
THE COLUMBIA
SCIENCE & TECHNOLOGY
LAW REVIEW

VOLUME XXIV

STLR.ORG

SPRING 2023

ARTICLE

NOTICING PATENTS

John R. Thomas*

Patents take the form of public letters that the U.S. Patent and Trademark Office (USPTO) actively disseminates. Whether these documents sufficiently provide the public with notice of the technologies they describe, as well as the proprietary rights that they assert, has been subject to long-standing debate. Many commentators conclude that patents are often filed too early in the research and development cycle, are deliberately drafted in a vague or obtuse manner, or are simply too numerous. As a result, identifying the relevant patent landscape is not just difficult for technology implementers, but possibly undesirable as a matter of innovation policy. Yet prior scholarship has seldom acknowledged current statutory mechanisms to improve the notice function of patents after they issue. This Article endeavors to fill that gap.

Congress has long encouraged intellectual property rights holders to identify their patents on the products they sell. Patent marking has traditionally occurred on physical products or their packaging, although it has been recently extended to Internet-based virtual marking. The marking statute stipulates that patent proprietors that fail to mark face severe remedial restrictions when challenging infringers. Congress has assigned the Food & Drug Administration (FDA) a part in providing patent notice as well. In keeping with federal legislation, the agency maintains two publications, commonly known as the Orange and Purple Books, that act as a patent clearinghouse for approved drugs and licensed biologics.

* Professor of Law, Georgetown University. I thank participants at the 2022 Intellectual Property Scholars Conference for their helpful observations.

The role of a patent within the marketplace provides perhaps the most valuable form of notice that that instrument may offer. Yet the marking statute and FDA publications suffer from some apparent flaws. In combination they project a failure to identify all patents that are relevant to the product, favor patent trolls, involve dubious practical workings, promote misleading advertising, and impose punitive sanctions in comparison to the notice requirements of peer intellectual property rights. For its part, the FDA has proven an untutored and unreliable patent publicist for the past four decades.

This Article offers specific suggestions to improve the notice functions of patents after they issue. It calls for the USPTO to develop and populate its own virtual marking database that correlates individual patents with the marketplace. It also encourages the FDA to take further steps to counter abuses of the Orange and Purple Books and to accelerate their patent notice functions. Finally, this Article takes broader lessons from this effort, offering pathways for policymakers to look beyond the patent instrument as they endeavor to improve the patent system's notice functions.

I.	INTRODUCTION.....	301
II.	INNOVATION POLICY AND PATENT NOTICE	305
III.	THE STATUTORY PATENT NOTICE SYSTEMS	307
	<i>A. Physical Marking</i>	310
	<i>B. Virtual Marking</i>	314
	<i>C. The Orange Book</i>	315
	<i>D. The Purple Book</i>	321
IV.	SHORTCOMINGS OF THE STATUTORY NOTICE SYSTEMS	323
	<i>A. Circumscribed Scope</i>	323
	<i>B. Product-Patent Misalignment</i>	325
	<i>C. Favoring Trolls</i>	327
	<i>D. Harsh Consequences for the Rights Holder</i>	328
	<i>E. Unnecessary and Misleading Communication</i>	331
	<i>F. Costs to the Private Sector</i>	334
	<i>G. Cost-Shifting by the FDA</i>	335
	<i>H. The Problem of Patent Use Codes</i>	337
V.	REFORMING THE MARKING STATUTE.....	339
VI.	REFORMING THE FDA PUBLICATIONS	342
	<i>A. Initial Orange Book Patent Listings</i>	342
	<i>B. Resolution of Orange Book Patent Listing Disputes</i>	343
	<i>C. Eliminating Use Codes</i>	344
	<i>D. Updating the Orange and Purple Books</i>	345
VII.	CONCLUSION	346

I. INTRODUCTION

Patents take the form of public letters that the U.S. Patent and Trademark Office (USPTO) actively disseminates.¹ That patents are readily and freely available makes good sense as a matter of innovation policy. After all, public disclosure of the claimed invention, in exchange for proprietary rights, forms the fundamental bargain that animates the patent system.²

Many commentators nonetheless believe that patents do not do a particularly good job of disclosing technical information.³ Patents are said to be drafted in an obtuse or vague fashion,⁴ making them difficult for technical personnel to parse. Because the patent system encourages inventors to file applications early in the research and development cycle, patents may not neatly pair with commercialized technologies.⁵ Evaluating whether patents are not invalid and infringed may be an uncertain and costly matter, an issue exacerbated by the explosion in the number of issued patents and the increasing technical complexity of products.⁶ These circumstances may lead to information costs that render patent clearance not just difficult but undesirable as a matter of innovation policy.⁷

Most of the scholarly discussion of patent notice policies focuses upon the extent to which they are fulfilled by patent documents themselves.⁸ Less attention has been paid to how Congress has endeavored to serve these policies beyond the

¹ 35 U.S.C. § 12. See *Subcomm. on Patents, Trademarks, and Copyrights of the S. Comm on the Judiciary, 85th Cong., An Economic Review of the Patent System* 1 (Comm. Print 1958) (describing the term “patent” as being derived from the phrases “open letter” or “letters patent,” which are literal translations of the Latin phrase *litterae patentēs*).

² See, e.g., Alan Devlin, *The Misunderstood Function of Disclosure in Patent Law*, 23 HARV. J.L. TECH. 401, 407 (2010); *Blanchard v. Sprague*, 3 F.Cas. 648, 650 (C.C.D. Mass. 1839) (observing that patents should secure “to the whole community great advantages from the free communication of secrets, and processes, and machinery . . .”). But see Shubha Ghosh, *Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor After Eldred*, 19 BERKELEY TECH. L.J. 1315 (2004) (contesting the patent bargain metaphor).

³ See, e.g., Timothy R. Holbrook, *Patent Disclosures and Time*, 69 VAND. L. REV. 1459 (2016); J. Jonas Anderson, *Nontechnical Disclosure*, 69 VAND. L. REV. 1583 (2016); Jeanne C. Fromer, *Dynamic Patent Disclosure*, 69 VAND. L. REV. 1715 (2016); Colleen V. Chien, *Contextualizing Patent Disclosure*, 69 VAND. L. REV. 1849 (2016); John R. Allison & Lisa Larrimore Oullette, *How Courts Adjudicate Patent Definiteness and Disclosure*, 65 DUKE L.J. 609 (2016); Jason Rantanen, *Patent Law’s Disclosure Requirement*, 45 LOY. UNIV. CHI. L.J. 369 (2013); Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539 (2009).

⁴ See Colleen V. Chien, *Contextualizing Patent Disclosure*, 69 VAND. L. REV. 1849, 1851 (2016); *Brenner v. Manson*, 383 U.S. 519, 534 (1966) (taking note of “the highly developed art of drafting patent claims so that they disclose as little useful information as possible—while broadening the scope of the claim as widely as possible . . .”).

⁵ Chien, *supra* note 3, at 1852.

⁶ William F. Lee & A. Douglas Melamed, *Breaking the Vicious Cycle of Patent Damages*, 101 CORNELL L. REV. 385 (2016).

⁷ *Id.*

⁸ See *supra* note 3.

patent instrument.⁹ In particular, few have considered long-standing congressional incentives encouraging technology implementers to identify their patents on the products they sell.¹⁰ The encouragement takes the form of the so-called “marking” statute, which calls for the placement of relevant patent numbers on individual products or, where that is impracticable, on their packaging.¹¹ Although Congress has recently allowed patentees to identify patents via websites rather than physical marking,¹² technology implementers that do not mark either physically or virtually face severe remedial restrictions.¹³

Congress has also established two additional systems of patent notice maintained by the Food and Drug Administration (FDA). That agency publishes two compendia, commonly known as the Orange and Purple Books,¹⁴ that correlate patents with approved small-molecule drugs and licensed biologics. The FDA passively administers these texts by merely listing patents identified by the sponsor of the drug or biologic in the appropriate volume.¹⁵ The Orange and Purple Books assist manufacturers to identify patents that might limit the availability of generic drugs and follow-on biologics. Orange Book listings hold significant procedural implications as well, for they may trigger an elaborate, specialized pharmaceutical patent dispute resolution system.¹⁶

The role of a patent within the marketplace provides perhaps the most valuable form of notice that may be offered. Congress arguably shares this view, as it has recently enacted legislation impacting each of the notice statutes.¹⁷ Yet the

⁹ Some commentators have focused attention upon the patent recording statute, which allows interested parties to discern the ownership of a particular patent. *See, e.g.*, Jonathan Stroud & Levi Lall, *Paper of Record: Modernizing Ownership Disclosure for U.S. Patents*, 124 W. VA. L. REV. 449 (2022).

¹⁰ One such piece is Jessica S. Siegel, *The Patent Marking & Notice Statute: Invitation to Infringe or Protection for the Unwary?*, 36 HOUS. L. REV. 583, 591–93 (1999).

¹¹ 35 U.S.C. § 287(a).

¹² Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 16, 125 Stat. 284, 328–39 (2011) (“AIA”). *See, e.g.*, Corey McCaffrey, *The Virtues of Virtual Marking*, 105 NW. UNIV. L. REV. 367 (2011).

¹³ 35 U.S.C. § 287(a).

¹⁴ The term “Orange Book” is the informal name for *Approved Drug Products with Therapeutic Equivalence Evaluations*. *See, e.g.*, *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, 24 F.4th 1354, 1361 (Fed. Cir. 2022). The other FDA publication noted here, *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, is commonly known as the “Purple Book.” *See, e.g.*, *Sandoz, Inc. v. Amgen, Inc.*, 773 F.3d 1274, 1280 (Fed. Cir. 2014).

¹⁵ *See* Rebecca S. Eisenberg & Daniel A. Crane, *Patent Punting: How FDA and Antitrust Courts Under the Hatch-Waxman Act to Avoid Dealing with Patents*, 21 MICH. TELECOMM. TECH. L. REV. 197 (2015).

¹⁶ *See* 35 U.S.C. § 271(e)(2). These proceedings occur under the Hatch-Waxman Act, which is more formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 84-417, 98 Stat. 1585 (1984).

¹⁷ Orange Book Transparency Act, Pub. L. No. 116-290, 134 Stat. 4889 (2021); Purple Book Continuity Act (housed the Consolidated Appropriations Act, Pub. L. No. 116-260, § 325, 134 Stat. 1182, 2936–38 (2020)); Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

academic literature directed to the marking statute and two FDA publications remains scant. This Article endeavors to fill this gap by subjecting them to closer scrutiny. The results of this review should not surprise anyone concerned about the proper working of the patent system's disclosure functions. The notice statutes demonstrate questionable practical workings, unwelcome consequences, and indifferent administration; and ultimately need for reform.

For its part, the marking statute is based in part upon an astonishingly implausible justification—that technology implementers that sell unmarked products do so with an intent to mislead the public.¹⁸ It also operates in a warped manner. The marking statute projects an incomplete patent landscape and favors nonpracticing entities, for it applies neither to patented processes¹⁹ nor to enterprises that do not practice their patented inventions.²⁰ Unfamiliar with the standards of patentability and the operations of the USPTO, consumers also appear to be indifferent to, or possibly misled by, patent markings.²¹ Either outcome casts doubt upon the utility of patent marking for its primary audience.

Even for more sophisticated observers, the value of marking also seems doubtful, particularly when compared to its costs. Marking is of dubious relevance to infringement determinations; after all, the infringement inquiry does not set products side by side, but rather compares the specific wording of patent claims with accused products.²² The administrative burdens of physically stamping, labeling, embossing, or otherwise marking products or packaging with patent numbers may be considerable.²³ One also wonders what steps the patent proprietor has taken prior to marking to construe its claims and conduct an infringement analysis with respect to its own product—a potentially costly endeavor that serves no other purpose. And to the extent that peer intellectual property systems provide

¹⁸ *Wine Ry. Appliance Co. v. Enterprise Ry. Equip. Co.*, 297 U.S. 387, 398 (1936) (“Under the interpretation which we accept, [the marking statute] provides protection against deception by unmarked patented articles”); *Arctic Cat, Inc. v. Bombardier Recreational Prods., Inc.*, 950 F.3d 860, 865 (Fed. Cir. 2020) (“In Arctic Cat’s view, § 287 should be read to allow a patentee to mislead others that they are free to make and sell an article that is actually patented, but nonetheless allow the patentee to recover damages without undertaking any corrective action. We reject this view.”).

¹⁹ *Hanson v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1082 (Fed. Cir. 1983); *Bandag, Inc. v. Gerrard Tire Co., Inc.*, 704 F.2d 1578, 1581 (Fed. Cir. 1983).

²⁰ Carl Oppendahl, *Patent Marking of Systems*, 11 SANTA CLARA HIGH TECH. L.J. 205, 210 (1995).

²¹ See Christopher A. Cotropia, *Patents as Signals of Quality in Crowdfunding*, 2021 UNIV. ILL. L. REV. 193.

²² See, e.g., *Myco Indus., Inc. v. BlephEx, LLC*, 955 F.3d 1, 15 (Fed. Cir. 2020) (“The law is clear . . . that ‘infringement is determined on the basis of the claims, not on the basis of a comparison with the patentee’s commercial embodiment of the claimed invention.’”) (citation omitted); *Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994) (“As we have repeatedly said, it is error for a court to compare in its infringement analysis the accused product or process with the patentee’s commercial embodiment or other version of the product or process; the only proper comparison is with the claims of the patent.”).

²³ See McCaffrey, *supra* note 12, at 369.

guidance, patent marking imposes punitive sanctions in comparison to the notice standards of the copyright, trademark, and semiconductor chip protection laws.²⁴

The FDA-administered publications suffer many of the same problems as marking. Worse yet, the FDA has proven an untutored and unreliable patent propagator for the past four decades. The FDA repeatedly disclaims expertise with respect to the patent system and adamantly refuses to develop its capabilities further.²⁵ The agency is also a begrudging implementer of legislation intended to improve the Orange Book, taking nearly thirteen years to implement the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.²⁶

Despite the extensive literature on the disclosure function of the patent system,²⁷ the statutory notice systems have rarely been considered in that context, nor have they been subject to an appraisal collectively. This Article undertakes that task in five Parts. Part I begins by identifying the theory and literature regarding the role of patent notice within the U.S. innovation environment. In Part II, this Article describes the legislative, judicial, and institutional frameworks pertaining to physical marking, virtual marking, the Orange Book, and the Purple Book. Part III next advances criticism of congressional efforts to correlate patents with marketplace products. Each fall short of its goal of effectively and efficiently conveying the patent status of individual marketplace offerings.

In Part IV, this Article considers different normative options. One option is to eliminate the marking requirement entirely, or alternatively soften the harsh consequences of the failure to mark patented articles. Another is to extend the scope of the notice requirement to the entire community of patent proprietors, including patent owners that do not practice their claimed inventions, proprietors of process patents, and those not subject to FDA approval or licensure.

Part V of this Article further proposes substantive and institutional reforms to the Orange and Purple Books. It asserts that the USPTO, perhaps in concert with or as a successor to the FDA, should supervise initial Orange Book listings and resolve patent listing disputes. It also calls for the elimination of so-called “patent use codes” and for the expansion of these two publications in terms of the timing and extent of patent listings. Part VI concludes with observations about the role of the legislative patent notice systems with respect to the larger patent disclosure project.

²⁴ See 15 U.S.C. § 1111 (trademark); 17 U.S.C. § 401 (copyright); 17 U.S.C. § 909 (semiconductors).

²⁵ See Eisenberg & Crane, *supra* note 15, at 211.

²⁶ See Pub. L. No. 108-173, 117 Stat. 2066 (2003); *Abbreviated New Drug Applications and 505(b)(2) Applications*, 81 FED. REG. 69580 (Oct. 6, 2016). See also Matthew M. D’Amore, Steve Keane & David C. Doyle, *FDA (Finally!) Issues New Regulations to Clarify Pharmaceutical Patent Litigation: How to Use Patent “Use Codes”*, 29 No. 1 INTELL. PROP. TECH. L.J. 10 (2017).

²⁷ See *supra* note 3.

II. INNOVATION POLICY AND PATENT NOTICE

Much of what the patent system sets out to achieve is accomplished by providing the public with notice of patented inventions. Sitting at its core is the basic patent bargain: in exchange for the grant of proprietary rights, individuals and enterprises disclose their inventions to the public.²⁸ Patents are intended to provide cutting-edge technical information from which others may learn. Rivals of the patentee may practice the claimed inventions even while the patent remains in force through licensed or unlicensed use.²⁹ When a patent expires, others may practice the inventions claimed therein without regard to that patent.³⁰ In this manner the patent system encourages sound innovation policy by contributing to the expansion of the public domain, technological progress, and economic growth.³¹

Patents may stimulate additional innovation to address similar and expanded demands in the marketplace. They may point the way to new products, markets, economies of production, and even entire industries.³² They may also encourage others to “invent around” the patentee’s proprietary interest. Others can build upon the disclosure of a patent instrument to market their own products and processes not covered by another’s exclusive patent rights.³³

Through these mechanisms, the patent system can act in more socially desirable ways than its chief legal alternative, trade secret protection.³⁴ Trade secrecy guards against the improper appropriation of valuable, commercially useful, and secret information.³⁵ Because of this requirement of secrecy, trade secret protection does not result in the disclosure of information to the public in the manner of the patent system.³⁶ Taking the steps necessary to maintain secrecy, such as implementing physical security measures, also imposes costs that may ultimately be unproductive for society.³⁷

Patents also memorialize knowledge by providing a stable, searchable library that may be accessed from anywhere on the planet. Some sources assert that up to

²⁸ See, e.g., *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 114, 142 (2001); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 161 (1989); *Brenner v. Manson*, 389 U.S. 519, 534 (1966). *But see* Ghosh, *supra* note 2 (contesting the patent bargain metaphor).

