MANDATORY INFRINGEMENT

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In 2005, the Food and Drug Administration required the use of CFC-free propellants in albuterol inhalers. But 3M held patents on the only U.S.-approved CFC-free inhaler. The FDA's regulations forced multiple generic albuterol manufacturers to choose between infringing 3M's patents and exiting the market. This state of affairs was lucrative for 3M, perhaps good for the environment, bad for competition, and terrible for patients faced with high costs for essential medical devices.

This is an example of a general phenomenon: mandatory infringement. Intellectual property prohibits certain activities, but sometimes the government also mandates these very same activities. Such situations arise surprisingly frequently in fields including environmental protection, pharmaceutical labeling, information technology, and access to justice. The manifest injustice of regulatory law requiring what IP law disallows has sparked vigorous debates over individual cases in all these fields. Yet there has been no unified treatment of how the law should address mandatory infringement. Courts and scholars have taken approaches that are scattershot, idiosyncratic, and even inconsistent with each other.

The key to fixing mandatory infringement is understanding why it is a problem in the first place: competition. Mandatory infringement creates outsized market power due to an inverse relationship between regulation's and IP's effects on competition. It further induces passing the buck between regulators and courts, incentives to rent-seek rather than innovate, and government offloading of IP costs onto regulated entities that produces a principal–agent disconnect. These phenomena explain why regulators and courts applying antitrust or IP laws have difficulties resolving mandatory infringement. Although they try hard to reach fair outcomes and often succeed, the distinctive aspects of mandatory infringement and authorities' failure to recognize them frequently have left unjustified market dominance intact. A new approach is required: a trans-substantive doctrine that excuses mandatory infringement, not tied to specific legal regimes but broadly encompassing matters of competitive markets and public welfare.

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Introduction

When filling my prescription for the albuterol inhaler I had used for asthma since childhood, I was shocked to discover it cost eight times what I expected.[1]

Mike Meurer, Andrew Michaels, Chris Morten, Tejas Narechania, Blake Reid, Pam Samuelson, Josh Sarnoff, Brian Scarpelli, Sean Tu, and workshop participants at the 2018 and 2022 Intellectual Property Scholars Conferences, the 2022 Works-in-Progress for Intellectual Property Scholars Colloquium, the 2022 PatCon Annual Patent Conference, Cornell Law School, Boston University Law School, and Marquette University Law School for thoughts and conversations that have contributed to my thinking on this project. The many attorneys with whom I have worked on *Google v. Oracle*, *ASTM v. Public Resource*, *Georgia v. Public Resource*, *GlaxoSmithKline v. Teva*, and other cases and proceedings described in this Article have also been immensely helpful, as have the research librarians at the Law Library of Congress and the Cornell University Law Library.

1. *See also* Rita F. Redberg, *Not Breathing Easier with the US FDA's Ban on Chlorofluorocarbons in Inhalers*, 175 JAMA Internal Med. 1086, 1086 (2015) (describing similar experience).

Certain there was a mistake, I asked the pharmacist to dispense the generic I had received many times in the past,[2] only to be told that no generic existed. I walked home befuddled—had something changed with the medicine I depended on?

The answer, it turned out, was that brand-name pharmaceutical companies had lobbied the Food and Drug Administration ("FDA") to ban generic albuterol inhalers by virtue of their containing chlorofluorocarbons as their propellant gas, and the FDA had agreed.[3] Requiring environmentally friendly inhalers was a laudable goal, but there was a catch: Those pharmaceutical companies, 3M in particular, held patents on the only alternative approved propellant, HFA-134a.[4] Mandating CFC-free inhalers replaced a robustly competitive generic market with patent-backed monopoly control. The pharmaceutical industry reaped nearly a billion dollars per year at the expense of asthma patients, and some low-income asthmatics could no longer afford their medication.[5]

The asthma inhaler dispute was no one-off: In a wide range of industries, one can find similar conflicts between legal mandates and intellectual property ("IP") rights. Statutes on generic drugs and pesticides expect competitors to duplicate copyrighted labeling text.[6] Vehicle emissions standards unwittingly required use of a patented composition of gasoline.[7] The FDA and state governments mandate drug formulations for safety, quality, and other reasons.[8] Telecommunications regulators require television broadcasters to comply with highly patented digital standards.[9] Official codes of law, even binding ones, are frequently copy-

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2. In 2006, there were four generic albuterol inhalers. *See* Food & Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations [Orange Book] 3-12 (26th ed. 2006), https://www.drugpatentwatch.com/p/fda-orange-book/edition/26/annual/.

