 2021).

[44] LG Düsseldorf, July 15, 2021, 4c O 73/20 openJur (Ger.); LG Düsseldorf, July 15, 2021, 4c O 74/20 openJur (Ger.); LG Düsseldorf, 4c O 75/20 openJur (Ger.); LG Munich, June 24, 2021, 7 O 36/21 openJur (Ger.).

Table 1: Summary of Anti-Suit Injunctions and Anti-Anti-Suit Injunctions Issued in FRAND Cases

Case	Year	1st Juris.	Foreign Juris.	ASI Granted	AASI Issued
Microsoft v. Motorola	2012	US	DE	Yes	N/A
Vringo v. ZTE	2015	US	CN	No	N/A
TCL v. Ericsson	2015	US	FR,BR, RU, UK, DE, AR	Yes	N/A
Apple v. Qualcomm	2017	US	UK, JP, CN, TW	No	N/A
Conversant v. Huawei and ZTE	2018	UK	CN	Yes*	N/A
Optis v. Huawei	2018	US	CN	No	N/A
Huawei v. Samsung	2018	US	CN	Yes	N/A
Continental v. Avanci	2019	US	DE	N/A	DE
IPCom v. Lenovo	2019	US	UK, FR	N/A	UK, FR
Conversant v. Huawei	2020	CN	DE	Yes	N/A
InterDigital v. Xiaomi	2020	CN	IN, DE	Yes	IN, DE
Oppo v. Sharp	2020	CN	JP, DE, TW	Yes	DE
Ericsson v. Samsung	2020	CN	US	Yes	US
IPBridge v. Huawei	2021	CN	DE	N/A	DE
Philips, GE, Mitsubishi v. Xiaomi	2021	CN	DE	N/A	DE
Ericsson v. Apple	2021	US	NL	N/A	No

IV
CONCERN FROM POLICYMAKERS

The complexity, cost, and unpredictability of high-stakes global FRAND disputes have increased markedly with the introduction of ASIs, AASIs, and AAASIs, and policymakers around the world have taken notice. For example, the U.S. Trade Representative, in her *2021 Special 301 Report*, specifically identified China's increased use of ASIs as "worrying" in the context of international trade.[45] In its *Intellectual Property Action Plan*, the European Commission observed that "very broad extraterritorial anti-suit injunctions" are particularly challenging to European companies operating internationally.[46] In July 2021, the European Union issued a formal request for information to China under Section 63.3 of the

[45] OFF. OF THE U.S. TRADE REP., 2021 SPECIAL 301 REPORT 40 (2021).

[46] EUR. COMM'N, COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE ON THE REGIONS (2020).

Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"), asking for clarification, among other things, regarding the legal basis for blocking the enforcement of European actions in *Conversant* and *OPPO*.[47]

Despite these expressions of concern, strategic races to the courthouse will likely continue until a more rational, transparent, and comprehensive system for determining FRAND royalty rates is established. In the past, I have proposed a number of potential solutions to the FRAND litigation race and the inefficient, non-transparent, and inconsistent negotiation of FRAND royalties, including the use of interpleader to determine aggregate FRAND royalty rates in a single proceeding that involves all interested parties,[48] the collective negotiation of aggregate royalty rates applicable to a particular standard,[49] and the establishment of a non-governmental FRAND rate-setting tribunal.[50] Professor Thomas Cotter has suggested that national governments seek to develop consensus, or at least best practices, around certain contentious FRAND calculation issues, which could alleviate "race to the bottom" concerns that arise from current jurisdictional differences.[51] Additionally, the European Commission's Expert Group on Standards Essential Patents has made a range of proposals, both substantive and procedural.[52] Yet, each of these reforms will take time to develop, enact, and implement. So, what should be done in the meantime to stem the increasing incidence of jurisdictional clashes in global FRAND litigation?

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[47] Communication from the European Union to China, *Request for Information Pursuant to Article 63.3 of the TRIPS Agreement*, WTO Doc. IP/C/W/682 (July 6, 2021); *see* Jacob Schindler, *China Brushes Off EU Request for More Information on Controversial SEP Decisions*, INTELL. ASSET MGT. (Sept. 8, 2021), https://www.iam-media.com/frandseps/china-brushes-eu-request-more-information-controversial-sep-decisions.

[48] Jason R. Bartlett & Jorge L. Contreras, *Rationalizing FRAND Royalties: Can Interpleader Save the Internet of Things?*, 36 REV. LITIG. 285 (2017).

[49] Jorge L. Contreras, *Fixing FRAND: A Pseudo-Pool Approach to Standards-Based Patent Licensing*, 79 ANTITRUST L.J. 47 (2013); Jorge L. Contreras, *Aggregated Royalties for Top-Down FRAND Determinations: Revisiting 'Joint Negotiation,'* 62 ANTITRUST BULL. 690 (2017).

[50] Contreras, *supra* note 1.

[51] Thomas F. Cotter, *Is Global FRAND Litigation Spinning Out of Control?*, 2021 PATENTLY-O L.J. 1, 24 (2021). Cotter also suggests that governments "devote more effort to developing the sort of empirical evidence that would enhance rational decisionmaking with regard to SEPs and FRAND." *Id.*

[52] SEPS EXPERT GROUP, CONTRIBUTION TO THE DEBATE ON SEPS (2021).