²⁹ See Chien, *supra* note 3, at 1851.

³⁰ 35 U.S.C. § 154(a)(2).

³¹ ROGER E. SCHECHTER & JOHN R. THOMAS, *PRINCIPLES OF PATENT LAW* 5 (3d ed. 2019).

³² See *Wendy H. Schacht & John R. Thomas*, Cong. Rsch. Serv., R41638, Patent Reform in the 112th Congress: Innovation Issues 4 (2011).

³³ See Dan L. Burk, *Perverse Innovation*, 58 WM. & MARY L. REV. 1, 24 (2016).

³⁴ See *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974). *But see* J. Jonas Anderson, *Secret Inventions*, 26 BERKELEY TECH. L.J. 917 (2011); SCHECHTER & THOMAS, *supra* note 31, at 10.

³⁵ See Defend Trade Secrets Act of 2016 §§ 2–5, 18 U.S.C. §§ 1831–39.

³⁶ See Camilla A. Hrdy & Mark A. Lemley, *Abandoning Trade Secrets*, 73 STAN. L. REV. 1, 14–15 (2021).

³⁷ As a result, trade secrets do not add to the body of public knowledge; nor do they deter repetitive R&D and inefficient patent races. SCHECHTER & THOMAS, *supra* note 31, at 10.

80% of current technical knowledge may be found only in patents.³⁸ Although this number has been contested,³⁹ few would disagree that the thousands of patents issued each week contribute to a growing body of “codified knowledge” presented in a freely obtained database.⁴⁰

The patent system also provides an effective mechanism for publicizing inventions in a standardized, longstanding, and accepted manner. Because this disclosure takes place under the supervision of the federal government, and because patentees have attested to the truth of the statements they make to the USPTO, patents impart a degree of credibility to their audiences.⁴¹ Industry observers consult patents in order to assess the efficiency of a firm’s R&D spending⁴² and as a window into that firm’s technological trajectory.⁴³ Patents also signal that the patent proprietor is innovative, sophisticated, and a worthy target for investment.⁴⁴

Legal doctrines reflect the policy goals associated with patent notice.⁴⁵ Patent infringement is a strict liability offense.⁴⁶ This rule implies the view that technology implementers that undertake reasonable diligence should be able to locate pertinent patents.⁴⁷ In particular, rather than misappropriating the patented invention of another, infringers should have conducted a clearance search of the patent rolls. They then should have designed around the scope of the patents of others or negotiated with the patentee for a license.⁴⁸

Courts have also developed rules for patent damages that operate similarly.⁴⁹ Courts ordinarily assess the most common measure of damages, a reasonable royalty, as the value that the parties would have agreed upon at the time

³⁸ European Commission (DG Research) & European Patent Office, *Why Researchers Should Care About Patents 2* (2007), https://ec.europa.eu/invest-in-research/pdf/download_en/patents_for_researchers.pdf.

³⁹ See Geert Edzard Asche, *80% of Technical Information Found Only in Patents— Is There Proof of This?*, 48 *WORLD PATENT INFORMATION* 16 (2017).

⁴⁰ Peter Lee, *Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer*, 100 *CALIF. L. REV.* 1503, 1525 (2012).

⁴¹ Clarisa Long, *Patent Signals*, 69 *U. CHI. L. REV.* 625, 668–69 (2002). This trust may well be unfounded. See Krista L. Cox, *Elizabeth Holmes and the Great Patent Scam*, *ABOVE THE LAW* (Mar. 7, 2019, 1:18 PM), <https://abovethelaw.com/2019/03/elizabeth-holmes-and-the-great-patent-scam/>.

⁴² See generally, e.g., John Thomas et al., *Using Patents and Publications to Assess R&D Efficiency in the States of the USA*, 33 *WORLD PATENT INFORMATION* 4 (2011).

⁴³ See, e.g., *Patently Apple*, <https://www.patentlyapple.com/apple-watch/> (last accessed Apr. 7, 2023) (tracks pending applications and issued patents associated with Apple Inc.).

⁴⁴ See David O. Taylor, *Patent Eligibility and Investment*, 41 *CARDOZO L. REV.* 2019, 2036, 2041 (2020).

⁴⁵ See generally Christopher A. Cotropia & Mark A. Lemley, *Copying in Patent Law*, 87 *N.C. L. REV.* 1421 (2009).

⁴⁶ 35 U.S.C. § 271(a).

⁴⁷ See generally Patrick R. Gould, *Patent Accidents: Questioning Strict Liability in Patent Law*, 95 *IND. L. J.* 1075 (2020).

⁴⁸ Lee & Melamed, *supra* note 6, at 385.

⁴⁹ See Jonathan S. Masur, *Patent Liability Rules as Search Rules*, 78 *U. CHI. L. REV.* 187, 190–91 (2011).

infringement began.⁵⁰ This framework implies that the adjudicated infringer could have identified patents that covered its products and then commenced license negotiations with the patent proprietor.

Many observers have nonetheless questioned whether our current system of patent notice operates effectively. Observers have expressed concerns that patent proprietors may have deliberately withheld valuable information from patents⁵¹ or drafted them in a purposefully equivocal manner.⁵² Other studies have suggested that patents are not often read, and when they are consulted, they are not perceived to be as useful as other sources.⁵³ Liability and damages rules are viewed as resting upon this shaky foundation, and they may inappropriately discount or entirely ignore the costs of identifying patents and negotiating with the patent proprietor.⁵⁴

Largely absent from the academic literature considering the disclosure functions of patents is thorough consideration of the specific efforts Congress has made to correlate individual patents with marketplace activity. Previous discussion of the notice function of patents has principally focused upon the content of individual patents themselves, rather than legislative efforts establishing additional duties and incentives for patent proprietors to notify others of their proprietary rights. Yet understanding of our patent notice system is incomplete absent consideration of traditional marking, virtual marking, the Orange Book, and the Purple Book, a task this Article takes up next.

III. THE STATUTORY PATENT NOTICE SYSTEMS

The USPTO has long engaged in extensive efforts to afford the public access to patents. In keeping with the Patent Act of 1870, the agency began to print copies of patents and make them available to the public.⁵⁵ The USPTO also established a Scientific and Technical Information Center on its own campus featuring a vast collection of patent and technical documents from around the world.⁵⁶ The agency further developed what are now styled as the Patent and Trademark Resource Centers, a nationwide network of libraries that provide members of the public with collections of patent-related materials.⁵⁷

⁵⁰ *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1121 (S.D.N.Y. 1970).

⁵¹ *Id.*

⁵² *See Brenner v. Manson*, 383 U.S. 519, 534 (1966) (taking note of “the highly developed art of drafting patent claims so that they disclose as little useful information as possible—while broadening the scope of the claim as widely as possible . . .”).

⁵³ *See Chien*, *supra* note 3, at 1852.

⁵⁴ *See Lee & Melamed*, *supra* note 6.

⁵⁵ Patent Act of 1870, Ch. 230, 16 Stat. 198 § 20 (1870) reprinted in 35 U.S.C. § 12.

⁵⁶ *See* USPTO, *Scientific and Technical Information Center (STIC) Library Public Access Information* <https://www.uspto.gov/learning-and-resources/support-centers/patent-and-trademark-resource-centers-ptrcs>.

⁵⁷ *See* USPTO, *Patent and Trademark Resource Centers* <https://www.uspto.gov/learning-and-resources/support-centers/patent-and-trademark-resource-centers-ptrcs>.

These brick-and-mortar facilities have been augmented to provide a vast library of patent information to anyone able to access the Internet. The USPTO recently launched a freely accessible modern Patent Public Search that replaces legacy search tools and allows the user to choose from two modern interfaces.⁵⁸ The public may also freely access the Patent Center online database, which records virtually every interaction between patent applicants and the USPTO.⁵⁹

Numerous other enterprises have established additional information resources that supplement the USPTO databases. Two international organizations, the World Intellectual Property Organization and the European Patent Office (EPO), publish multinational databases that are freely available.⁶⁰ The EPO's Espacenet database, for example, offers advanced search tools, identifies patent families, provides status information, and includes original documents from over 100 countries.⁶¹ Other free resources include Google Patents, Patent Quality Through AI (PQAI), and Lens.⁶² Additional, commercially available databases offer search engines and data visualization of growing sophistication.⁶³ Those who require assistance navigating these data repositories may reach out to a competitive market of search firms that identify and analyze relevant patents.⁶⁴

Despite these efforts, the operations and effectiveness of our current disclosure system have been subject to an outpouring of criticism.⁶⁵ Asking an enterprise to identify patents that it might infringe, and then design around them or obtain licenses from their owners, may have been more plausible in the past. Products were simpler, industries featured fewer actors, and fewer patents issued a century or more ago.⁶⁶ But contemporary products often incorporate numerous complex components, each of which may be subject to multiple patents. By itself, a

⁵⁸ See USPTO, *Convenient Patent Public Search tool replacing four legacy systems this fall*, (Sept. 20, 2022) <https://www.uspto.gov/subscription-center/2022/convenient-patent-public-search-tool-replacing-four-legacy-systems-fall>.

⁵⁹ See Kevin Rizzuto, *Fixing Continuing Application Practice at the USPTO*, 13 MARQ. INTELL. PROP. L. REV. 411, 426 (2009).

⁶⁰ See Patentscope, <https://patentscope.wipo.int/search/en/search.jsf>; Inspire, <https://inspire.wipo.int/>; Espacenet, <https://worldwide.espacenet.com/>.

⁶¹ See The University of Bath, *Find patent information: Espacenet*, <https://library.bath.ac.uk/patents/espacenet>.

⁶² Google Patents database, patents.google.com; PQAI, <https://projectpq.ai/>. (PQAI is an open-source platform sponsored by AT&T that uses AI and Natural Language Processing; The Lens database, www.lens.org. (The Lens database includes patents, scholarly records, and biological sequences, and was developed by Cambia, an Australian non-profit organization).

⁶³ They include the Derwent World Patents Index, Drug Patent Watch, PatBase, Patent Inspiration, Patseer, and Patsnap. See MaxVal, *5 Free Patent Search Engines and Databases*, (June 3, 2021) <https://www.maxval.com/blog/5-free-patent-search-engines-and-databases/>.

⁶⁴ See *Patent Search Firm: Everything You Need to Know*, Upcounsel, www.upcounsel.com/patent-search-firm; Mark R. Patterson, *Leveraging Information About Patents: Settlements*, 50 HOUS. L. REV. 483, 488 (2012).

⁶⁵ See Chien, *supra* note 3, at 1851–52.

⁶⁶ See Lee & Melamed, *supra* note 6, at 404.

microprocessor may deploy thousands of proprietary technologies,⁶⁷ while a smartphone reportedly embodies hundreds of thousands of patents.⁶⁸

An enterprise might reasonably be expected to identify patents that its marketplace competitors put into practice.⁶⁹ But nonpracticing entities, ranging from universities to patent assertion entities, have acquired an ever-increasing number of patents.⁷⁰ Identification of potentially relevant but never-commercialized patents, maintained by a fragmented array of enterprises that do not participate in relevant product markets, presents a difficult task in part due to the sheer number of issued patents. The USPTO issued 359,000 patents in 2022⁷¹—which represented a decline from the pre-pandemic level of 391,103 patents granted in 2019.⁷² Many more patents appear to be on the way, for as of February 2023, the USPTO maintained an inventory of 722,775 patent applications that had been filed but not yet examined.⁷³

Another hurdle to identifying relevant patents are patent instruments themselves. Observers have also expressed concerns that patent proprietors may have deliberately withheld valuable information from patents⁷⁴ or drafted them in a purposefully equivocal manner.⁷⁵ Computer-based patent searching methodologies also present significant limitations. Technologists ordinarily delve through the patent rolls using specific terms or key words.⁷⁶ But communities of practice often do not develop common language to describe new technologies until many years after patents have been obtained.⁷⁷ Patent claims often use newly coined words, using the “lexicographic privilege” extended to inventors,⁷⁸ or employ different terms to describe the same product or process. Finally, many types of inventions are more effectively disclosed through diagrams and illustrations—

⁶⁷ See Brian J. Love, *Patentee Overcompensation and the Entire Market Value Rule*, 60 STAN. L. REV. 263, 288 (2007).

⁶⁸ See Bernhard Chao, *Causation and Harm in a Multicomponent World*, 164 U. PA. L. REV. ONLINE 61, 64 (2016).

⁶⁹ See Lee & Melamed, *supra* note 6, at 403.

⁷⁰ See Mark A. Lemley & A. Douglas Melamed, *Missing the Forest for the Trolls*, 113 COL. L. REV. 2117, 2118–19 (2013).

⁷¹ Dennis Crouch, USPTO Grants 2022, Patentlyo, (December 27, 2022), <https://patentlyo.com/patent/2022/12/uspto-grants-2022.html#:~:text=The%20US%20Patent%20and%20Trademark,the%20number%20of%20issued%20patents>.

⁷² USPTO, U.S. Patent Statistics Chart, Calendar Years 1963–2020 (updated May 2021), [uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm](https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm).

⁷³ USPTO, Patent Production, Unexamined Inventory and Filings February 2023 (2023) <https://www.uspto.gov/dashboard/patents/production-unexamined-filing.html>.

⁷⁴ *Id.*

⁷⁵ See *Brenner v. Manson*, 383 U.S. 519, 534 (1966) (taking note of “the highly developed art of drafting patent claims so that they disclose as little useful information as possible—while broadening the scope of the claim as widely as possible . . .”).

⁷⁶ See Andrew Chin, *Search for Tomorrow: Some Side Effects of Patent Office Automation*, 87 N.C. L. REV. 1617, 1619–20 (2009).

⁷⁷ See Mark A. Lemley, *Chief Justice Webster*, 106 IOWA L. REV. 299, 309 (2020); Greg Reilly, *Judicial Capacities and Patent Claim Construction: An Ordinary Reader Standard*, 20 MICH. TELECOMM. TECH. L. REV. 243, 264–65 (2014).

⁷⁸ See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (*en banc*).

consider how the structure of a simple paperclip might be described in words—and may require a painstaking, manual search to review. Liability and damages rules are viewed as resting upon this shaky foundation, and they may inappropriately discount or entirely ignore the costs of identifying patents and negotiating with the patent proprietor.

By allowing members of the public to correlate specific patents with commercially available products, the statutory patent notice systems endeavor to fill this gap. The marking systems and FDA publications, if effective, would address many of the criticisms directed towards the current state of patent disclosures. Technology implementers would be able to identify relevant patents by looking at the products their competitor's market. In addition to identifying a specific patent as potentially pertinent to a technology implementer, this connection would lend clarity to its context, content, and coverage. Further, because the statutory notice systems operate outside the patent instrument, they may be updated at any time, without running afoul of the statutory directive that patents must not be amended to include new subject matter.⁷⁹ The different statutory patent notice systems—physical marking, virtual marking, the Orange Book, and the Purple Book—therefore bear closer consideration.

A. Physical Marking

The most apparent form of notice *ab extra* the patent consists of the marking of physical products or their packaging. Section 287 of the Patent Act provides that patentees and their licensees that make, offer to sell, or sell embodiments of their patented invention should fix the word “patent” or abbreviation “pat.” along with the number of the patent, on patented articles. The statute stipulates that if “the character of the article” makes such a fixation impracticable, a label may be placed on the article or its packaging.⁸⁰ If a technology implementer fails to mark its products with relevant patents, then it may not recover damages for infringement unless the infringer “was notified” of the infringement and continued to infringe thereafter.⁸¹

The statutory inducement for physical marking therefore amounts to a significant restriction upon the remedies available against infringers. Absent the marking statute, any patent proprietor could obtain damages for infringement up to six years before it filed an infringement complaint or countercomplaint.⁸² Section 287 essentially provides the patent proprietor with the choice of either marking its

⁷⁹ See 35 U.S.C. § 132(a) (“No amendment shall introduce new matter into the disclosure of the application.”); § 251(a) (“No new matter shall be introduced into the application for reissue.”).

⁸⁰ See, e.g., *Sessions v. Romadka*, 145 U.S. 29, 49–50 (1892) (noting the difficulty of patent marking on goods of small size); *Rutherford v. Trim-Tex, Inc.*, 803 F. Supp. 158, 161–64 (N.D. Ill. 1992) (considering defacement of the article, expense, trade, custom, and size of the article).

⁸¹ 35 U.S.C. § 287.

⁸² 35 U.S.C. § 286.

products or relinquishing damages until it provides actual notice of infringement to the infringer.⁸³

The first U.S. patent statutes did not speak to marking.⁸⁴ Through the early nineteenth century, individuals who wished to review patents needed to visit the Patent Office in Washington, DC. Congress grew to recognize the possible inconvenience of traveling to access the central patent library—or hiring another to do so—to assess the proprietary rights of others. The 1836 Patent Office fire compounded this burden.⁸⁵

An additional, unstated rationalization may relate less to the temporal dimension of the damages determination than the analytical method courts use to calculate them, regardless of the relevant timeframe. The Patent Act stipulates that adjudicated infringers face liability for “damages adequate to compensate for the infringement, but in no event less than a reasonable royalty”⁸⁶ Judicial interpretation has equated the phrase “damages adequate to compensate for the infringement” with the patentee’s lost profits—an amount that ordinarily exceeds a reasonable royalty.⁸⁷ In usual course, an enterprise cannot suffer lost profits unless it markets its patented product, and therefore stands in a position to mark that product.⁸⁸

The marking requirement might also find support with respect to the award of equitable relief. Following the Supreme Court’s decision in *eBay v. MercExchange LLC*,⁸⁹ courts are more likely to enjoin an adjudicated infringer from future infringement if the patent proprietor puts its claimed invention into practice.⁹⁰ The same may be said with respect to the award of a preliminary injunction.⁹¹ Here too, the marking requirement may be justified because patents that are commercially embodied by their proprietors may present more severe

⁸³ See Steven C. Sereboff, *New Requirements in Patent Marking and Notice*, 76 J. PAT. TRADEMARK OFF. SOC’Y 793, 794 (1994).