3. Use of Ozone-Depleting Substances, 70 Fed. Reg. 17167, 17192 (Food & Drug Admin. Apr. 4, 2005) [hereinafter Albuterol V] (codified at 21 C.F.R. § 2.125(e)(2)(i)); *see* National Cooperative Research Notice; International Pharmaceutical Aerosol Consortium for Toxicology Testing, 55 Fed. Reg. 36710 (U.S. Dep't of Justice Sept. 6, 1990) (noting formation of pharmaceutical joint venture "in connection with seeking U.S. and foreign governmental approval of HFA-134a for use as a propellant in pocket size, metered dose inhalers").

4. *See* Medicinal Aerosol Formulations, U.S. Patent No. 5,605,674 (issued Feb. 25, 1997); Food & Drug Admin., *supra* note 2, at ADA2 (listing patents for 3M's product Proventil HFA).

5. *See* Anupam B. Jena et al., *The Impact of the US Food and Drug Administration Chlorofluorocarbon Ban on Out-of-Pocket Costs and Use of Albuterol Inhalers Among Individuals with Asthma*, 175 JAMA Internal Med. 1171, 1176 (2015); *infra* Section III.A.

6. *See infra* Section I.E.

7. *See infra* Section I.B.

8. *See infra* Section I.A.

9. *See infra* Section I.D.

righted.[10] And a recently introduced bill in Congress would authorize the Library of Congress to mandate technical measures for mitigating copyright piracy—technical measures that, if patented, could force every website operator to pay licensing fees.[11] In these diverse fields, IP and regulatory mandates have perversely combined to threaten important interests such as consumer welfare, public health, and due process of law.

The term I give to this class of situations is "mandatory infringement."[12] It requires two ingredients: A regulation and IP rights such as patents or copyrights.[13] Superficially, the two seem similar in effect—like a regulatory mandate, a patent or copyright proscribes certain conduct that infringes a protected invention or creative work—and one might wonder whether mandatory infringement is simply a species of overlapping regulations.[14] Yet the vigorous debates and striking outcomes in cases of mandatory infringement suggest that the phenomenon is distinct, warranting further exploration and specialized treatment in the law.[15]

Scattered scholarship has sought to characterize possible solutions to mandatory infringement. Environmental law commentators describe regulation–IP

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10. *See infra* Section I.F; *infra* Section I.G.

11. *See* SMART Copyright Act of 2022, S. 3880, 117th Cong. sec. 3, § 514(c)(1)(A) (Mar. 17, 2022).

12. Several people have suggested to me that "mandatory licensing" more accurately describes the phenomenon discussed in this Article. For a discussion of this, see *infra* note 219.

13. For purposes of this Article, I consider the two major forms of federal IP, largely because they have been the primary sources of mandatory infringement disputes. Other forms of IP, such as trademarks and trade secrets, also interact with regulatory mandates. *See, e.g.*, Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1004–05 (1984) (considering intersection of trade secrets and environmental regulation); Christopher J. Morten & Amy Kapczynski, *The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines*, 109 Cal. L. Rev. 493 (2021). Future research is warranted to assess whether these forms of IP also present mandatory infringement problems similar to those described in this Article.

14. *See* F. Scott Kieff, *Patents for Environmentalists*, 9 Wash. U. J.L. & Pol'y 307, 318 (2002) (suggesting that patent–regulation overlaps are of minimal concern because "the patent right to exclude use would not interfere with a regulatory system's own effort to exclude use"). On overlapping regulations, see, for example, FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 142–43 (2000); Matthew C. Turk, *Overlapping Legal Rules in Financial Regulation and the Administrative State*, 54 Ga. L. Rev. 791, 800–14 (2020); Todd S. Aagaard, *Regulatory Overlap, Overlapping Legal Fields, and Statutory Discontinuities*, 29 Va. Envtl. L.J. 237, 240–41 (2011); Jacob E. Gersen, *Overlapping and Underlapping Jurisdiction in Administrative Law*, 2006 Sup. Ct. Rev. 201, 211–16.