V
JUDICIAL RESTRAINT AND FRAND LITIGATION

As noted above, a court confronted with a global FRAND case has two basic choices. It may determine FRAND royalty rates associated with the national patents issued in its jurisdiction, or it may determine the FRAND royalty rates applicable around the world. The latter option, pioneered by the U.K. courts in *Unwired Planet* and now embraced by courts in the United States and China, has led to the jurisdictional competition exemplified by the cases discussed above. It is the first option—a court's assessment of royalty rates applicable to patents issued in its own jurisdiction—that will eliminate costly and chaotic jockeying among jurisdictions and parties. This approach was adequate for the "first generation" of FRAND royalty determination cases (e.g., *Innovatio* and *D-Link*, discussed above) and is grounded in judicial restraint and international comity.

Thus, while courts around the world may have the legal *authority* to determine global FRAND rates as incidental to contractual commitments, doing so may not be in the best interests of the parties or the market. Accordingly, courts that are considering FRAND cases should *voluntarily refrain* from determining global FRAND rates and instead limit their determinations to royalty rates for patents issued in their own jurisdictions, at least until a more effective global system is in place to assess FRAND rates on a comprehensive basis.

While some predict that such a voluntary relinquishment of global rate-setting authority could result in FRAND rates that vary from jurisdiction to jurisdiction,[53] this is *not* an undesirable result given that patent portfolios, substantive patent laws, and product markets also vary from country to country. Moreover, the inconsistency that individual parties may experience by having FRAND rates vary from country to country may, in fact, lend *greater* consistency to the global FRAND licensing market, as it will eliminate the extreme variations in global FRAND rates that occur from party to party. National patent royalty rates are the norm in patent disputes. The fact that parties may privately negotiate blanket royalty rates in global license agreements—the underlying motivation for the U.K. court's decision to set global rates in *Unwired Planet*—does not change the national character of patent law. Until patent law is unified through a single, global system (an unlikely prospect for the

[53] *See* Richard Vary, *Samsung v Ericsson and Why Anti-Anti-Suit Injunctions Are a Dead End*, IAM (Mar. 17, 2021), https://www.iam-media.com/frandseps/samsung-v-ericsson-and-why-anti-anti-suit-injunctions-are-dead-end.

foreseeable future), courts will, and should, continue to adjudicate patent remedies on a national basis.[54]

There are numerous ways to coordinate international judicial activity to achieve such an accord. The most direct route would be a formal treaty agreement. However, treaty negotiations are time-consuming and politically fraught. Less formal approaches may thus be more expedient in this context. Judges from around the world meet regularly at events sponsored by the International Bar Association, the American Bar Association International Law Section, and other groups. The U.S.-based Judicial Conference Committee on International Judicial Relations coordinates interactions between members of the U.S. judiciary and foreign judicial systems,[55] the American Law Institute has developed a comprehensive set of principles governing jurisdiction, choice of law, and judgments in transnational disputes,[56] and the World Intellectual Property Organization is coordinating an international effort on patent case adjudication in which, among others, the Chinese courts are currently participating.[57] Any of these organizations or fora could serve as a focal point for much-needed harmonization of judicial practices regarding global FRAND disputes.

CONCLUSION

The proliferation of international jurisdictional conflicts and competing anti-suit injunctions in FRAND litigation has raised legitimate concerns among policymakers around the world. Such conflicts have already resulted in the predicted "race to the courthouse" and "race to the bottom" in FRAND disputes with no end in sight. This Essay suggests that, in order to give international bodies time to develop a more comprehensive, efficient, and transparent methodology for resolving FRAND licensing disputes, national courts should voluntarily "stand down" from assessing global FRAND royalty rates and instead limit their adjudication to

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[54] *See id.*

[55] *See* Sam F. Halabi & Hon. Nanette K. Laughrey, *Understanding the Judicial Conference Committee on International Judicial Relations*, 99 MARQ. L. REV. 239 (2015).

[56] AM. LAW. INST., INTELLECTUAL PROPERTY: PRINCIPLES GOVERNING JURISDICTION, CHOICE OF LAW, AND JUDGMENTS IN TRANSNATIONAL DISPUTES (2008); *see also* Rochelle Dreyfuss, *The ALI Principles on Transnational Intellectual Property Disputes: Why Invite Conflicts?*, 30 BROOK. J. INT'L L. 819, 820-26 (2005) (discussing the motivation for the American Law Institute's principles and drafting status); Graeme B. Dinwoodie, *Developing a Private International Intellectual Property Law: The Demise of Territoriality?*, 51 WM. & MARY L. REV. 711, 720-21 (2009) (discussing the impact of the American Law Institute's principles).

[57] *See* Mark Cohen, *Three SPC Reports Document China's Drive to Increase Its Global Role on IP Adjudication*, CHINA IPR (May 5, 2021), https://chinaipr.com/2021/05/05/three-spc-reports-document-chinas-drive-to-increase-its-global-role-on-ip-adjudication/.

royalties covering patents issued within their own jurisdictions. While such a limitation on judicial authority is not mandated by national law or international agreement, this modest exercise of judicial restraint could clear the way for these important issues to be resolved in a more rational, transparent, and balanced manner.