⁸⁴ See *Nike, Inc. v. Wal-Mart Stores, Inc.*, 138 F.3d 1437, 1443 (Fed. Cir. 1998).

⁸⁵ See Dane D. Sowers, *Ensuring Proper Notice: Clearing the Fog Surrounding Virtual Patent Marking*, 54 CREIGHTON L. REV. 107 (2020); Tim Hsieh, *The Adequacy of the Mark: Raising the Standard Under 35 U.S.C. § 287(a) for Patented Online Software Methods*, 48 IDEA 69 (2007).

⁸⁶ 35 U.S.C. § 284.

⁸⁷ See Mark A. Lemley, *Distinguishing Lost Profits from Reasonable Royalties*, 51 WM. & MARY L. REV. 655, 655 (2009).

⁸⁸ The Federal Circuit has, in rare circumstances, awarded lost profits damages based upon the sale of unpatented products where the adjudicated infringer sold both infringing and noninfringing products in direct competition with the patentee. See *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1546 (Fed. Cir. 1995) (*en banc*).

⁸⁹ 547 U.S. 388 (2006).

⁹⁰ See Hannibal Travis, *Injury, Inequality, and Remedies: Developments in Injunctive Relief and Damages in Intellectual Property Cases*, 21 J. HIGH TECH. L. 34, 36 (2021) (observing that practicing patent owners may enjoy a presumption in favor of injunctive relief).

⁹¹ See John C. Jarosz, Jorge L. Contreras, & Robert L. Vigil, *Preliminary Injunction in Patent Cases: Repairing Irreparable Harm*, 31 TEX. INTELL. PROP. L.J. 63, 93–94 (2022) (noting that direct competition between the patentee and accused infringer strongly supports the grant of a preliminary injunction).

consequences for infringers. The disastrous loss of patent records led to several changes to the Patent Act, including the numbering of patents and the requirement that the applicant submit multiple copies of illustrations of the invention.⁹²

By far the most aggressive congressional response to the 1836 conflagration was the marking requirement. The Patent Act of 1842 required “all patentees and assignees of patents to stamp on each article vended, or offered for sale, the date of the patent.”⁹³ Patentees that failed to do so faced the criminal penalty of a fine “not less than one hundred dollars.”⁹⁴ The Patent Act of 1861 eliminated this fine and instead opted for the marking standard that continues to be used today.⁹⁵

Over the years, the courts have viewed the marking statute as encouraging patent owners to give public notice that an article is patented, helping to avoid innocent infringement, and aiding the public in identifying whether an article is patented or not.⁹⁶ However, at other times they justify the patent marking statute in starker terms. The Supreme Court long ago concluded that patent marking provided “protection against deception by unmarked patented articles”⁹⁷ The Federal Circuit has continued to employ this sort of rhetoric, explaining that those who fail to mark “mislead the public.”⁹⁸ The notion that technology implementers intend to deceive or mislead anyone regarding their patents simply by selling products seems on its face absurd. Patents are public instruments that may be consulted using numerous freely available search tools. They are far more readily retrieved than judicial opinions, the statutes and regulations of many state and local governments, and other primary sources of law.⁹⁹

Strict judicial interpretation of the actual notice requirement of Section 287 has nonetheless placed a premium upon marking. That statute’s alternative to marking—that the “infringer was notified of the infringement and continued to infringe thereafter”—arguably suggests only that the infringer was aware that a relevant patent might cover its products. After all, Congress drafted the statute in

⁹² See KENNETH W. DOBYNS, *THE PATENT OFFICE PONY: A HISTORY OF THE EARLY PATENT OFFICE* (1994).

⁹³ Act of Aug. 29, 1842, ch. 263, § 5, 6, 5 Stat. 543, 544–45.

⁹⁴ *Id.*

⁹⁵ See, e.g., Elizabeth I. Winston, *The Flawed Nature of the False Marking Statute*, 77 TENN. L. REV. 111, 120 n.61 (2009).

⁹⁶ *Arctic Cat, Inc. v. Bombardier Rec. Prods., Inc.*, 950 F.3d 860, 866 (Fed. Cir. 2020).

⁹⁷ *Wine Ry. Appliance Co. v. Enterprise Ry. Equip. Co.*, 297 U.S. 387, 398 (1936) (“Under the interpretation which we accept, [the marking statute] provides protection against deception by unmarked patented articles”).

⁹⁸ *Arctic Cat, Inc. v. Bombardier Rec. Prods., Inc.*, 950 F.3d 860, 866 (Fed. Cir. 2020) (“In *Arctic Cat*’s view, § 287 should be read to allow a patentee to mislead others that they are free to make and sell an article that is actually patented, but nonetheless allow the patentee to recover damages without undertaking any corrective action. We reject this view.”).

⁹⁹ In addition, Congress has addressed concerns over fraudulent marking with a specific “false marking” statute. If the technology implementer marks in a misleading fashion, then it may be subject to prosecution by the Department of Justice. 35 U.S.C. § 292. See generally Tony Zeuli, Ethan Bell & Elizabeth Muirhead, *A Marked Improvement™—False Marking and the AIA*, FED. LAW. Jan.–Feb. 2015 at 50 (2015).

passive voice and did not specify how notification should occur. A manufacturer that conducted a “freedom to operate” search and obtained a lawyer’s opinion that its competitor’s patent covers its product appears to have been notified of infringement; as has the reader of a judicial ruling that an identical product, sold by a third party, is patent-infringing. The Supreme Court nonetheless has held that, absent marking, the patentee must provide actual notice “to the particular defendants by informing them of his patent and of their infringement of it.”¹⁰⁰

The Federal Circuit has advanced the actual notice requirement even further. The Court of Appeals consistently requires that a patent holder provide an “affirmative communication of a specific charge of infringement by a specific accused product or device.”¹⁰¹ Whether the alleged infringer knew of the patent or its own infringement prior to receiving actual notice from the patentee is irrelevant.¹⁰²

These interpretations of Section 287 sometimes lead to harsh outcomes for patent owners. In one case, the patentee gave a presentation to its customer that asserted that the customer’s planned purchase of a competitor’s product may hold “implications” for several of its patents.¹⁰³ After the customer forwarded a copy of the presentation to the competitor, the competitor responded by engaging a law firm to conduct a review of the identified patents. An internal email from the competitor’s in-house counsel explained that the patentee had alleged that the competitor’s product “infringed” the patents.¹⁰⁴

The patentee subsequently communicated directly with its competitor. Its letter stated that it had amassed a patent portfolio that related to the competitor’s product, attached copies of the patents, and expressed hope that the competitor would “take adequate precautions to avoid infringement of these . . . patents.”¹⁰⁵ Under these facts, Judge Stark of the U.S. District Court for Delaware, as he was then, ruled on summary judgment that a reasonable juror could not conclude that the patentee had provided actual notice of its patents to the accused infringer. As a result, despite being well aware of the asserted patents for many years—indeed, it had been notified of them by the patentee, at first indirectly and then directly—the accused infringer evaded damages prior to being sued for infringement.¹⁰⁶

The marking statute leads to other apparent anomalies. Under section 287 of the Patent Act, a patent proprietor that makes a single sales offer featuring a marked

¹⁰⁰ *Dunlap v. Schofield*, 152 U.S. 244, 247–48 (1894).

¹⁰¹ *Amsted Indus. Inc. v. Buckeye Steel Castings Co.*, 24 F.3d 178, 187 (Fed. Cir. 1994); *see also SRI Int’l, Inc. v. Advanced Tech. Labs., Inc.*, 127 F.3d 1462, 1470 (Fed. Cir. 1997).

¹⁰² *Amsted Indus.*, 24 F.3d at 187.

¹⁰³ *Siemens Mobility, Inc. v. Westinghouse Air Brake Techs. Corp.*, 2018 WL 7893901 (D. Del. 2018).

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Siemens Mobility, Inc. v. Westinghouse Air Brake Techs.*, Memorandum in Support of Wabtec’s Motion for Partial Summary Judgment of No Pre-Suit Damages, 2018 WL 5281379 at *1 (Aug. 31, 2018).

article may obtain damages for infringing acts that took place up to six years before an infringement suit was filed.¹⁰⁷ On the other hand, an infringer that consults another's patent and deliberately copies its claimed inventions may entirely avoid liability, at least prior to the receipt of actual notice of infringement from the patentee, merely because the patentee did not mark its products.¹⁰⁸ Seemingly untroubled by this situation, Congress not only sustained the marking requirement during its 2011 enactment of sweeping patent reforms, but it also took the further step of ushering it into the twenty-first century.

B. *Virtual Marking*

The marking requirement established in 1861 remained unmodified for the next 150 years. The motivation for the 2011 amendments was not a catastrophe at the USPTO, but rather the recognition that Internet-based patent notifications might provide a more convenient means of informing the public about relevant patents than traditional, physical marking.¹⁰⁹ Following the America Invents Act of 2011, patent proprietors may now place the word "patent" or abbreviation "pat." on their products, along with a freely accessible Internet address that identifies patents that correspond to their products.¹¹⁰

Virtual marking potentially holds many advantages over traditional physical marking. By disconnecting marking from the manufacturing process, technology implementers may more conveniently provide notice of relevant proprietary rights.¹¹¹ They also avoid the expenses associated with retooling, remolding, or other manufacturing changes; may easily mark small articles that may be covered by numerous patents; and may readily update virtual marking as new patents issue and old ones expire.¹¹²

Although virtual marking was heralded as an innovative modernization,¹¹³ the patent system in fact has been engaged in a sort of remote marking for the past four decades. The Hatch-Waxman Act long ago repurposed an existing FDA publication, the Orange Book, as a means of notification external to the patent instrument. Plagued with controversy over the years,¹¹⁴ and subject to recent legislative amendments,¹¹⁵ the Orange Book bears further consideration.

¹⁰⁷ 35 U.S.C. § 286.

¹⁰⁸ *Arctic Cat, Inc. v. Bombardier Recreational Prod. Inc.*, 950 F.3d 860, 866 (Fed. Cir. 2020).

¹⁰⁹ Dane D. Sowers, *Ensuring Proper Notice: Clearing the Fog Surrounding Virtual Patent Marking*, 54 CREIGHTON L.REV. 107 (2020).

¹¹⁰ See AIA, *supra* note 12, at § 16.

¹¹¹ See McCaffrey, *supra* note 12, at 369.

¹¹² USPTO, REP. TO CONG.: REP. ON VIRTUAL MARKING (2014).

¹¹³ See McCaffrey, *supra* note 12, at 384.

¹¹⁴ See, e.g., Eva A. Temkin *et al.*, "Purple Book" Patent Listing Under Biological Product Patent Transparency Act: What is Required, and What to Expect?, 33 No. 8 INTELL. PROP. TECH. L.J. 13 (Sept. 2021); Jane F. Djung, Insufficient Mechanisms for Orange Book Corrections and the FDA's Ministerial Role: A Need for Reform, 47 CONN. L. REV. 299 (2014).

¹¹⁵ Pub. L. No. 116-290, 134 Stat. 4889 (Jan. 5, 2021).

C. *The Orange Book*

Many Orange Books have been published over the years, directed towards such subjects as analytical chemistry,¹¹⁶ crisis management,¹¹⁷ and the rules of bridge.¹¹⁸ However, the most important Orange Book in the United States is an FDA publication more formally known as *Approved Drug Products with Therapeutic Equivalence Evaluations*.¹¹⁹ The FDA's Orange Book, originally intended for an audience of pharmacists, prescribing physicians, and state health agencies, identifies drugs that the agency deems safe and effective.¹²⁰

The FDA published the Orange Book several years before it would play a role in the intellectual property law.¹²¹ Reflecting concerns over both medical innovation and the growing cost of health care, the Hatch-Waxman Act establishes mechanisms through which a generic manufacturer may more rapidly obtain approval to market a drug that the FDA previously approved.

In this capacity, the Orange Book plays two intellectual property roles. The first concerns the FDA administration of “regulatory exclusivities”—sixteen *sui generis* rights that, to varying degrees, afford an approved drug protection from competing applications for marketing approval.¹²² The Orange Book identifies the relevant regulatory exclusivities that are pertinent to each approved drug. For example, if the FDA deems a drug to qualify as a “new chemical entity”¹²³—a status that ordinarily precludes generic firms from seeking marketing approval for at least four years—the agency will provide that information in the Orange Book. The FDA publishes the Orange Book in physical form, on its website, and via its “Orange Book Express” app.

¹¹⁶ INTERNATIONAL UNION OF PURE AND APPLIED CHEMISTRY, COMPENDIUM OF ANALYTICAL NOMENCLATURE (3d ed. 1997) (available at iupac.org).

¹¹⁷ HM GOVERNMENT, THE ORANGE BOOK: MANAGEMENT OF RISK-PRINCIPLES AND CONCEPTS (2020).

¹¹⁸ ENGLISH BRIDGE UNION, ORANGE BOOK 2006: HANDBOOK OF EBU DIRECTIVES AND PERMITTED AGREEMENTS (2010) (available at www.bridge.is).

¹¹⁹ The Orange Book may be located at Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, (2023), www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

¹²⁰ U.S. DEP'T OF HEALTH & HUMAN SERVS., FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (42d ed. 2022).

¹²¹ See *supra* note 119, *Preface* (noting that the FDA published the first edition of the Orange Book in October 1980).

¹²² JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 454 (3d ed. 2015) (observing 15 regulatory exclusivities as of 2015); see also FDA Reauthorization Act of 2017, Pub. L. No. 115-52, 131 Stat. 1005 § 803 (introducing a sixteenth “competitive generic therapy” regulatory exclusivity codified at 21 U.S.C. § 506H).

¹²³ 21 U.S.C. § 355(j)(5)(F)(ii). See Erin H. Ward, Louis Fisher, Cong. Rsch. Serv., RS46110, *Defining Active Ingredient: The U.S. Food and Drug Administration's Legal Interpretation of Regulatory Exclusivities* (2019) (“In the context of the five-year-exclusivity, which FDA has coined ‘new chemical entity’ or NCE exclusivity, FDA interprets the term ‘active ingredient’ to mean ‘active moiety.’”).

The Orange Book also provided the nation's first form of virtual notice in its role as a clearinghouse for pharmaceutical patents.¹²⁴ The Hatch-Waxman Act requires brand-name drug companies—which are more accurately termed the owners of the “New Drug Application” or NDA—to identify relevant patents to the FDA.¹²⁵ The patent information is then published—or “listed,” in the preferred industry parlance, in the Orange Book.¹²⁶

Generic drug companies respond by stating their views regarding Orange Book-listed patents when they seek FDA marketing approval via an Abbreviated New Drug Application (ANDA). They may assert that no patents have been listed, that any listed patents have already expired, or that the generic manufacturer will not market its product until they do.¹²⁷ Generic companies may also respond in a less convivial manner by instead asserting that the brand-name firm's patents are invalid, unenforceable, or not infringed.¹²⁸ The generic firm must then provide notice of this so-called “paragraph IV certification” to the brand-name firm and, if ownership is distinct, the patent holder.¹²⁹

Filing an ANDA with a paragraph IV certification “means provoking litigation.”¹³⁰ Under the Hatch-Waxman Act, a generic drug company commits patent infringement when it submits an application for marketing approval to the FDA for “a drug claimed in a patent or the use of which is claimed in a patent.”¹³¹ At this point, the generic drug company need not have marketed any competing product. Petitioning the government to obtain marketing approval nonetheless fulfills the Hatch-Waxman's standard of “artificial infringement.”¹³² The patent owner may sue for infringement immediately, and if successful, will block generic competition until the asserted patents expire.¹³³

Orange Book listings hold important consequences for the availability of generic drugs in the United States. The FDA nonetheless views its role in

¹²⁴ See Djung, *supra* note 114.

¹²⁵ 21 U.S.C. § 355(b)(1)(A)(viii).

¹²⁶ 21 U.S.C. § 355(c)(2); see *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 3 (1st Cir. 2020).

¹²⁷ 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(III); 21 U.S.C. § 355(j)(5)(B)(i),(ii). The Hatch-Waxman Act provided for analogous patent certifications and other provisions for so-called “Section 505(b)(2)” applications, also known as “paper NDAs.” 21 U.S.C. § 355(b)(2)(A); see also THOMAS, *supra* note 122, at 387–88. For sake of clarity, this Article will limit its citations for ANDAs.

¹²⁸ This situation represents the usual practice for the pharmaceutical industry. However, because 35 U.S.C. § 271(e)(2) makes no mention of either the Orange Book or any intellectual property position taken by a generic drug manufacture, not every court requires an assertion of invalidity, unenforceability, or noninfringement of an Orange-Book listed patent for artificial infringement to occur. See, e.g., *Allergan Sales, LLC v. Teva Pharms. USA, Inc.*, 2017 WL 3446634 at *6 (E.D. Tex. July 25, 2017); *Takeda Pharm. Co. v. TWI Pharms., Inc.*, 2013 WL 12164680, at *21 (N.D. Cal. May 20, 2013).

¹²⁹ 21 U.S.C. § 355(j)(B)(iii).

¹³⁰ *Caraco Pharm. Lab'ys., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399 (2012).

¹³¹ 35 U.S.C. § 271(e)(2).

¹³² *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 675 (1990).