15. *See infra* Section I.H.

overlaps simply as a "super-monopoly" to be avoided.[16] More detailed studies characterize the problem as a conflict between IP law and government policy to be resolved through agency expertise and authority,[17] eminent domain,[18] or realignment of IP doctrine.[19] Yet the literature to date has not addressed the nature of the problem itself—why, beyond a general distaste for "super-monopolies," mandatory infringement is harmful at all. Indeed, the lack of clarity about the problem has led several commentators to suggest that a regulation mandating a patented technology or copyrighted work could be socially desirable.[20]

This Article aims to discern how mandatory infringement transcends IP and regulatory regimes to affect behaviors and incentives of regulators, courts, innovators, and industry participants. I first identify the heart of the problem with mandatory infringement: competition. Intellectual property and regulatory mandates affect competition in an inverted manner: Regulation permits activity within a sphere and prohibits activity outside, while IP excludes activity within a sphere and permits competition outside.[21] Neither should preclude competition entirely, and yet the two put together create strong, durable market power. Mandatory infringement further exhibits three problems that make this market power difficult to undo:

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16. Michael A. Gollin, *Using Intellectual Property to Improve Environmental Protection*, 4 HARV. J.L. & TECH. 193, 219 n.128 (1991); *see* Michael A. Gollin, *Patent Law and the Environment/Technology Paradox*, 20 ENVTL. L. REP. 10171, 10173 (1990); Antonio G. Fraone, *Shucking a Patent: How a Simple Best Available Technology Law Can Break the Shell of Patent Protections*, 59 B.C. L. REV. 1049, 1081–83 (2018).

17. *See* Tejas N. Narechania, *Patent Conflicts*, 103 GEO. L.J. 1483, 1529–38 (2015); COLTER DONAHUE ET AL., ADDRESSING PATENT AND COPYRIGHT CHALLENGES AT THE FEDERAL COMMUNICATIONS COMMISSION 19 (2016), https://tlpc.colorado.edu/wp-content/uploads/2016/12/2016.12.14-FCC-IP-Whitepaper-Final.pdf (recommending greater agency expertise to identify IP conflicts).

18. *See* Janice M. Mueller, *Patent Misuse Through the Capture of Industry Standards*, 17 BERKELEY TECH. L.J. 623, 684 (2002); Brian Cook, *Clearing a Path for Digital Development: Taking Patents in Eminent Domain Through the Adoption of Mandatory Standards*, 82 S. CAL. L. REV. 97, 100–01 (2008) (recommending exercise of eminent domain over mandatory technology standards).

19. *See* Pamela Samuelson, *Questioning Copyrights in Standards*, 48 B.C. L. REV. 193, 221 (2007).

20. *See* Natalie M. Derzko, *Using Intellectual Property Law and Regulatory Processes to Foster the Innovation and Diffusion of Environmental Technologies*, 20 HARV. ENVTL. L. REV. 3, 21 (1996) (suggesting, in the environmental context, that a regulatory mandate could make it "advantageous to develop a new environmental technology, protect it using an environmental patent, and then sell it"); Wesley A. Magat, *The Effects of Environmental Regulation on Innovation*, 43 L. & CONTEMP. PROBS. 4, 18 (1979) (arguing that a mandate to use a firm's technology "creates a widely-expanded market for that firm's innovation," which can "encourage abatement technology innovation").

21. *See infra* Section II.

- *Buck passing*: Since both IP rights and regulation must combine to restrain competition, neither seems to be at fault alone. As a result, courts adjudicating IP rights can pass the buck to the regulator, while agencies implementing regulatory objectives can pass the buck to courts to use IP law to accommodate competition.[22]

- *Rent seeking*: Mandatory infringement detaches the IP holder's profits from the societal value of their work. Rather than investing in useful research and development, IP creators may expend resources on marginal or worthless improvements if they anticipate regulations eliminating the competition. Indeed, they face strong incentives to divert resources into lobbying for these regulations.[23]

- *Cost offloading*: In mandating use of an IP-protected work, the government itself receives some of the benefits of the work, but instead of paying for those benefits it offloads the costs onto regulated entities in the form of infringement liability. Among other things, this creates a principal–agent problem.[24]

A key finding is that these attributes of mandatory infringement turn upside-down several basic premises of IP theory. The market power phenomenon subverts the oft-repeated mantra that IP rights are not economic monopolies, rent seeking challenges IP as an innovation incentive, cost offloading questions technology transfer efficiency, and buck passing undermines the private-action nature of IP infringement. It is not difficult to see how inattention to these alterations to IP theory could lead commentators and policymakers astray.

Indeed, outcomes in mandatory infringement cases have often gone astray for these very reasons. Broadly speaking, there are two points of entry: The agency or legislature[25] imposing the mandate, which could mitigate the market power problem *ex ante*; and the courts, which *ex post* could use the competition laws or IP doctrine to undo anticompetitive consequences. These approaches have occasionally been successful at restoring competition in regulated, IP-intensive mar-

22. *See infra* Section II.B.