¹³³ 35 U.S.C. § 271(e)(4).

administering the Orange Book as purely ministerial.¹³⁴ Repeatedly asserting its lack of patent expertise—and apparently unwilling to have acquired any since 1984—the agency has declined to weigh into disputes about whether a patent has been appropriately listed or not.¹³⁵ If a third party disputes the accuracy of a patent listing before the FDA, then the agency will forward that statement to the brand-name drug company with no substantive review whatsoever. Unless the brand-name drug company withdraws or amends the listing, the FDA will not alter the patent information in the Orange Book.¹³⁶

The precise language of the Orange Book patent listing statute bears further examination. Under the Hatch-Waxman Act, brand-name companies are required to submit to the FDA patents that fall into one of two categories. The first are patents that claim “the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent.”¹³⁷ The second are patents that claim “a method of using such drug for which approval is sought or has been granted in the application.”¹³⁸ In either case, the patent must fall within the scope of the “New Drug Application” that the FDA approved for marketing. Finally, the patent may only be identified to the FDA if “a claim of patent infringement could be reasonably be asserted” against an unlicensed user of the patented invention.¹³⁹

Principally due to lax FDA oversight of the patent listing requirement, the Orange Book has been a problematic document from the outset. Brand-name drug companies have long recognized that they obtain significant benefits when they identify patents to the FDA for listing. Most notable among them is the 30-month stay. If a brand-name firm responds to a paragraph IV certification by filing a patent infringement lawsuit, then the FDA is subject to a 30-month stay of regulatory approval during which the agency cannot approve the generic drug.¹⁴⁰ As a practical matter, the 30-month stay amounts to a preliminary injunction against generic manufacturers that the brand-name drug company obtains automatically upon bringing charges of artificial infringement.¹⁴¹ This approach stands in high relief to garden variety patent cases, where the award of the preliminary injunction depends

¹³⁴ See, e.g., *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191, 196 (D.D.C. 2002).

¹³⁵ See, e.g., *Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not be Infringed*, 68 FED. REG. 36676, 36683 (June 18, 2003) (to be codified at 48 C.F.R. pt. 1). (“Indeed, the requirement of prompt publication (“upon submission”), combined with the 30-day time frame for updating the Orange Book, are strong evidence that Congress did not intend us to undertake anything other than a ministerial action.”).

¹³⁶ 21 C.F.R. § 314.53(f).

¹³⁷ 21 U.S.C. § 355(b)(1)(A)(viii)(I).

¹³⁸ 21 U.S.C. § 355(b)(1)(A)(viii)(II).

¹³⁹ 21 U.S.C. § 355(b)(1)(A)(viii).

¹⁴⁰ 21 U.S.C. § 355(j)(5)(B)(iii).

¹⁴¹ See John R. Thomas, *Hatch-Waxman’s Renegades*, 2023 U. ILL. L. REV. ____ (forthcoming).

upon demonstration of the four customary equitable factors and further requires the posting of a bond.¹⁴²

This strong remedial incentive strongly encourages brand-name companies to list as many patents in the Orange Book as they can. This incentive, combined with the lack of FDA supervision, has led to the listing of numerous patents that fail to meet the statutory criteria. Those included patents on such inventions as scoring patterns on tablets, tablet shapes, bottles, and other inventions that generic firms could readily avoid. Each of these patents nonetheless prevented generic competition for at least the duration of the 30-month stay.¹⁴³

In view of this troubled history,¹⁴⁴ the FDA issued regulations in 2003 that attempted to clean up the Orange Book.¹⁴⁵ With regard to the first of the two categories of patents, relating to drug substances or drug products, the FDA asks not to learn of patents claiming metabolites¹⁴⁶ and chemical intermediates¹⁴⁷ because they do not consist of the substance or product itself.¹⁴⁸ And even though a drug's container or packaging may form part of the drug product that the FDA does approve, the agency has observed that it does not grant regulatory approval to containers or packaging *per se*. As a result, the agency does not wish to receive information on packaging or container patents either.¹⁴⁹

As later confirmed by Congress,¹⁵⁰ the FDA interprets the second statutory category of patents—pertaining to methods of using the drug—to preclude from listing what it terms “process patents.”¹⁵¹ Given that the Patent Act defines the terms “method” and “process” synonymously,¹⁵² this terminology often proves puzzling to intellectual property lawyers. The FDA nonetheless distinguishes between method patents, which pertain to methods of using the drug, from process

¹⁴² FED. R. CIV. P. 65(c).

¹⁴³ See Elizabeth H. Dickinson, *FDA's Role in Making Exclusivity Determinations*, 54 FOOD DRUG L.J. 51, 71–73 (1999); Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 J.L. TECHNOLOGY 389, 415 (1999).

¹⁴⁴ See FTC, *GENERIC DRUG EXPIRATION PRIOR TO PATENT EXPIRATION: AN FTC STUDY*, 39–40 (July 2022).

¹⁴⁵ *Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed*, 68 FED. REG. 36676 (June 18, 2003).

¹⁴⁶ Patents claiming metabolites claim the chemical compound formed from the active ingredient of a drug after being processed by the body. *Id.* at 36680.

¹⁴⁷ Patents claiming intermediates include those that claim “materials that are produced during preparation of the active ingredient and are not present in the finished drug product.” *Id.* The FDA considers intermediates as “in-process materials” rather than drug substances or components in the finished drug product. *Id.*; see also 21 C.F.R. §§ 210.3(b)(9), 211.110. It, therefore, considers that patents that claim intermediates do not claim the approved drug product and fail to satisfy the requirements for listing. See 68 FED. REG. at 36680; 21 C.F.R. §§ 210.3(b)(9), 211.110.

¹⁴⁸ 21 C.F.R. §§ 315.53(b), (c)(2).

¹⁴⁹ 67 FED. REG. at 65451; see 21 C.F.R. § 314.50(d)(1)(ii)(a).

¹⁵⁰ See Orange Book Transparency Act of 2020, Pub. L. No. 116-290, 134 Stat. 4889 (2021).

¹⁵¹ 21 C.F.R. § 314.53(b)(1).

¹⁵² 35 U.S.C. § 100(b).

patents, which claim methods for manufacturing the drug. Because process patents do not claim the drug itself, but the method of making it, the agency does not wish to receive information on them either.

The FDA requires brand-name drug companies to submit additional information for each method of use patent submitted for listing in the Orange Book.¹⁵³ This information, known as the “use code,” includes a narrative of 250 characters or fewer that describes the patented method of medical treatment. Representative use code narratives include “method of treating grout flares,”¹⁵⁴ “prophylaxis of deep vein thrombosis,”¹⁵⁵ and “treatment of mantle cell lymphoma.”¹⁵⁶ The “use code” must also identify the approved method of use and the related claim of the relevant patent. Most patent claims comprise quite a bit more than 250 characters, however, so brand-name drug companies ordinarily frame their use codes to maximize the extent of their exclusivity.

Despite the detail found within the FDA’s regulations, the agency does not verify any of the submitted “use code” information provided by the brand-name drug company.¹⁵⁷ More particularly, the FDA does not review the patent’s scope and compare it with the use code; it merely accepts the use code as given. The FDA nonetheless holds generic drug manufacturers accountable for these highly condensed summaries of what may amount to dozens of claims within a single patent. If the generic manufacturer submits to the FDA a proposed label that provides for indications of its product that do not fall within the use code narrative, then it may launch its product immediately upon obtaining regulatory approval.¹⁵⁸ Such a “carve-out” label will be accompanied by a so-called “section viii statement” asserting that the generic drug company will not market its product for methods of use that remain under patent.¹⁵⁹ Otherwise, the generic drug company must submit a paragraph IV certification with its ANDA,¹⁶⁰ which in ordinary course subjects it to the Hatch-Waxman Act’s 30-month stay of FDA approval.¹⁶¹

Congress made some additional efforts to improve the function of the Orange Book with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).¹⁶² The MMA modestly improved the opportunity for generic firms

¹⁵³ 21 C.F.R. § 314.53(c)(2)(i)(O).

¹⁵⁴ The FDA identifies this narrative as U-1007 and associates it with U.S. Patent No. 7,601,758. *See* FDA, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, Patent and Exclusivity for: N022352 (Mar. 2023) (“Orange Book”).

¹⁵⁵ The FDA identifies this narrative as U-1167 and associates it with U.S. Patent No. 6,967,208. *See* Orange Book, Patent and Exclusivity for: 202155 (Mar. 2023).

¹⁵⁶ The FDA identifies this narrative as U-1456 and associates it with U.S. Patent No. 8,476,284. *See* Orange Book, Patent and Exclusivity for: N205552 (Mar. 2023).

¹⁵⁷ *See* Caraco Pharm. Lab’ys, Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 403 (2012).

¹⁵⁸ 21 C.F.R. § 314.127(a)(7).

¹⁵⁹ 21 U.S.C. § 355(j)(2)(A)(viii).

¹⁶⁰ 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

¹⁶¹ 21 U.S.C. § 355(j)(5)(B)(iii).

¹⁶² *See* Greater Access to Affordable Pharmaceuticals Act of 2021, S. 812, 107th Cong. (2002). The bill was signed into law as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

to delist patents from the Orange Book by allowing generic firms that were sued for patent infringement to bring a counterclaim requesting delisting of the patent.¹⁶³ As the statute expressly provides that it does not authorize any other cause of action other than this limited counterclaim,¹⁶⁴ and further stipulates that the generic firm may not receive damages in the event of an improper listing,¹⁶⁵ its utility is limited.

The Supreme Court's decision in *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S* provides an example of use code abuse and the workings of the MMA's counterclaim.¹⁶⁶ In that case, a brand-name drug company, Novo Nordisk, had obtained a patent covering the active ingredient of the diabetes drug repaglinide.¹⁶⁷ Although the active ingredient patent had expired,¹⁶⁸ Novo Nordisk further acquired and maintained an additional patent claiming a method of using repaglinide in combination with another diabetes drug, metformin—a so-called combination therapy.¹⁶⁹ Novo Nordisk had also obtained FDA approval for three uses of repaglinide to treat diabetes: repaglinide by itself; repaglinide in combination with thiazolidinediones (TZDs); and repaglinide in combination with metformin.

In sum, Novo Nordisk held FDA approval for three methods of using repaglinide, but only one of them, the combination therapy of repaglinide and metformin, remained under patent. Novo Nordisk nonetheless presented to the FDA a use code narrative reciting a “method for improving glycemic control in adults with type 2 diabetes.”¹⁷⁰ This expansive use code covered each of the three approved methods for using repaglinide—which, in effect, amounted to Novo Nordisk awarding itself proprietary rights far beyond what the USPTO had authorized.

In its *Caraco v. Novo Nordisk* opinion, the Supreme Court held that use code narratives such as this qualified as “patent information” capable of challenge through the MMA's counterclaim provision.¹⁷¹ As a result, Caraco was able to argue before a court that the submitted use code was too broad. The larger takeaway, however, was that absent litigation, generic manufacturers were prevented from drafting a label limiting the use of its generic drug by itself or with TZDs. They instead were required to engage in costly courtroom battles over a self-serving summary of a patent they had no intention of infringing.¹⁷² Despite such

¹⁶³ 21 U.S.C. § 355(j)(5)(C)(ii)(I).

¹⁶⁴ 21 U.S.C. § 355(j)(5)(C)(ii)(II).

¹⁶⁵ 21 U.S.C. § 355(j)(5)(C)(iii).

¹⁶⁶ *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399 (2012).

¹⁶⁷ U.S. Patent No. RE 37,035 (the “’035 patent”).

¹⁶⁸ The ’035 patent expired in 2009.

¹⁶⁹ U.S. Patent No. 6,677,358 (the “’358 patent”). The ’358 patent expired in 2018 but was still in effect at the time generic manufacturers sought FDA marketing approval.

¹⁷⁰ *Caraco Pharm. Lab'ys*, 566 U.S. at 410.

¹⁷¹ *Id.* at 417–20.

¹⁷² *Id.* at 411.

apparent abuses of use code narratives, the FDA makes no effort to review them upon submission, nor does the agency adjudicate disputes involving them.

Almost thirteen years would pass before the FDA implemented the MMA.¹⁷³ As part of the MMA rollout, the agency at last established a procedure through which inappropriate Orange Book patent listings may be challenged.¹⁷⁴ As might be expected, however, the FDA plays no substantive role in the proceedings. It merely allows any interested person to dispute the accuracy or relevance of patent information in the Orange Book—or the lack of information in the Orange Book—by communicating a statement of dispute to the agency. The agency’s response to alleged abuse of use codes was particularly restrained. The relevant regulation limits statements of dispute regarding use codes to 250 words directed towards the scope of the listed patent.¹⁷⁵ The agency then forwards the information to the brand-name drug company. No matter how plain the disconnect is between the use code narrative and the claims of its associated patent, the FDA will not alter the use code narrative absent action from the NDA holder.¹⁷⁶

Congress returned to the Orange Book in 2021 with the Orange Book Transparency Act,¹⁷⁷ legislation that had proceeded with great fanfare. Its sponsor claimed the legislation would “more efficiently achieve lower drug costs and higher quality, lifesaving medicines for Americans while at the same time enhance market competition by getting generic drugs to market more quickly.”¹⁷⁸ In fact, the bill for the most part codified existing FDA regulations with respect to patent listings. Its chief contribution is to require the FDA to publish the expiration date of Orange Book-listed patents—information the agency receives from the brand-name drug company without further review.¹⁷⁹ Even following the Orange Book Transparency Act, the FDA continues to play no substantive role in determining whether patents are suitable for listing.

D. *The Purple Book*

The final form of statutory notice beyond the patent instrument is akin to the Orange Book, albeit with different listing mechanics and a much shorter history. The FDA publishes the Purple Book, a reference guide to licensed biologic products formally titled *Lists of Licensed Biological Products with Reference Product*

¹⁷³ *Abbreviated New Drug Applications and 505(b)(2) Applications (Final Rule)*, 81 FED. REG. 69580 (Oct. 6, 2016).

¹⁷⁴ 21 C.F.R. § 314.53(f)(1).

¹⁷⁵ *Id.*

¹⁷⁶ 21 C.F.R. § 314.53(f)(1)(i). Unless the NDA holder withdraws or amends its patent information in response to the patent listing dispute, the Agency will not change the patent information in the Orange Book.

¹⁷⁷ Pub. L. No. 116-290 (2021).

¹⁷⁸ Press Release, *President signs Rep. Kelly-introduced Orange Book Transparency Act into Law* (Feb. 25, 2021), <https://robinkelly.house.gov/media-center/press-releases/president-signs-rep-kelly-introduced-orange-book-transparency-act-law>.

¹⁷⁹ 21 U.S.C. § 355(c)(2).

Exclusivity and Biosimilarity or Interchangeability Evaluations.¹⁸⁰ The publication provides information on whether the agency has identified a product as a biosimilar or interchangeable biologic, along with any relevant regulatory exclusivities.¹⁸¹

Since the enactment of the Biological Product Patent Transparency Act (BPPTA) in 2020,¹⁸² the Purple Book also incorporates a patent listing function. In contrast to small-molecule drugs, providers of licensed biologics need not submit any patent information to the FDA when they obtain FDA licensure or subsequently obtain patents from the USPTO. Rather, the biologics sponsor identifies patents to the FDA only after it has asserted them in litigation.¹⁸³

Purple Book patent listings come on the heels of enactment of 2010 legislation, the Biologics Price Competition and Innovation Act (BPCIA).¹⁸⁴ The BPCIA provided an abbreviated regulatory pathway for manufacturers to obtain FDA approval for follow-on products, known as biosimilars or interchangeable biologics. The BPCIA further established a specialized patent dispute resolution proceeding between brand-name and follow-on biologics manufacturers. Because of their complex nature, practitioners frequently refer to these statutory provisions as the “Patent Dance.”¹⁸⁵

Participation in the Patent Dance is optional.¹⁸⁶ But if the brand-name firm and biosimilar manufacturer choose to do so, the Patent Dance calls for a series of information-sharing steps. One of them calls for the brand-name firm to present a list of patents for which it believes a claim of patent infringement could reasonably be asserted against a biosimilar.¹⁸⁷ The brand-name firm must provide this list to the biosimilar manufacturer and, following the BPPTA, to the FDA. The FDA then publishes this information in the Purple Book. As with the Orange Book, the FDA’s role is ministerial. The agency undertakes no substantive review before publishing patent information in the Purple Book.¹⁸⁸

¹⁸⁰ The Purple Book is available at www.fda.gov. It should be distinguished from other Purple Books, including INTERNATIONAL UNION OF PURE AND APPLIED CHEMISTRY, COMPENDIUM OF POLYMER TERMINOLOGY AND NOMENCLATURE (2d ed. 2008); as well as the Plum Book, U.S. HOUSE OF REPRESENTATIVES, COMMITTEE ON OVERSIGHT AND REFORM, UNITED STATES GOVERNMENT POLICY AND SUPPORTING POSITIONS (Dec. 2020).

¹⁸¹ See, e.g., Temkin *et al.*, *supra* note 114, at 13.

¹⁸² Biological Product Patent Transparency Act, Pub. L. No. 116-260, § 325, 134 Stat. 2936 (2020).

¹⁸³ 42 U.S.C. § 262(k)(9)(A)(iii).

¹⁸⁴ The BPCIA appears as Title VII of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

¹⁸⁵ THOMAS, *supra* note 122, at 848.

¹⁸⁶ Sandoz, Inc. v. Amgen, Inc., 137 U.S.1664 (2017); See Yang Li, *Does it Still Take Two to Tango? A Modern Interpretation of the BPCIA’s Patent Dance*, 9 N.Y.U. J. Intell. Prop. Ent. L. 107, 124 (2019).

¹⁸⁷ 42 U.S.C. § 262(l)(3)(A)(i).

¹⁸⁸ FDA, Purple Book, <https://purplebook.fda.gov/patent-list>.

IV. SHORTCOMINGS OF THE STATUTORY NOTICE SYSTEMS

At first blush, physical and virtual marking, as well as the patent listing functions of the Orange and Purple Books, appear beneficial or, at the very least, harmless. Each seemingly provides a quick, convenient way to correlate patents with products available in the marketplace. A hard look at these systems nonetheless uncovers fundamental pathologies that cause them to present a distorted view of the patent landscape, while at the same time doing violence to sound innovation policy. This Article next identifies persistent problems with current patent notice systems en route to proposing suggestions for reform.

A. *Circumscribed Scope*

A striking defect of the statutory notice systems is that each paints a substantially incomplete portrait of the patent landscape. By design, each applies only to a limited set of patent proprietors and to restricted types of patents. As a result, even if every eligible patent proprietor fully participated, members of the public would continue to possess an inadequate view of the patents that pertain to particular products.

The marking statute, by its nature, applies only to patentees that use their patented inventions commercially. No patent proprietor is required to practice its patented inventions, however, and patents owned by nonpracticing entities may cover products marketed by others.¹⁸⁹ This reality is particularly compelling in an era where products are increasingly complex and may incorporate numerous different components, each of which may be subject to dozens or even thousands of patents with a fragmented ownership.¹⁹⁰ As a result, even if the patent proprietor diligently marked its product with its own patents, or those it licenses from others, the public would remain unaware of relevant patents that may be owned by others.

To phrase the matter differently, infringers do not mark their products with the patents of others. Any member of the public who consulted an unmarked infringing product would, under the logic of the legislation, arrive at the impression that the product was unpatented. Because the marking statute operates only to limit the liability of adjudicated infringers, it essentially fails in its purposes every time courts apply it.

Notoriously, the marking requirement also does not apply to patents that claim methods, rather than products.¹⁹¹ The courts have reasoned that methods cannot be

¹⁸⁹ See *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995).

¹⁹⁰ See Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 1992 (2007).

¹⁹¹ Christina Sharkey, *Strategic Assertions: Evading the Patent Marking Requirement*, 12 NW. J. TECH. INTEL. PROP. 103 (2014); Krista S. Jacobsen, *Methods, Marking, and Messiness: Revisiting the Federal Circuit's Rule That Product Marking Is Not Required Where a Patent is Directed to a Method*, 13 INTEL. PROP. L. BULL. 107 (2009); James M. Markarian, *Can the Marketing Requirements for a Patented Article Be Circumvented by Obtaining a Process Patent?*, 79 J. PAT. & TRADEMARK OFF. SOC'Y 365 (1997).

marked because they concern incorporeal behavior rather than an instantiated article.¹⁹² This rule has been roundly criticized because of the ease with which claims may be converted from product format to process format and back again.¹⁹³ After all, any complex machine, ranging from an engine to an escalator to a lawn mower, essentially consists of a physically embodied process. The ruling further seems to defy the wording of Section 287, which implies only that the patentee markets a tangible article, not necessarily that it claims one.¹⁹⁴ This loophole in the coverage of the marking statute further limits its ability to achieve its policy goals.

The Orange Book too may represent only a partial picture of the patents pertaining to a particular small-molecule drug. According to the FDA, several types of patents are inappropriate for listing in the Orange Book.¹⁹⁵ These include processes for manufacturing the drug,¹⁹⁶ packaging,¹⁹⁷ metabolites,¹⁹⁸ and chemical intermediates.¹⁹⁹ Further, the agency and the courts have rebuffed efforts by third parties to include patents in the Orange Book.²⁰⁰ Only the enterprise that has obtained FDA approval may do so. These rules collectively restrict the ability of

¹⁹² See, e.g., *Arctic Cat, Inc. v. Bombardier Recreational Prods., Inc.*, 950 F.3d 860, 864 (Fed. Cir. 2020); *ActiveVideo Networks, Inc. v. Verizon Commc'ns., Inc.*, 694 F.3d 1312, 1334 (Fed. Cir. 2012); *Fujitsu Ltd. v. Netgear, Inc.*, 620 F.3d 1321, 1332 (Fed. Cir. 2010); *Hanson v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1083 (Fed. Cir. 1983).

¹⁹³ See John R. Thomas, *Of Text, Technique, and the Tangible: Drafting Patent Claims Around Patent Rules*, 17 *John MARSHALL J. COMPUT. INFO. L.* 219, 255–57 (1998); *Bandag, Inc. v. Al Bolser's Tire Stores, Inc.*, 750 F.2d 903, 922 (Fed. Cir. 1984) (“It is commonplace that the claims defining some inventions can by competent draftsmanship be directed to either a method or an apparatus.”); Jim Singer, *Why do patents often include method claims and apparatus claims?*, IP Spotlight (Dec. 6, 2017) (noting that the claims of a patent often “repeat themselves” between method claims, on one hand, and apparatus or system claims, on the other), <https://ipspotlight.com/2017/12/06/why-do-patents-often-include-method-claims-and-apparatus-claims/>; Kenneth Horton, *Restriction Requirements: Strategies for Defeating Patent Application Restriction Requirements*, 6 *Bloomberg L. Reps.* 29, 29 (Feb. 27, 2012) (“When drafting the patent application, method claims and product claims can be written to share as many similar limitations as possible.”); SCHECHTER & THOMAS, *supra* note 31, at 26.

¹⁹⁴ 35 U.S.C. § 287(a) (encouraging marking by “[p]atentees, and persons making, offering for sale, or selling within the United States *any patented article* for or under them, or importing *any patented article* into the United States”) (emphasis added).

¹⁹⁵ 21 C.F.R. § 314.53(b).

¹⁹⁶ *Id.*

¹⁹⁷ 67 FED. REG. 65,451; see 21 C.F.R. § 314.50(d)(1)(ii)(a). In contrast, drug-delivery systems, including “metered aerosols, capsules, metered sprays, gels, and pre-filled drug delivery systems,” are drug products, as discussed above, and patents covering them should be listed. *Id.*; see also *In re Lantus Direct Purchaser Antitrust Litig.*, 284 F. Supp. 3d 91, 104 (D. Mass. 2018) (finding that a prefilled injector pen approved as a drug delivery device for treating diabetes is not packaging and that patents covering the device may be listed in the Orange Book).

¹⁹⁸ 68 FED. REG. at 36,680. See *id.* (citing 67 FED. REG. at 65,451).

¹⁹⁹ 21 C.F.R. 315.53(b), (c)(2). The FDA considers intermediates as “in-process materials” rather than drug substances or components in the finished drug product. *Id.*; see also 21 C.F.R. § § 210.3(b)(9), 211.110. It, therefore, considers that patents that claim intermediates do not claim the approved drug product and fail to satisfy the requirements for listing. See 68 FED. REG. 36,680.

²⁰⁰ See *aaiPharma, Inc. v. Thompson*, 296 F.3d 227, 233 (4th Cir. 2002) (“Only the NDA holder can submit patents claiming its approved drug for listing in the Orange Book . . .”).

pharmaceutical firms to resolve patent disputes prior to the entry of generics into the marketplace.²⁰¹

Purple Book patent listings stand to be even more fragmentary than those of the Orange Book. Patents make their way into the Orange Book when the FDA approves a brand-name drug company's New Drug Application.²⁰² The brand-name firm also informs the FDA of subsequently issued patents so that they may be listed.²⁰³ In contrast, a brand-name biologics manufacturer need not provide any patent information to the agency upon licensure. The FDA lists patents in the Purple Book only when the brand-name firm identifies them to the biosimilar applicant as part of the Patent Dance.²⁰⁴

The result of this statutory scheme is that the FDA lists biologics patents in the Purple Book only after they have been identified during infringement litigation proceedings. Brand-name manufactures are certainly not required to enforce all their patents and may choose to hold some of them in reserve.²⁰⁵ As a result, subsequent biosimilar applicants may still need to participate in the Patent Dance in order to obtain disclosure of patents that are relevant to them.²⁰⁶ Because the Patent Dance is optional, if either party opts not to participate, then no patents will be listed in the Purple Book at all.²⁰⁷

B. Product-Patent Misalignment

Congress premised each of the four statutory notice statutes on the assumption that technology implementers will be readily able to pair their patents with the products they sell. Undoubtedly this circumstance may often be the case. But the assumption that patents and products align evenly is not one that may always be made. This problem is potentially more acute with respect to physical and virtual marking, but it may arise as well with patents listed in the Orange and Purple Books.

Incongruities between a technology implementer's product lines and its patents may result from patent doctrines that encourage the prompt filing of applications.²⁰⁸ Under the novelty standard, for example, even a single sales offer or public use of an invention, even one day before the filing date, invalidates the patent.²⁰⁹ As a result, technology implementers often file applications at the USPTO long before

²⁰¹ See THOMAS, *supra* note 122, at 421.

²⁰² 21 U.S.C. § 355(b)(1)(A)(viii).

²⁰³ 21 U.S.C. § 355(b)(1)(B).

²⁰⁴ 42 U.S.C. § 262(k)(9)(A)(iii).

²⁰⁵ See, e.g., Temkin et al., *supra* note 114, at 14 (suggesting that biologics manufacturers might strategically hold some patents in reserve by not asserting them in particular litigation against biosimilar applicants).

²⁰⁶ Charlotte Geaghan-Breiner, *The Patent Trap: The Struggle for Competition and Affordability in the Field of Biologic Drugs*, 54 COLUM. J. L. SOCIAL PROBLEMS 589, 620 (2021).

²⁰⁷ *Sandoz, Inc. v. Amgen, Inc.*, 137 S. Ct. 1664 (2017).

²⁰⁸ See Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. TECH. L. REV. 345, 351 (2007).

²⁰⁹ 35 U.S.C. § 102(a)(1). The statute exempts disclosures made one year or less before a patent is filed, provided that the applicant made the disclosure. 35 U.S.C. § 102(b)(1).

they have finalized their product designs, or obtained FDA approval or licensure.²¹⁰ Patent prosecutors are also more concerned with distinguishing an invention from the prior art than aligning claims with products that have not yet been made, approved, or licensed.²¹¹ To be sure, savvy applicants may be able to craft additional claims that better align with the products they ultimately market by filing a continuing application.²¹² The success of this strategy depends upon the extent of an earlier disclosure provided to the USPTO, as well as the sophistication and resources of the applicant.²¹³

Within this context, the marking statute supposes that technology implementers have determined that the products they bring to market are covered by their own patents. That patent proprietors routinely engage in a self-infringement analysis with the required rigor seems doubtful. The patent infringement inquiry implicates esoteric legal and technical issues.²¹⁴ It involves particularized conventions including canons of construction,²¹⁵ the use of expert testimony, documents extrinsic to the patent, and the prosecution history,²¹⁶ as well as an extensive jurisprudence concerning the doctrine of equivalents.²¹⁷ In combination with the growing complexity of the patent instruments themselves,²¹⁸ determining whether a product infringes a patent often involves considerable expenditures needed to harness advanced legal and technical expertise.

Even if the patent proprietor has accurately concluded that its products infringe its patents, this inquiry seems of doubtful relevance. Questions of infringement do not involve a comparison of the patentee's product or process to that of the accused infringer. The relevant determination is whether at least one claim of a patent

²¹⁰ See John R. Thomas, *The End of "Patent Medicines?" Thoughts on the Rise of Regulatory Exclusivities*, 70 FOOD DRUG L.J. 39, 43 (2015).

²¹¹ *Id.*

²¹² Applicants file continuing applications in order to pursue additional claims to an invention that was disclosed to the USPTO in an earlier application that has not been abandoned. See 35 U.S.C. § 120 (continuation applications); 35 U.S.C. § 132(b) (requests for continued applications). See also Casare Righi, Davide Cannito, & Theodor Vlasel, *Continuing patent applications at the USPTO*, 52 RSCH. POL'Y 104742,5 (2023) (noting the use of continuation applications to account for the time lag between the acts of invention and commercialization).

²¹³ In particular, the earlier application must provide a disclosure that enables practice of the invention and, via the written description requirement, notify the public that the applicant was in possession of the subsequently claimed invention as of the filing date of the earlier application. 35 U.S.C. § 112(a).

²¹⁴ Janet Freilich, *Paths to Downstream Innovation*, 55 U.C. DAVIS L. REV. 2209, 2268 (2022) ("Determining if a particular action infringes a patent is notoriously difficult.").

²¹⁵ See, e.g., *Autogiro Co. v. United States*, 384 F.2d 391, 397 (Ct. Cl. 1967).

²¹⁶ See, e.g., Jeremy W. Bock, *Behavioral Claim Construction*, 102 MINN. L. REV. 1273 (2018).

²¹⁷ See, e.g., Daryl Lim, *The (Unnoticed) Revitalization of the Doctrine of Equivalents*, 95 ST. JOHN'S L. REV. 65 (2021).

²¹⁸ See John R. Allison & Mark A. Lemley, *The Growing Complexity of the United States Patent System*, 82 B.U. L. REV. 77 (2002).

corresponds to an accused infringement,²¹⁹ a question to which the marking statute is not addressed.

With respect to the FDA publications, the Purple Book allows patent proprietors to avoid the expense of determining whether their own products infringe. Purple Book patent listings are based upon a statement by the licensed biologics manufacturer that it “believes a claim of patent infringement could reasonably be asserted” against a competitor.²²⁰ In contrast, the Orange Book patent listing requirements act similarly to the marking statute. Patents amenable to listing must claim the applicant’s own drug or method of using that drug.²²¹ Manufacturers of small-molecule drugs are therefore tasked with undertaking the ultimately irrelevant inquiry of whether their patents cover their own products.

C. Favoring Trolls

The crusade against patent trolls has been the driving force of U.S. patent policy for more than a decade.²²² Although the term “patent troll” is not subject to a single definition, it is generally associated with entities that do not practice their inventions, engage in abusive litigation, or do not contribute to technological innovation.²²³ Patent trolls—perhaps less pejoratively known as nonpracticing or patent assertion entities, or as repeat litigants—use their patents solely to collect licensing fees from technology implementers.²²⁴

Much case law, legislation, and commentary has been directed towards trolling, and the impact upon fundamental patent doctrines has been transformative. With trolls in mind, the Supreme Court issued rulings limiting the availability of injunctive relief and restricting access to patent-friendly fora.²²⁵ Congress established *inter partes* review and other administrative opposition proceedings that provide an expedient and cost-effective means for challenging patents at the

²¹⁹ *Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994) (“As we have repeatedly said, it is error for a court to compare in its infringement analysis the accused product or process with the patentee’s commercial embodiment or other version of the product or process; the only proper comparison is with the claims of the patent.”).

²²⁰ 42 U.S.C. § 262(l)(3)(A)(i).

²²¹ 21 U.S.C. § 355(b)(1)(A)(viii).

²²² See Robert Merges, *After the Trolls: Patent Litigation as Ex Post Market-Making*, 54 AKRON L. REV. 555, 556 (2020) (“Patent policy has been shaped for the past 15 years by a single imperative: reduce rent-seeking patent litigation.”).

²²³ See Robert P. Merges, *The Trouble with Trolls: Innovation, Rent-Seeking, and Patent Law Reform*, 24 BERK. TECH. L.J. 1583 (2009).

²²⁴ See, e.g., Ryan T. Holte, *Trolls or Great Inventors: Case Studies of Patent Assertion Entities*, 59 ST. LOUIS U. L.J. 1 (2014).

²²⁵ See *eBay, Inc. v. MercExchange LLC*, 547 U.S. 388, 396 (2006); *TC Heartland LLC v. Kraft Foods Group Brands LLC*, 137 S.Ct. 1514 (2017).

USPTO.²²⁶ Even President Barack Obama weighed in and urged confrontation with patent trolls in order to protect U.S. innovation.²²⁷

Given the patent community's collective focus on patent trolls, that the Patent Act would house a statute that encourages trolling—or, at the very least, favors trolls over technology implementers—would seem an extraordinary proposition. Yet the patent marking statute does precisely that. Marking simply does not apply to patentees that do not themselves make, use, offer to sell, sell, or import the patented invention into the United States.²²⁸ A patentee that never makes or sells a patented article may recover damages for past infringements even absent actual notice to an accused infringer.²²⁹ As a result, patent trolls stand in a superior position to obtain monetary recovery for infringement than do patentees that make their products available to the public. The relative advantage of patent trolls over technology implementers, conferred by the marking statute, seems extraordinary in view of longstanding and consistent patent policies to the contrary.

D. Harsh Consequences for the Rights Holder

The patent marking statute invites comparison with other intellectual property legislation that includes similar provisions. The Copyright Act, the Lanham Act, and the Semiconductor Chip Protection Act speak to the provision of notice upon copies of works of authorship,²³⁰ alongside trade-identifying symbols,²³¹ and upon mask works and semiconductor chip products respectively.²³² Like the Patent Act, these statutes make marking optional but encourage it through remedial restrictions. Each treats holders of proprietary rights less harshly, however, raising the question of why the law treats inventions more poorly than other intellectual goods.

In copyright law, placement of the familiar © symbol, or other options identified by statute,²³³ precludes adjudicated infringers from asserting that they acted innocently.²³⁴ Even absent marking, courts rarely find that infringers were innocent.²³⁵ Yet in those uncommon occasions, innocent infringers remain

²²⁶ See JOHN R. THOMAS, INTER PARTES REVIEW OF PATENTS: INNOVATION ISSUES 1 (Congressional Research Service Report No. R44905, July 26, 2017) (available at [crsreports.congress.gov](https://www.crsreports.congress.gov)).