23. *See infra* Section II.C.

24. *See infra* Section II.D.

25. Because almost every mandatory infringement case I have studied involved a regulatory agency, I generally refer to regulations and agencies. Nevertheless, my analysis does not depend on the regulator being administrative.

kets.[26] But no less often, agencies and courts fail to take action, leaving mandatory infringement intact. Agencies overlook IP holders' and their own incentive distortions and pass the buck to courts.[27] The competition laws encourage buck-passing to both IP law and the regulator, and courts applying those laws often ignore how legal mandates drastically alter the usual ways in which IP and antitrust law interact.[28] And courts considering IP infringement cases fall back to standard IP theory, ignoring rent-seeking and cost-offloading behavior.[29]

A new approach to mandatory infringement is needed—one that transcends boundaries of IP regimes and that better responds to the market power and incentive misalignment problems that mandatory infringement causes. Drawing from cases and other trans-substantive doctrines of IP law, I propose a judicial defense to infringement when use of the IP is mandated by law.[30] At the same time, the IP holder should receive compensation for use of its works, not from regulated entities but from the government itself.[31] The government IP use statute already provides a workable vehicle for providing such compensation in most situations,[32] and charging the public for using IP with a public benefit is defensible on both policy and practical grounds.

I. Case Studies

Mandatory infringement is surprisingly common: Government mandates often implicitly call for patent or copyright infringement. Through case studies of mandatory infringement, this Part will identify how IP rights overlapped with regulatory mandates, the conflicts that those overlaps produced, and public reactions. How courts and agencies responded to mandatory infringement under current law will largely be reserved for the remainder of this Article.

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26. *See, e.g.*, Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (CREATES Act) § 610, 133 Stat. at 3130, *in* Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, § 610, 133 Stat. 2534, 3130 (2019) (resolution to mandatory infringement in drug safety by legislation, *see infra* Section I.C); *In re* Union Oil Co. of Cal., 140 F.T.C. 123, 160–61 (2005) (resolution by competition authority); Veeck v. S. Bldg. Code Cong. Int'l, Inc., 293 F.3d 791, 801 (5th Cir. 2002) (resolution by court applying IP law). These cases are discussed *infra* Section I.

27. *See infra* Section III.A.

28. *See infra* Section III.B.

29. *See infra* Section III.C.

30. *See infra* Section IV.A.

31. *See infra* Section IV.B.

32. *See* 28 U.S.C. § 1498.

These case studies reveal the deep divisions and often manifest injustice that accompanies almost every mandatory infringement situation, as IP holders wield power that intuitively seems excessive or unjustified. They also show that a general framework for mandatory infringement will affect and hopefully alleviate a broad spectrum of unfair situations.

A. Product Hopping

Product hopping is a notorious practice in which the maker of a patented drug switches the market over to a new formulation just before or soon after the patents expire.[33] If the new formulation is also patented and the market switches over, then the drug maker effectively prolongs its monopoly profits in the market for the therapeutic.[34] For example, pharmaceutical firm Reckitt Benckiser's regulatory exclusivity over the opioid addiction treatment buprenorphine (Suboxone) expired in 2009.[35] Shortly before the expiration, Reckitt reformulated the drug as a quick-dissolving sublingual film, patented the reformulation, and switched patients to it, thereby averting competition from several generic buprenorphine tablet manufacturers.[36] Product hopping forces patients and the health care system to pay monopoly prices for a treatment that ought to have been competitive,[37] which has attracted widespread criticism from patient advocates, health care experts, legal scholars, competition authorities, and lawmakers.[38]

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33. *See, e.g.*, Kevin T. Richards et al., Cong. Research Serv., Report No. R46221, Drug Pricing and Pharmaceutical Patenting Practices 20 (Feb. 11, 2020), https://www.everycrsreport.com/reports/R46221.html; Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 Notre Dame L. Rev. 167, 171 (2016) (defining product hopping as "reformulating a product in a way that makes a generic version of the original product not substitutable;" and "encouraging doctors to write prescriptions for the reformulated rather than the original product.").

34. *See* Carrier & Shadowen, *supra* note 33, at 181–82.

35. *See In re* Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 673–74 (E.D. Pa. 2014). *See generally* Carrier & Shadowen, *supra* note 33, at 195–96.

36. *See Suboxone*, 64 F. Supp. 3d at 674–75.