²²⁷ See The White House, Gene Sperling, *Taking on Patent Trolls to Protect American Innovation* (June 4, 2013); EXECUTIVE OFFICE OF THE PRESIDENT, PATENT ASSERTION AND U.S. INNOVATION (June 2013) (both available at obamawhitehouse.archives.gov).

²²⁸ Carl Oppendahl, *Patent Marking of Systems*, 11 SANTA CLARA COMP. & HIGH TECH. L.J. 205, 210 (1995) (noting that the marking statute does not apply to nonpracticing entities.).

²²⁹ *Arctic Cat, Inc. v. Bombardier Recreational Prods., Inc.*, 950 F.3d 860, 864 (Fed. Cir. 2020).

²³⁰ 17 U.S.C. § 401(b).

²³¹ 15 U.S.C. § 1111.

²³² 17 U.S.C. § 909.

²³³ Other possibilities include “Copyright” or the abbreviation “Copr.” 17 U.S.C. § 401(b). The Copyright Act permits use of the symbol ® on phonograms of sound recordings. 17 U.S.C. § 402(b). In each case, copyright notice must include the date of first publication and the name of the owner of copyright.

²³⁴ 17 U.S.C. §§ 401(d), 402(d), 404(a).

²³⁵ 17 U.S.C. § 504(b).

infringers. Only the third possible form of damages for copyright infringement, statutory damages, is diminished. Under the Copyright Act, the prevailing copyright proprietor may obtain statutory damages of \$750 to \$30,000 per infringed work. For innocent infringement statutory damages are reduced to a sum “not less than \$200.”²³⁶ Failure to mark therefore often has little or no impact upon the rights afforded by copyright.

Trademark notice acts differently.²³⁷ Owners of federally registered trademarks may display the symbol ®, or a phrase designated in the statute, alongside it.²³⁸ Failure to mark precludes the award of damages until the adjudicated trademark infringer “had actual notice of the registration.”²³⁹ The courts allow use of circumstantial evidence to prove the defendant knew that the trademark was federally registered. Evidence that the infringer was sophisticated in trademark matters, had registered its own marks, and had engaged an attorney to advise it on trademarks may qualify as notice of the registration, even if the trademark owner failed to mark.²⁴⁰

The marking provision of the Chip Act acts somewhat similarly to the Lanham Act. Under that somewhat obscure statute, owners of registered mask works may place the symbol (M) or similar indicators on their mask works or semiconductor chip products.²⁴¹ Marking establishes *prima facie* evidence of the infringer’s knowledge of protection.²⁴² Even if the rights holder fails to mark, purchasers with actual knowledge or who have reasonable grounds to believe that a mask work was protected remain fully liable for infringement.²⁴³

Whether sound intellectual property policy supports these distinct outcomes seems doubtful. In support of these variable marking requirements, one might distinguish the different intellectual property statutes on the basis that copying a work of authorship, trademark, or even a mask work may seem more intuitively improper as compared to patent infringement. In addition, the validity of a patent may be more readily contested than other intellectual property rights, and determinations of patent infringement are often more complex than those pertaining to copyright and trademark. These arguments find support in criminal statutes

²³⁶ 17 U.S.C. § 504(c)(1).

²³⁷ See generally Angela Peterson, *Overdue Notice: Using Virtual Marking to Modernize Trademark Notice Requirements*, 25 STAN. TECH. L. REV. 247 (2022).

²³⁸ Other forms of statutory notice include using the words “Registered in U.S. Patent and Trademark Office” or “Reg. U.S. Pat. & Tm. Off.” 15 U.S.C. § 1111. In addition to these examples of statutory notice for a federally registered mark, enterprises often use the “TM” symbol to provide notice of asserted marks that are not federally registered. See James Juo, *Notice That Registered Trademark in the Window?*, 10 JOHN MARSHALL REV. INTELL. PROP. L. 736, 737 n.1 (2011).

²³⁹ 15 U.S.C. § 1111.

²⁴⁰ See *Int’l Stamp Art, Inc. v. U.S. Postal Service*, 2005 WL 3947951 at *8 (N.D. Ga. 2005); *Derrick Mfg. Corp. v. Southwestern Wire Cloth, Inc.*, 934 F. Supp. 796, 812 (S.D. Tex. 1996).

²⁴¹ The other possible forms of notice are the symbol *M* or the words “mask work.” The owner of the mask work must also be identified. 17 U.S.C. § 909(b).

²⁴² 17 U.S.C. § 909(a).

²⁴³ For the Chip Act, innocent purchasers—and not others that reproduce, import, or distribute a mask work—may only be liable upon actual notice by the rights holder. 17 U.S.C. §§ 907.

addressing copyright and trademark counterfeiters, while no such legislation deters “patent pirates.”

Particularly with respect to copyright, however, the complexities of determining whether rights exist and who owns them may present profound difficulties. So-called “orphan works”—copyright-protected works with unknown owners—have proliferated due to lengthy copyright terms and the conferral of rights without any requirement of government registration.²⁴⁴ This indeterminate ownership means that archivists, broadcasters, filmmakers, musicians, and other members of the user community may face infringement liability despite their best efforts to conduct copyright clearance.²⁴⁵ Users may simply be unable to determine whether a work of authorship remains under copyright, as the term of rights is most often calculated upon the date of publication or the author’s death,²⁴⁶ and if the work is protected, whether anyone would object to its use.²⁴⁷

Adding to this legal uncertainty is the Supreme Court’s recent elimination of the laches defense in copyright cases,²⁴⁸ which has allowed creators of older works to sue for infringement.²⁴⁹ Further, many commentators believe that for a signature class of copyrighted expression, musical works, findings of infringement have been far too readily reached.²⁵⁰ Yet despite these realities, copyright owners may be fully compensated even though infringement was innocent, while patent owners may obtain no damages from innocent patent infringers whatsoever. This result holds even though the Copyright Act provides for more generous damages awards than apply to patents, allowing the award of both the actual damages suffered as well as the infringer’s profits,²⁵¹ in addition to statutory damages.²⁵²

The marking statute acts in a more draconian fashion for patents even though marking of works of authorship and trademarks is ordinarily more readily accomplished. The copyright concept of a “work of authorship” necessarily implies substantiated expression,²⁵³ often easily allowing the placement of a copyright notice. Trademarks too consist of identifying words, symbols, and designs that most often may be readily accompanied by a single-character ideogram. Marking with specific patent numbers may be far more difficult with respect to chemical

²⁴⁴ See David R. Hansen et al., *Solving the Orphan Works Problem for the United States*, 37 COLUM. J.L. ARTS 1, 12–14 (2013).

²⁴⁵ See Sanjiv D. Sarwate, *Rescuing Orphan Works: An Analysis of Current Legislation*, 26 INTELL. PROP. L. NEWSL. no. 4 at 21,22 (2008).

²⁴⁶ 17 U.S.C. § 302.

²⁴⁷ See Ryan Andrews, *Contracting Out of the Orphan Works Problem: How the Google Book Search Settlement Serves as a Private Solution to the Orphan Works Problem and Why It Should Matter to Policy Makers*, 19 S. CAL. INTERDISC. L.J. 97, 98 (2009).

²⁴⁸ *Petrella v. Metro-Goldwyn-Mayer, Inc.*, 572 U.S. 663, 667–68 (2014).

²⁴⁹ See Dylan Fulop, *Petrella v. Metro-Goldwyn-Mayer: A ‘Stairway’ to Countless Copyright Claims*, 39 NOVA L. REV. 437, 446–48 (2015).

²⁵⁰ See, e.g., Nilay Patel, *Good 4 Who? How Music Copyright Has Gone Too Far*, THE VERGE (Sept. 15, 2021).

²⁵¹ 17 U.S.C. § 504(b).

²⁵² 17 U.S.C. § 504(c).

²⁵³ 17 U.S.C. § 102(a).

compounds,²⁵⁴ nanotechnology,²⁵⁵ genetically altered life forms,²⁵⁶ and other products amenable for patenting. In an era where courts increasingly recognize the historic kinship of the nation's intellectual property rights,²⁵⁷ the harshness of the patent marking statute warrants reappraisal.

E. Unnecessary and Misleading Communication

The patent marking statute should also be considered with specific reference to its audience, which may be roughly divided into two categories. The first category consists of potential competitors that wish to copy the patented product. The second consists of consumers, who may glance at the physical marking of a product but are unlikely to pursue the matter further. The questionable need of the first audience of competitors to rely upon patent markings, along with the potentially misleading nature of patent markings to the second audience of consumers, casts further doubt upon the patent marking project.

With respect to the first audience, the patent notice statutes operate under an unlikely assumption: although individuals or enterprises may be sophisticated enough to identify and copy the high-technology inventions of their competitors, they are nonetheless incapable of determining whether those competitors own patents covering those products or not. This conclusion is questionable, as demonstrated by the most recent Supreme Court opinion considering patent notice. In *Global-Tech Appliances, Inc. v. SEB S.A.*,²⁵⁸ an opinion addressing induced infringement, the Supreme Court discounted the lack of marking when it ruled that the accused infringer was willfully blind to the existence of the patent-in-suit. To be clear, the *Global-Tech* case assessed whether one marketplace actor should be liable for promoting the infringement of others, rather than the relevant timeframe for assessing damages once liability had been established. This holding nonetheless provides a more realistic assessment of the ability of a technology implementer to locate the patents of its competitor when it designs its own products, even when the competitor's product is unmarked.

The *Global-Tech* case concerned SEB's patented deep fryer for use in home kitchens. The controversy began when a competitor of SEB asked Pentalpha to develop a deep fryer with similar features. Pentalpha subsequently sought a freedom-to-operate opinion from a patent attorney with respect to its deep fryer but did not tell him that it had copied SEB's product. The patent attorney failed to locate SEB's patent and issued an opinion stating that Pentalpha did not infringe any of

²⁵⁴ See, e.g., *Brenner v. Manson*, 383 U.S. 519, 520 (1966).

²⁵⁵ See, e.g., Michael Collins-Caulkins, *Nanotechnology Patent Law: A Case Study of United States and European Patent Applications*, 37 SANTA CLARA HIGH TECH. L.J. 337, 340 (2020–21).

²⁵⁶ See *Diamond v. Chakrabarty*, 447 U.S. 303, 303 (1980).

²⁵⁷ See, e.g., *Allen v. Cooper*, 140 S.Ct. 994, 1005 (2020); *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 137 S.Ct. 1523, 1526 (2017); *SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 137 S.Ct. 954, 957 (2017).

²⁵⁸ *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 758 (2011).

the patents that he had identified. Pentalpha ultimately sold its product to retailers that resold them under their own trademarks.²⁵⁹

When SEB subsequently brought an infringement suit against Pentalpha, the Supreme Court took the opportunity to set forth the appropriate standard for inducement of infringement. The relevant statute, section 271(b) of the Patent Act, is admirably succinct, stating only that “[w]hoever actively induces infringement of a patent shall be liable as an infringer.”²⁶⁰ The Court interpreted this provision as requiring that the accused infringer both knew of the patent and that the induced acts constitute patent infringement.²⁶¹ The Court nonetheless tempered the knowledge requirement by allowing it to be proven through the doctrine of “willful blindness.” If the defendant subjectively believed that there was a high probability that a patent exists and took deliberate actions to avoid learning of it, then it may be deemed willfully blind and liable for induced infringement.²⁶²

Under the facts of *Global-Tech*, the Supreme Court readily concluded that Pentalpha had been willfully blind towards SEB’s patent. Pentalpha knew that the SEB fryer embodied an advanced technology but failed to inform its patent attorney that it had copied that product.²⁶³ The Court further dismissed the fact that Pentalpha had copied an unmarked model of the SEB fryer from abroad, reasoning that products intended for foreign markets do not usually bear U.S. patent markings.²⁶⁴

Although the *Global-Tech* opinion arose with respect to substantive infringement standards, the Supreme Court’s indifference to the absence of patent markings on the patented product is remarkable. The Court’s reasoning further suggests that any enterprise that seeks to knock off a high-technology product should know that its manufacturer might have procured patents claiming it. This reality should be contrasted with the obligations imposed upon patent applicants and proprietors. Patentees face the prospect of invalidated patents due to obscure references that no reasonable search could have unearthed.²⁶⁵ In contrast, and in conflict with the reasoning of *Global-Tech*, the marking statute exempts enterprises that copy their competitor’s high technology products from undertaking any review of the U.S. patent rolls whatsoever.

Concerns over patent notice admittedly possess more currency when the relevant patent has been licensed or assigned. The Patent Act does not require technology implementers to inform the USPTO that they are operating under a

²⁵⁹ *Id.* at 758.

²⁶⁰ 35 U.S.C. § 271(b).

²⁶¹ 563 U.S. at 765–66.

²⁶² *Id.* at 769.

²⁶³ *Id.* at 770–71.

²⁶⁴ *Id.* at 771.

²⁶⁵ See John R. Thomas, *The Scope of the Prior Art* (draft); Stephen Yelderman, *Prior Art in Inter Partes Review*, 104 IOWA L. REV. 2705, 2724–26 (2019).

license.²⁶⁶ With respect to assignments, the patent recording statute incentivizes parties to update patent ownership information but does not require it. As a result, no one may be certain who owns a particular patent, nor may anyone be sure of what patents a particular individual or enterprise owns.²⁶⁷ A copyist who diligently searches through the patent databases may reasonably fail to discern all the patents owned or licensed by that competitor.

Whether the marking statute provides an appropriate response to these legitimate concerns seems doubtful. Because the marking statute encourages notice for only a limited set of patents, it provides no solution to the woeful state of the patent recording statute. Commentators widely agree that more comprehensive reforms to the recording of patent ownership and licensing records are needed.²⁶⁸ Although several sessions of Congress have proposed reforms to the recording of ownership, the legislation has yet to be enacted.²⁶⁹

Patent markings are read not just by marketplace rivals, of course, but also by individuals and enterprises that do not intend to compete with the patentee. In an era where everyday products have become increasingly complex, the assumption that members of the public may discern an invention from its commercial embodiment—not to mention reproduce it—seems doubtful.²⁷⁰ They also most often lack experience with the patent system, of course, and whether they receive an appropriate impression from patent markings may reasonably be questioned. Many enterprises boast of their patent portfolios to the lay public, of course, and in this vein patent markings serve as a form of advertising.²⁷¹ Many lay persons likely believe that approval of a patent by a federal agency indicates that the product is superior to the state of the art.²⁷² Informed observers know well, however, that the grant of a patent does not imply that its claimed inventions amount to an improvement over existing technology.²⁷³

Other studies suggest that the patent status of products disinterests most consumers. Professor Cotropia recently conducted both a survey of Kickstarter

²⁶⁶ See *Uniloc USA, Inc. v. Apple, Inc.*, 25 F.4th 1018, 1023 (Fed. Cir. 2022) (“The court thus made an error of law in making a blanket ruling that the public has a broad right to licensing information relating to patents.”).

²⁶⁷ See Colleen Chien, *The Who Owns What Problem in Patent Law*, *Santa Clara Law Digital Commons* (Jan 1., 2012), <https://digitalcommons.law.scu.edu/facpubs/190>.

²⁶⁸ See Jonathan Stroud & Levi Lall, *Paper of Record: Modernizing Ownership Disclosures for U.S. Patents*, 124 W. VA. L. REV. 449 (2022); Jonathan Stroud, *Pulling Back the Curtain on Complex Funding of Patent Assertion Entities*, 12 LANDSLIDE 2 (2019).

²⁶⁹ See, e.g., *Pride in Patent Ownership Act*, S.2774, 117th Cong. (2021); *End Anonymous Patents Act*, H.R. 2370, 114th Cong. (2015); *Patent Transparency and Improvements Act of 2013*, S.1720, 113th Cong. (2013).

²⁷⁰ Joel Voelzke, *Patent Marking Under 35 U.S.C. § 287(a): Products, Processes, and the Deception of the Public*, 5 FED. CIR. B.J. 317 (1995).

²⁷¹ See Ann Bartow, *Separating Marketing Innovation from Actual Invention: A Proposal for a New, Improved, Lighter, and Better-Tasting Form of Patent Protection*, 4 J. SMALL & EMERGING BUS. L. 1, 2 (2000).

²⁷² J. Jonas Anderson, *Nontechnical Disclosure* 69 VAND. L. REV. 1583, 1593–95 (2016).

²⁷³ See, e.g., *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999).

campaigns as well as a “mock” Kickstarter campaign using Amazon Mechanical Turk.²⁷⁴ His study concluded that consumers rarely perceive whether an article bears a patent marking or not and, when they do, they place little weight upon the grant of a patent.²⁷⁵ His conclusions were consistent with other studies suggesting the indifference of a lay audience towards the patent status of a particular product.²⁷⁶ Although this topic remains worthy of further examination, our current knowledge suggests patent markings are at best of little interest or consequence to consumers, and in the worst case they are misleading.

F. Costs to the Private Sector

Given the many flaws that attend the statutory patent notice systems, one might hope that the cost of administering them would be low. Yet physically marking products or their packaging may be inconvenient and costly, particularly as the patent landscape shifts and notice must be updated.²⁷⁷ Patents issue,²⁷⁸ expire,²⁷⁹ are amended,²⁸⁰ are interpreted,²⁸¹ are invalidated during litigation,²⁸² and are canceled by the USPTO’s Patent Trial and Appeal Board.²⁸³ In each circumstance, manufacturers that physically mark their products must engage in a potentially expensive and time-consuming process of changing the stamping, engraving, impressing, embossing, or other means for placing a patent number on a product. Although altering a product’s packaging would presumably be less costly, the marking statute only allows the marking of packaging if marking of the product “can not be done”²⁸⁴ While some courts have read this language to afford discretion to the patentee on where marking should be placed,²⁸⁵ others have denied recovery of damages when a package was marked rather than the product itself.²⁸⁶

²⁷⁴ See Cotropia, *supra* note 21, at 227.

²⁷⁵ *Id.* at 227–28.

²⁷⁶ See Azzurra Meoli, Federico Munari & James Bort, *The Patent Paradox in Crowdfunding: An Empirical Analysis of Kickstarter Data*, 28 INDUS. CORP. CHANGE 1321, 1321 (2019) (discussing the “negative signaling role of patents” in crowdfunding and angel investor situations); Gerrit K.C. Ahlers, Douglas Cumming, Christina Gunther, & Denis Schweizer, *Signaling in Equity Crowdfunding*, 39 ENTREP. THEORY PRAC. 955, 974 (2015).

²⁷⁷ H.R. Rep. No. 112-98, at 53 (2011) (“For many products, it is difficult and expensive to change a mold or other means by which a product is marked as patented”); *Pequignot v. Solo Cup Co.*, 646 F.Supp.2d 790, 793 (E.D. Va. 2009), *rev’d*, 608 F.3d 1356 (Fed. Cir. 2010) (noting substantial costs associated with replacement of parts bearing patent markings, as well as labor and production downtime).

²⁷⁸ 35 U.S.C. § 151.

²⁷⁹ 35 U.S.C. § 154(a).

²⁸⁰ *See, e.g.*, 35 U.S.C. §§ 251, 154, 255, 257.

²⁸¹ *See, e.g.*, *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318 (2015).

²⁸² 35 U.S.C. § 282(b).

²⁸³ *See, e.g.*, 35 U.S.C. § 318(b).

²⁸⁴ 35 U.S.C. § 287(a).

²⁸⁵ *See, e.g.*, *Rutherford v. Trim-Tex, Inc.*, 803 F. Supp. 158, 161–62 (N.D. Ill. 1992).

²⁸⁶ *See Creative Pioneer Prods. Corp. v. K Mart Corp.*, 1987 WL 54482 at *6 (S.D. Tex. 1987); *John L. Rie, Inc. v. Shelly Bros., Inc.*, 366 F. Supp. 84, 90–91 (E.D. 1973).

For its part, virtual marking has been met with surprisingly unsteady adoption by industry.²⁸⁷ The courts have insisted that virtual marking provide a direct association between specific products and individual patents. They have chided patent owners who have developed websites associating patents with a category of products, rather than a specific one,²⁸⁸ affixing the address of an Internet site without the term “patent” or “pat.”;²⁸⁹ or otherwise creating a “research project for the public.”²⁹⁰ The virtual marking statute also implies that members of the public must traverse websites maintained by different manufacturers. The lack of a common format may increase search costs and create inefficiencies.

G. Cost-Shifting by the FDA

Unwarranted delays in lawful generic competition, even for a short period of time, may hold enormous negative consequences for public health. The FDA has nonetheless inferred that its role regarding patent listings is purely ministerial.²⁹¹ On its face, the Hatch-Waxman Act neither requires nor precludes FDA review of patents for Orange Book listing. However, the legislation requires the FDA to update the Orange Book with patent submissions every 30 days.²⁹² In the view of the FDA, this abbreviated time frame does not contemplate that the agency undertake a substantive comparison of the patent with the approved drug.²⁹³ In addition, the statute provides that “[p]atent information that is not the type of patent information required . . . shall not be submitted,”²⁹⁴ a command that may be viewed as placing the onus of identifying appropriate patents upon the NDA holder.

The FDA has also pointed to institutional concerns to justify its hands-off approach towards patents. The agency has asserted that it lacks patent expertise,²⁹⁵ and after four decades of Orange Book administration has been unwilling to acquire any. Finally, the FDA reasoned in 2003 that a “fundamental assumption of the Hatch-Waxman Amendments is that the courts are the appropriate mechanism for the resolution of disputes about the scope and validity of patents.”²⁹⁶ This stance

²⁸⁷ See Dane D. Sowers, *Ensuring Proper Notice: Clearing the Fog Surrounding Virtual Marking*, 54 CREIGHTON L. REV. 107, 110 (2020); USPTO, REPORT TO CONGRESS, REPORT ON VIRTUAL MARKING (Sept. 2014), https://www.uspto.gov/sites/default/files/aia_implementation/VMreport.pdf.

²⁸⁸ See *VLSI Tech. LLC v. Intel Corp.*, 2021 WL 2773013 (W.D. Tex. 2021).

²⁸⁹ *A to Z Machining Serv., LLC v. Nat'l Storm Shelter, LLC*, 2011 WL 6888543 (W.D. Okla. 2011).

²⁹⁰ *Mfg. Res. Int'l Inc. v. Civiq Smartscales LLC*, 397 F.Supp.3d 560, 577 (D. Del. 2019). See also *Nat'l Prods. V. Akron Res., Inc.*, 2019 U.S. Dist. LEXIS 42119 at *50 (effectiveness of website requiring navigation to the “Patents and Trademarks” page with over 100 patents not specifically paired with products creates an “intriguing issue” of compliance with § 287).

²⁹¹ FDA, Report to Congress, The Listing of Patent Information in the Orange Book 5 (Jan. 2022), <https://www.fda.gov/media/155200/download>.

²⁹² 21 U.S.C. § 355(j)(7)(A)(ii), (iii).

²⁹³ FDA 2003 Notice, *supra* note 135, at 36683.

²⁹⁴ 21 U.S.C. § 355(c)(2).

²⁹⁵ FDA 2003 Notice, *supra* note 135, at 36683.

²⁹⁶ *Id.*

shifts the burden of challenging Orange Book listings from the FDA to generic drug companies, as well as to antitrust enforcers far in the future.

Each FDA rationale possesses noticeable shortcomings. The primary purpose of the Hatch-Waxman Act is to facilitate prompt availability of generic medications while sustaining innovation incentives.²⁹⁷ The institutional architecture adopted by that legislation places the FDA in an advantageous position to ensure that patents appropriately sustain that balance.²⁹⁸ Surely the FDA is best suited to review approved drug applications, legal instruments that it approves and ultimately will be assessed alongside patents. The agency also possesses the scientific expertise to understand the terminology used within pharmaceutical patents. And if the FDA remains disinclined to acquire further patent expertise, it could enlist the aid of the USPTO in doing so.

The FDA's foisting of responsibility on the courts also bears reconsideration. The courts possess institutional limitations as well, particularly in view of the timing of their decision making. In contrast to the FDA, which may assess the propriety of patent listings at the outset, jurists reach decisions years later, long after generic entry has been inappropriately delayed. Courts also focus upon the conservation of their own resources, frequently encouraging the private settlement of pharmaceutical patent disputes without regard to their impact upon public health.²⁹⁹

Whether the FDA fairly characterized the "fundamental assumption" of the Hatch-Waxman Act that courts should address the scope and validity of patents, the enactment of the America Invents Act in 2011 has altered that assumption. Congress has dramatically increased the role of the administrative state to determine the scope and validity of patents.³⁰⁰ Further, the statutory requirements that NDA holders supply only patents appropriate for Orange Book listing, and that the FDA promptly publish them, simply does not imply that the FDA cannot review this information. In framing its responsibilities, the FDA should instead take greater account of the purposes of the Hatch-Waxman Act, recognize its institutional capabilities, and cease foisting responsibility for statutory compliance upon other government entities, including the Federal Trade Commission.³⁰¹

²⁹⁷ See, e.g., Orrin G. Hatch, *Foreword*, 40 WM. MITCHELL L. REV. 1194, 1199 (2014).

²⁹⁸ See Eisenberg & Crane, *supra* note 15, at 204 ("FDA also has the advantage of being in the right place at the right time to make timely decisions."); Jacob S. Sherkow, *Administering Patent Litigation*, 90 WASH. L. REV. 205, 214–16 (2015).

²⁹⁹ See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006).

³⁰⁰ See, e.g., Michael Xun Liu, *Patent Policy Through Administrative Adjudication*, 70 BAYLOR L. REV. 43 (2018).

³⁰¹ See Federal Trade Commission's Brief as *Amicus Curiae*, *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 2022 WL 17084371 (No. 21-691-GBW).

H. The Problem of Patent Use Codes

As noted previously, the FDA requires brand-name pharmaceutical firms to provide so-called “use codes” pertaining to patents claiming methods of medical treatment.³⁰² Each use code identifies the FDA-approved method of use and the related claim or claims of the relevant USPTO-approved patent. Most importantly, the brand-name drug company also drafts and submits to the FDA a narrative of 250 characters or fewer that describes the patented method of use. The FDA apparently did not establish the 250-character limit—which the agency increased from 240 characters in 2016—following consultation with the USPTO, jurists, practitioners, academics, or apparently any member of the patent community whatsoever. Rather, this truncated description of the legal texts granted by the USPTO is apparently based upon the limitations of the FDA’s aging database system.³⁰³

Setting FDA-administered use codes side-by-side with the claims of USPTO-granted patents provides astounding comparisons. For example, with respect to U.S. Patent No. 10,426,743, the FDA’s Orange Book provides use code U-2625, which reads in its entirety as follows:

Topical treatment of plaque psoriasis in adults.

For its part, the ’743 patent incorporates 116 claims. The first of them provides:

1. A method of treating an inflammatory disease or disorder in a patient in need thereof, the method comprising administering to said patient a topical pharmaceutical oil-in-water emulsion composition comprising:

3,5-dihydroxy-4-isopropyl-trans-stilbene or a pharmaceutically acceptable salt thereof in an amount of about 0.05% to about 2% by weight, based on the total weight of the composition;

an oil phase comprising medium chain triglycerides of a carbon length from six to twelve carbons in an amount of about 2% to about 30% by weight, based on the total weight of the composition;

a water phase;

a surfactant in an amount of about 1% to about 20% by weight, based on the total weight of the composition, wherein the surfactant comprises at least one non-ionic emulsifying wax NF; and

a dermatologically acceptable excipient selected from the group consisting of an antioxidant, a pH adjusting agent, a chelating agent, a preservative, a co-solvent and combinations thereof;

³⁰² 21 C.F.R. § 314.53(c)(2)(i)(O).

³⁰³ See 81 FED. REG. 69580, 69598 (Oct. 6, 2016).

wherein the 3,5-dihydroxy-4-isopropyl-trans-stilbene or a pharmaceutically acceptable salt thereof is solubilized in the oil phase and is the only active ingredient in the oil phase;

wherein the oil phase is substantially free of petrolatum and mineral oil;

wherein the oil-in-water emulsion is homogeneous; and

wherein the average droplet size of the oil phase is from about 0.1 microns to about 35 microns.

This single comparison should strike any knowledgeable observer as laughable. USPTO examiners appropriately emphasize the precise language of claims when reviewing patent applications and allowing them to issue. Courts and other readers of patents do not award a scope of exclusive rights, or assess the validity of a patent, based upon a condensed overview of well over 100 patent claims in 250 characters or fewer.³⁰⁴

Further, as a general matter, the fewer the number of words in a patent claim, the broader the scope of exclusive rights that it grants. Allowing terse summaries to replace USPTO-granted claims almost inevitably means that the FDA awards broader proprietary rights than the Patent Act allows. Use code practice is even less rational than accepting abstracts of patents as a measure of their exclusive rights—at least the abstracts of patents were placed before the USPTO, sometimes parrot the patent’s first claim, and ordinarily contain 150-250 words, as compared to no more than 250 characters.³⁰⁵ No lawyer should accept an abstract or use code as the appropriate measure of the proprietary interests a patent affords.

The FDA nonetheless affords use codes significant consequences. At the outset, the agency does not verify any of the submitted use code information provided by a brand-name drug company. It does rely wholly on use codes to determine whether a method of use patent is relevant to a particular ANDA. If the use code indicates that the patent claims a method of use for which approval is sought, then the generic applicant must submit an ANDA with either a paragraph III or paragraph IV certification. Otherwise, the generic applicant may submit a section viii statement asserting that the Orange Book-listed patent “does not claim a use for which the applicant is seeking approval.”³⁰⁶ Absent any other relevant regulatory or intellectual property issue, the FDA will approve an ANDA with a section viii statement without delay.

This incongruous use code system effectively requires brand-name drug companies to paraphrase their patent claims, which in turn leads to unchecked opportunities for strategic behavior. A single use code of 250 characters or fewer

³⁰⁴ See SCHECHTER & THOMAS, *supra* note 31, at 207 (“The claims form the most significant part of the patent instrument, for it is the claims themselves that set forth the proprietary technological rights possessed by the patentee.”).

³⁰⁵ See USPTO, MANUAL OF PATENT EXAMINING PROCEDURE § 1826.

³⁰⁶ 21 U.S.C. § 355(j)(2)(A)(viii).

may cover multiple patent claims that, in combination, incorporate many thousands of characters. Even if a use code relates to a single claim, however, that claim may well be quite a bit longer than the 250-character limit. Use code practice persistently results in overly broad use code narratives that inappropriately block generic competition.³⁰⁷

The FDA's dispute resolution process with respect to use codes is similarly constrained. The relevant FDA regulation limits statements of dispute regarding use codes to 250 words directed towards the "person's interpretation of the scope of the patent."³⁰⁸ The FDA then forwards the information to the brand-name drug company. Unless the brand-name drug company withdraws or amends its patent information in response to the patent listing dispute, the FDA will not change the information in the Orange Book.³⁰⁹

The gap between patents as the USPTO grants them, in comparison with the scope they are afforded by the FDA, seems troubling. Yet the lack of a sound empirical foundation precludes a precise balancing of the private costs and public benefits of the statutory notice systems. The expenses they impose may be considerable, however, particularly in relation to their contributions towards the patent system's notice function. This Article next considers how these contributions may be improved through specific substantive reforms.

V. REFORMING THE MARKING STATUTE

In an era where the USPTO no longer prints paper patents as a matter of course,³¹⁰ the marking statute seems at best a quaint relic of a bygone era. It nonetheless provides an archaic incentive with unsound foundations and deleterious impacts upon innovation policy. Its abolition presents the most straightforward path towards addressing these flaws.³¹¹ Following repeal of the marking statute, the decision to mark or not would have no remedial impact upon technology implementers. Interested members of the public could simply proceed to the USPTO website, or to numerous private sources, to align issued patents owned by that manufacturer to the product of interest.

Another possibility is to deemphasize marking, either by limiting its remedial impact in the manner of the Copyright Act, or by subordinating marking within a larger patent notice inquiry in a manner resembling the Lanham and Semiconductor Chip Protection Acts. Under the Copyright Act, for example, the placement of notice upon the protected work of authorship precludes adjudicated infringers from

³⁰⁷ See, e.g., *Caraco Pharm. Lab'ys. v. Novo Nordisk A/S*, 566 U.S. 399 (2012).

³⁰⁸ 21 C.F.R. § 314.53(f) ("For a dispute regarding the accuracy or relevance of patent information regarding an approved method of using the drug product, this statement of dispute must be only a narrative description (no more than 250 words) of the person's interpretation of the scope of the patent.").

³⁰⁹ *Id.*

³¹⁰ USPTO, Proposed Rule, *Electronic Patent Issuance*, 86 FED. REG. 71209 (Dec. 15, 2021).

³¹¹ See Siegel, *supra* note 10, at 607–08.

asserting that they acted innocently.³¹² Actual damages remain available in this circumstance, with the only remedial impact being a possible reduction in an award of statutory damages.³¹³

The Patent Act contains no analog to statutory damages or to the innocent infringer defense. But it does allow for the award of enhanced damages³¹⁴ in cases of willful infringement.³¹⁵ Following the lead of the Copyright Act, the patent marking statute could stipulate that technology implementers may not seek enhanced damages for willful infringement if they fail to mark their products. They would nonetheless retain the ability to obtain the usual measures of damages for patent infringement—a reasonable royalty or lost profits—even if they failed to mark.

Section 29 of the Lanham Act provides another comparative model, stipulating that the lack of marking precludes the award of damages until the adjudicated infringement “had actual notice of the registration.”³¹⁶ Under the Chip Act, the marking of mask works provides only ‘prima facie evidence of notice of protection.’³¹⁷ In contrast, Section 287 of the Patent Act explains that no damages may be awarded unless the infringer “was notified of the infringement and continued to infringe thereafter”³¹⁸ This minor difference in wording has led to significant differences in judicial interpretation. In trademark cases, courts determine whether the infringer knew of the federal registration even in the absence of marking.³¹⁹ In contrast, patentees that neither mark nor provide actual notice are ineligible to obtain damages, even when the adjudicated infringer was very much aware of the patent. To reconcile these approaches, Congress could recognize patent marking as just one possible component of whether the infringer knew, or should have known, about the asserted patent.

A final, more dramatic option is to replace both physical and virtual marking with a USPTO-administered database that collates patents with commercially available products and processes. Under this alternative, both patentees and third parties would be afforded the ability to identify commercially available products and processes that, in their opinion, correspond to issued patents. The agency would then simply include this correspondence in the prosecution history of the patent. Based upon this information, the USPTO could develop and maintain a single database that links claimed inventions with products and processes that embody them.³²⁰

³¹² 17 U.S.C. §§ 401(d), 402(d), 404(a).

³¹³ 17 U.S.C. § 504(c)(2).

³¹⁴ 35 U.S.C. § 284.

³¹⁵ See *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 98–99 (2016).

³¹⁶ 15 U.S.C. § 1111.

³¹⁷ 17 U.S.C. § 909.

³¹⁸ 35 U.S.C. § 287.

³¹⁹ See *supra* notes 239–42 and accompanying text.