37. *See* Alex Brill, Matrix Glob. Advisors, The Cost of Brand Drug Product Hopping 6 (Sept. 2020), http://getmga.com/wp-content/uploads/2020/09/CostofProductHoppingSept2020.pdf (estimating health care system cost of product hopping at $4.7 billion per year).

38. *See, e.g.*, Vikram Iyengar, *Should Pharmaceutical Product Hopping Be Subject to Antitrust Scrutiny?*, 97 J. Pat. & Trademark Off. Soc'y 663, 666 (2015), https://assets.fenwick.com/legacy/FenwickDocuments/Pharmaceutical-Product-Hopping.pdf ("Under such coercive circumstances, product hopping can have negative consequences for consumers and healthcare plans."); Mark Metzke, *Targeting Enantiomer Product Hopping with a New "Obviousness" Standard*, 14 UCLA J.L. & Tech. 1, 3 (2010); Jonathan J. Darrow et al., *Reconsidering the Scope of*

For product hopping to work, the drug maker must switch patients using the old, to-be-generic drug over to the new formulation.[39] Most of the time, the switch involves private conduct by the patent-holding drug manufacturer, such as advertising to doctors to prescribe the reformulation (a "soft switch") or pulling the old formulation from pharmacy shelves prior to patent expiration to get patients used to the new product (a "hard switch").[40] These tactics can be forceful, but they are not mandatory as they rely on doctors' prescription pads or patient inertia to disfavor the old formulation.[41]

On occasion, though, the product-hopping firm pulls off the market switch by having a regulator ban the older formulation. The generic albuterol ban can be thought of this way: 3M and its licensees hopped the asthma treatment market to HFA-134a inhalers by having the FDA outlaw the competition, drawing opposition from almost 10,000 public comments,[42] a heated congressional hearing,[43] and contention in the popular, legal, and medical literature.[44] Similarly, Purdue Pharma hopped its extended-release oxycodone (Oxycontin) product to a new for-

US State Laws Allowing Pharmacist Substitution of Generic Drugs, 369 BMJ m2236, 2–3 (2020), https://www.bmj.com/content/369/bmj.m2236; Markus H. Meier et al., Fed. Trade Comm'n, Overview of FTC Actions in Pharmaceutical Products and Distribution 83–84 (June 2019), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_june_2019.pdf (describing Federal Trade Commission ("FTC") efforts on product hopping); Diane Bartz, *U.S. House Panel Approves Three Bills Aimed at Tackling High Drug Prices*, Reuters (Sept. 29, 2021), https://www.reuters.com/business/healthcare-pharmaceuticals/us-house-panel-approves-three-bills-aimed-tackling-high-drug-prices-2021-09-29/ (discussing congressional product hopping bill); Daniel Burke, *An Examination of Product Hopping by Brand-Name Prescription Drug Manufacturers: The Problem and a Proposed Solution*, 66 Clev. St. L. Rev. 415, 418–19 (2018).

39. *See* Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 Tex. L. Rev. 685, 712 (2008–2009); Carrier & Shadowen, *supra* note 33, at 176–78.

40. *See* Carrier & Shadowen, *supra* note 33, at 168.

41. *See* Richards et al., *supra* note 33, at 20–21; Dogan & Lemley, *supra* note 39, at 712; Darrow et al., *supra* note 38, at 3. *But see* Charles Duan, Product Hopping: Federal and State Approaches 6 (R St. Inst., Policy Study No. 227, 2021), https://www.rstreet.org/2021/03/31/product-hopping-federal-and-state-approaches/ (arguing that legal requirements for prescriptions are a sort of regulatory mandate to use certain drugs over others).

42. *See* Use of Ozone-Depleting Substances, 64 Fed. Reg. 47719, 47736 (Food & Drug Admin. Sept. 1, 1999) [hereinafter Albuterol II].

43. *See Regulatory Efforts to Phaseout Chlorofluorocarbon-Based Metered Dose Inhalers: Hearing Before the Subcomm. on Health and Environment of the H. Comm. on Commerce*, 105th Cong. (May 6, 1998), https://catalog.hathitrust.org/Record/007605070.

44. *See* Una C. Fan, *Capture Your Breath: FDA Regulations Can Incentivize the Recapture of Off-Patent Drug Products*, 43 AIPLA Q.J. 189 (2015); Erik R. Swenson, *The True Environmental Cost of Chlorofluorocarbon-Based Inhalers*, 175 JAMA Internal Med. 1867 (2015); Redberg, *supra*

mulation and then on safety grounds convinced the FDA to withdraw approval of the older form.[45] Then there was buprenorphine. In a vigorous effort to switch patients to the sublingual film, Reckitt Benckiser and its spinoff Indivior claimed that the new product was safer for children, and convinced state insurers such as the Massachusetts Medicaid program to make it the preferred formulation.[46] Those state plans effectively mandated the patented product despite lower-priced unpatented competition.