³²⁰ Dylan Nguyen, *Improving the Patent Notice System: Replacing the Duty to Mark with a Unified Patent-Product Database*, 106 IOWA L. REV. 2049 (2021).

Incentives to inform the USPTO could be provided by remedial restrictions similar to the current copyright, patent, semiconductor chip, or trademark statutes. This proposal simply replaces physical or virtual marking with notice to the USPTO. Another or an additional possibility would borrow from our current system of copyright registration. Patent proprietors that fail to provide prior notice would be precluded from bringing an infringement suit until they provided notice to the USPTO.³²¹ In addition, the USPTO would also make better use of an existing statute, Section 290 of the Patent Act, that requires courts to notify the agency of patent lawsuits.³²² The USPTO could augment the database with information obtained through this mechanism.

A possible criticism of this approach is that patent trolls are unlikely to participate. Their business model rests upon surprising firms that have expended considerable sunk costs in commercializing a technology. Trolls would seem unlikely to notify technology implementers of their patents prior to suit, as a USPTO listing could potentially trigger an *inter partes* review or, depending upon the wording of the notice, a declaratory judgment action for patent invalidity.

Although these criticisms are valid, this approach would nonetheless level the playing field between trolls and technology implementers. Trolls too would face consequences for failure to notify the public of what they perceive to be the coverage of their patents. Listings based upon Section 290 could also better inform the public in circumstances where the troll might later sue other accused infringers.

In addition to leveling the field between trolls and technology implementers, a unitary database would hold many advantages over the current marking statutes. It would include patents directed towards both products and processes. Commercial embodiments marketed both by the patent proprietor and third parties could be identified. The database would entail fewer expenses than the physical marking of products and may be conveniently updated. And instead of a hodgepodge of differently formatted private websites, interested parties may consult a single online source presented in a uniform format.

Such a database potentially holds another advantage. It might better connect the USPTO with three out of the five categories of prior art for which the agency currently commits no examination resources. In addition to patents and documentary sources, the Patent Act denies the issuance of a patent when a product has previously been on sale, in public use, or otherwise available to the public.³²³ In practice, the USPTO does not examine patent applications based upon these latter prior art categories.³²⁴ The database would provide examiners with a link

³²¹ See 17 U.S.C. § 411(a) (requiring U.S. works of authorship to be registered with the Copyright Office prior to instituting a civil action for copyright infringement).

³²² 35 U.S.C. § 290.

³²³ 35 U.S.C. § 102(a)(1).

³²⁴ See, e.g., Greg Reilly, *The Complicated Relationship of Patent Examination and Invalidity*, 69 AM. U. L. REV. 1095, 1129–31 (2020).

between issued patents and their implementation in commercially realized products, which could also serve as prior art in appropriate cases.

Finally, the proposed USPTO database could wholly replace the two FDA patent-oriented publications. Indeed, we would do well to consider a change in administration with respect to the Orange and Purple Books. Four decades of experience have taught us an unsurprising lesson—that the USPTO stands in a better position to supervise the patent listing functions of the Orange and Purple Books than the FDA. The FDA should be released from administering patent functions that it has assumed begrudgingly and operated poorly. Unsurprisingly, the USPTO would serve as the most appropriate entity to facilitate notice of patents pertaining to pharmaceuticals and biologics—alongside the virtual marking for any other sort of patented invention. This article considers additional options with respect to the Orange and Purple Books next.

VI. REFORMING THE FDA PUBLICATIONS

Regardless of which agency administers the Orange and Purple Books, this Article encourages the FDA and USPTO to take four steps forward. First, the agencies should establish a mechanism for an initial review of patents to determine whether they should be listed in the Orange Book or not. Second, the agencies should establish administrative Orange Book Listings Review proceedings, adjudicated by the USPTO's Patent Trial and Appeal Board, to assess the propriety of patents that have been listed. Third, the FDA should abandon its patent use code practice. Finally, the definition of patents appropriate for listing in the FDA publications should be expanded. This Article reviews each of these subjects in turn.

A. *Initial Orange Book Patent Listings*

The FDA and USPTO possess several options with respect to a review of Orange Book patent listings. The most straightforward is an initial FDA assessment of submitted patents to determine whether they meet the statutory requirements for listing in the Orange Book.³²⁵ Such a review could take place on an *ex parte* basis, with the FDA interacting exclusively with the NDA holder should issues arise. The FDA could hire additional staff to undertake a limited appraisal of identified patents, alongside the scope of the NDA, to determine whether the patents are suitable for listing. Alternatively, the FDA could request that USPTO employees, such as Administrative Patent Judges detailed from the Patent Trial and Appeal Board (PTAB),³²⁶ undertake this task.

Another option would be to encourage the private sector to challenge Orange Book-listed patents through administrative proceedings at the USPTO. For

³²⁵ Professors Eisenberg and Crane previously offered this proposal, calling for a “rough administrative assessment of the merits of patent issues that determine the timing of regulatory approval.” Eisenberg & Crane, *supra* note 15, at 260.

³²⁶ 35 U.S.C. § 6.

example, in the 116th Congress, the Second Look at Drug Patents Act would have invited interested parties to file petitions for *inter partes* review of Orange Book-listed patents.³²⁷ This legislation was not enacted, but it may bear reconsideration as part of the whole-of-government approach.

A third option is for the FDA and USPTO to cooperate in reviewing the scope and validity of the Orange Book-listed patent. The agencies could conduct a coordinated search of the prior art, with possible solicitation of prior art references from members of the public in the manner of a reissue application.³²⁸ If questions about the validity of the patent arose, the USPTO Director could order an *ex parte* reexamination to resolve them.³²⁹ Alternatively, if questions about the suitability of the patent for listing in the Orange Book arose, the FDA could engage with the NDA holder as discussed above.

These options vary in the amount of time they would take to complete, as well as the degree of engagements between different administrative agencies and the private sector. As a result, their attractiveness may depend upon the availability of generic competition due to regulatory review periods as well as other intellectual property rights, in particular FDA-administered regulatory exclusivities. For example, if an approved drug qualifies as a new chemical entity, no generic drug company may file a paragraph IV ANDA for four years following FDA approval of the NDA.³³⁰ This lengthy period would allow for a full review of patents that had been identified for the Orange Book at the time the NDA was approved. Later-listed patents may be less amenable to extensive administrative review, depending upon the relevant timeframes.

B. Resolution of Orange Book Patent Listing Disputes

Disputes frequently arise as to the propriety of patent listings in the Orange Book. When Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), it authorized generic firms that were sued for patent infringement to bring a counterclaim requesting delisting of the patent.³³¹ As the statute expressly provides that it did not authorize any other cause of action other than this limited counterclaim, and further stipulates that the generic firm may not receive damages in the event of an improper listing, its utility is limited.³³²

³²⁷ The Second Look at Drug Patents Act was introduced both as S. 1617, 116th Cong. (2019) and S. 4253, 116th Cong. (2019). Although the bills differed in some respects, each encouraged eligible parties to file IPRs with respect to Orange Book-listed patents.

³²⁸ See 37 C.F.R. § 1.11 (stipulating that reissue applications are open to inspection by the public); USPTO, MANUAL OF PATENT EXAMINING PROCEDURE § 1430 (noting that the USPTO will announce the filing of reissue applications in the agency's *Official Gazette*, giving "interested members of the public an opportunity to submit to the examiner information pertinent to the patentability of the reissue application.").

³²⁹ The *ex parte* reexamination could occur under 35 U.S.C. § 302 in keeping with USPTO, MANUAL OF PATENT EXAMINING PROCEDURE § 2239.

³³⁰ 21 U.S.C. § 355(j)(5)(F)(ii).

³³¹ 21 U.S.C. § 355(j)(5)(C)(ii)(I).

³³² See Eisenberg & Crane, *supra* note 15, at 222.

In 2016, the FDA established an administrative procedure through which inappropriate Orange Book patent listings may be challenged.³³³ The FDA plays no substantive role in this procedure. Rather, the FDA merely allows any interested person to dispute the accuracy or relevance of patent information in the Orange Book—or the lack of information in the Orange Book—by communicating a statement of dispute to the FDA. Unless the brand-name drug company withdraws or amends its patent information in response to the patent listing dispute, the FDA will not change the information in the Orange Book.

The USPTO stands in a position to fill this gap in administrative adjudication of Orange Book patent listing disputes. The FDA and USPTO should support the creation of Orange Book Listing Review (OBLR) proceedings to be conducted by the Patent Trial and Appeal Board (PTAB). Such OBLR proceedings would involve a review of patent claims alongside the specification of an approved drug found within an approved New Drug Application—a paper-to-paper comparison well within the capabilities of the corps of Administrative Patent Judges (APJs). OBLR proceedings would comport with increased emphasis on administrative dispute resolution within the patent system,³³⁴ harness the considerable expertise of APJs in adjudicating adversarial proceedings,³³⁵ and, in view of the declining number of *ex parte* appeals to the PTAB, make use of available USPTO capacity.³³⁶

C. Eliminating Use Codes

The FDA should immediately abandon its outrageous use code practice, which wholly lacks a statutory basis and has been prone to abuse. As Professors Petherbridge and Wagner have eloquently stated, central to “perhaps all of patent law’s efforts to balance private rights with public interests is the law of claim construction.”³³⁷ Claim construction is also widely regarded as complex and time-consuming.³³⁸ The construction of a single claim limitation—not to mention the entirety of dozens of claims within a patent—may require statements of considerable length.³³⁹ Yet, for all the policy and practical significance of claim

³³³21 C.F.R. § 314.53(f)(1).

³³⁴ See, e.g., Liu, *supra* note 301.

³³⁵ The USPTO began to administer IPRs on September 16, 2012, more than a decade ago. See America Invents Act, Pub. L. No. 112-29, § 6(c)(2)(A) (2011).

³³⁶ See *Office of Audit & Evaluation*, U.S. DEPT. OF COMMERCE, THE PTAB FACES OPERATIONAL, INFORMATION TECHNOLOGY AND DATA RISKS 3–9 (2021).

³³⁷ Lee Petherbridge & R. Polk Wagner, *Teva and the Process of Claim Construction*, 70 FLA. L. REV. 379, 384 (2018).

³³⁸ See, e.g., *In re Automated Transactions LLC Pat. Litig.*, 938 F.Supp.2d 1353, 1354 (JPML 2013).

³³⁹ For example, the U.S. District Court for the Northern District of Illinois construed the claim limitation “pharmaceutical batches” to mean “may include a single batch, wherein the single batch is representative of all commercial batches (*see generally*, Manual of Policies and Procedures, Center for Drug Evaluation and Research, MAPP 5225.1, Guidance on the Packaging of Test Batches at 1) made by a compounding process, and wherein the levels of, for example, Asp 9-bivalirudin, total impurities, and largest unknown impurity, and the reconstitution time represent levels for all potential batches made by said process. ‘Batches’ may also include all batches prepared

construction, the FDA limits use codes to 250 characters, and disputes over use codes to 250 words.

Both FDA use code limitations, as well as limiting the construction of a dozen or more patent claims to 250 words, are so reductionist as to be absurd. The FDA should read the claims of issued patents as the USPTO granted them, not in a summary and potentially self-serving form that may inaccurately portray the scope of exclusivity they provide. If the FDA remains unwilling to acquire sufficient expertise to construe the legal texts to which members of the public are accountable, and which were granted by a sister agency, then the FDA ought to avail itself of USPTO resources as soon as possible.

D. Updating the Orange and Purple Books

The definitions of patents amenable to listing in the Orange and Purple Books are overly cabined. They provide only a partial set of patents that a generic drug company or follow-on biologic manufacturer might have to overcome or wait out before it can enter the market. This restricted definition leaves generics and biosimilars vulnerable to patent challenges even after clearing listed patents. It could also promote strategic behavior by brand-name firms, for they retain the ability to assert patents that could not be listed in the Orange Book; or, with respect to the Purple Book, were not previously asserted in litigation.

Congress should instead require that brand-name pharmaceutical and biologics companies identify for listing any patent that might be infringed by a generic or follow-on manufacturer. This simplified definition would be easier to administer and obviate the need for the patent proprietor to determine whether it infringes its own patents. It would also fulfill the goal of promoting market certainty by allowing potential competitors to be aware of all relevant patents that might block competition for pharmaceuticals and biologics.

The timing of patent listings in the Orange and Purple Books should also be accelerated. Under current law, brand-name drug companies apprise the FDA of relevant patents when they file their New Drug Applications.³⁴⁰ Biologics manufacturers provide this information even later in time, as they identify their patents to the FDA only after they have been identified in litigation against follow-on manufacturers.³⁴¹ Legislative reforms should require earlier notifications of both issued patents and pending patent applications—for example, at the time an Investigational New Drug application³⁴² is filed. Earlier disclosures would better allow USPTO to harness the expertise of the private sector when deciding whether to issue or maintain pharmaceutical and biologics patents or not, through such

by a same compounding process.” That interpretation, which consisted of 559 characters and related to just one of many construed limitations, was affirmed on appeal. *Meds. Co. v. Mylan, Inc.*, 2012 WL 3234282, at *4, *aff’d*, 853 F.3d 1296, 1301 (Fed. Cir. 2018).

³⁴⁰ 21 U.S.C. § 355(b)(1)(A)(viii).

³⁴¹ 42 U.S.C. § 262(k)(9)(A)(iii).

³⁴² *See* 21 C.F.R. § 312.1 *et seq.*

proceedings as third-party submissions,³⁴³ *inter partes* review,³⁴⁴ and post-grant review.³⁴⁵

VII. CONCLUSION

Review of the two marking provisions and two patent-oriented FDA publications provides a broader insight. Patent notice policy that focuses upon the patent instrument itself faces constraints because the disclosure of a patent is fixed on the date it issues.³⁴⁶ Policymakers should additionally explore efforts that extend beyond the patent instrument itself. To this end, Congress and the USPTO could undertake additional efforts through at least three different avenues.

First, as it did with the current statutory notice systems, Congress should encourage patent proprietors to provide information about the post-issuance life of their patents. To be sure, this effort may encounter resistance from members of the patent community. For example, the proposed Pride in Patent Ownership Act,³⁴⁷ which would encourage individuals and enterprises to record their ownership interests in a patent within 90 days of acquiring it, has met with a surprising amount of criticism.³⁴⁸ Yet with the proper incentives, patent proprietors could be better motivated to provide information about the commercial utilization of their claimed inventions.

The payment of maintenance affords an opportunity to obtain information about the ownership and marketplace impact of the patents. Currently, a U.S. patent expires after four, eight, or twelve years if maintenance fees are not timely paid on each occasion.³⁴⁹ This staggered fee schedule could be replaced with the requirement of an annual payment that could be discounted in exchange for improved patent notice. This approach provides a working pathway forward to improve patent notice.

Second, the USPTO could undertake additional efforts to improve patent notice beyond merely publishing pending applications and issued patents. It could, for example, provide patent proprietors and other interested parties with real-time updates of agency events. Automated notice could be sent out whenever an examiner cites a particular patent or other prior art, for example, or whenever a

³⁴³ 35 U.S.C. § 122(e).

³⁴⁴ 35 U.S.C. § 311 *et seq.*

³⁴⁵ 35 U.S.C. § 321 *et seq.*

³⁴⁶ The disclosure of most patents is in fact fixed as of their filing date, although the USPTO does allow for continuation-in-patent applications with augmented disclosures.

³⁴⁷ The Pride in Patent Ownership Act was introduced as S. 2774, 117th Cong. (2021).

³⁴⁸ See, e.g., Paul Morinville, *The Pride in Patent Ownership Act is Big Tech Boondoggling* (Oct. 12, 2022), <https://ipwatchdog.com/2022/10/12/pride-patent-ownership-act-big-tech-boondoggling/id=151990/>

³⁴⁹ 35 U.S.C. § 41(b). As of January 1, 2023, the maintenance fees are \$2000 owed by the fourth year, \$3760 by the eighth year, and \$7700 by the twelfth year. 37 C.F.R. §§ 1.20(e), (f), (g).

published application or issued patent contains an identified key word.³⁵⁰ This step would allow patent owners and technology implementers to track the patent landscape on a real-time basis.

Finally, the USPTO could continue to develop its information infrastructure. The agency should be applauded for improving its search tools, in particular by replacing Public Patent Application Information and Retrieval (PAIR) with Patent Center,³⁵¹ and also by introducing the Patent Public Search tool as the successor to four legacy systems.³⁵² Private databases and search engines also continue to evolve, and the USPTO should monitor these resources as it considers future enhancements to its capabilities. The USPTO could also work in concert with private scientific and technical database providers to ensure that patent documents become searchable sources of information.

These possibilities remind us that efforts to improve patent notice need not be confined to the patent instrument. Auxiliary measures may better correlate patents with commercially available products and processes, encourage patent proprietors to call their intellectual property rights to the attention of relevant communities, and improve awareness of the precise scope of the proprietary rights a patent affords. These projects should also improve our general understanding of the patent incentive, including the extent to which the grant of patents improves the availability of innovative technologies in the marketplace. The underappreciated marking statute, alongside the FDA's Orange and Purple Books, offer insights not just about each other, but also about the fundamental policy goal of noticing patents.

³⁵⁰ The European Intellectual Property Office (EUIPO) currently offers this service to some degree with respect to trademarks. A search tool, eSearch plus, allows registered users to configure automatic watch alerts and receive a notification whenever the EUIPO receives potentially conflicting trademark applications. See EUIPO, *Setting Alerts* <https://euiipo.europa.eu/ohimportal/en/setting-alerts>.

³⁵¹ USPTO, *Public PAIR to be retired* (2022), <https://www.uspto.gov/patents/public-pair-be-retired>.

³⁵² USPTO, Public Patent Search, *supra* note 59.