Thwarting generic competition through state-required product hopping "offers a potentially enticing new opportunity for anticompetitive behavior," an opportunity made possible by the IP–regulation confluence characteristic of mandatory infringement.[47] Adding to that concern is that product-hop reformulations often are not actual improvements.[48] Buprenorphine is a dramatic example: The sublingual film formulation was actually more dangerous to children, as it dissolved and took effect instantly unlike the tablet that could be spit out.[49] To convince Massachusetts and other states to mandate the film formulation, Indivior simply lied to regulators, a fact it admitted in pleading guilty to federal fraud charges.[50] The lure of mandatory infringement profits was enough to draw a pharmaceutical company to criminal conduct.

B. Gasoline Formulations

In the late 1980s, the California legislature tasked a state agency, the California Air Resource Board ("CARB"), to set standards for lower-emission gasoline

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note 1; Joseph S. Ross & Rita F. Redberg, *On Chlorofluorocarbon Bans and Inhaled Albuterol Prices*, 175 JAMA Internal Med. 1179 (2015).

45. *See* Lars Noah, *Product Hopping 2.0: Getting the FDA To Yank Your Original License Beats Stacking Patents*, 19 Marq. Intell. Prop. L. Rev. 161, 175–76 (2015).

46. *See* Plea Agreement at Exh. B, paras. 22–26, United States v. Indivior Sols., Inc., No. 1:19-cr-16 (W.D. Va. July 27, 2020) (Doc. No. 427-5), https://www.justice.gov/usao-wdva/press-release/file/1300366/download.

47. Noah, *supra* note 45, at 177. Curiously, Noah distinguishes mandatory product-hopping from drug label copyrights. *See id.* (citing SmithKline Beecham Consumer Healthcare, LP v. Watson Pharm., Inc., 211 F.3d 21 (2d Cir. 2000)). By contrast, I view both cases as falling within a single pattern. *See infra* Section I.E.

48. *See* Noah, *supra* note 45, at 178 ("For legitimate patients, OxyContin OP represents no improvement over the original formula.").

49. Plea Agreement at Exh. B, paras. 22–26, at 5–8, *Indivior*, No. 1:19-cr-16.

50. *See id.* at 3; Rebecca L. Haffajee & Richard G. Frank, *Generic Drug Policy and Suboxone to Treat Opioid Use Disorder*, 47 J.L. Med. & Ethics 43, 24 (2019); Alison Knopf, *Indivior CEO Sentenced to Prison over Marketing Schemes*, Alcoholism & Drug Abuse Wkly., Nov. 9, 2020, at 6, 7.

formulations.[51] In response, CARB initiated a number of rulemakings in which it took input from industry groups and members of the public on what gasoline formulation standards to mandate.[52] Among other participants in the rulemaking process was the oil refiner Unocal, which proposed adoption of its T50 gasoline standard.[53] Unbeknownst to CARB or the other participants, though, Unocal was simultaneously prosecuting a patent application involving that same T50 standard.[54] CARB issued its final regulations in June 1994, which included the T50 standard and other properties recited in Unocal's patent application.[55] Although its patent had issued in February 1994, Unocal waited until January 1995 to issue a gloating press release claiming that its patent "covers many of the possible fuel compositions that refiners would find practical to manufacture and still comply" with the CARB regulations.[56]

Between the patent and the CARB mandates, Unocal had brazenly obtained a textbook example of mandatory infringement. Competing oil refineries had no choice but to comply with the gasoline formulation mandates, and to do so they had to take patent licenses from Unocal, which the Federal Trade Commission ("FTC") estimated would cost over half a billion dollars per year, almost entirely passed onto consumers.[57] Commentators sharply criticized this "capture of an industry standard."[58]

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51. *See In re* Union Oil Co. of Cal. ("*Unocal*"), 138 F.T.C. 1, 4 (2004). Although this factual description is taken largely from the Federal Trade Commission ("FTC")'s complaint and thus are not proven assertions, they are also allegations that Unocal did not deny. *See* Anwer Resp't Union Oil Co. California, Mar. 1, 2003, https://www.ftc.gov/sites/default/files/documents/cases/2003/03/030321unocalanswer.pdf.

52. *See Unocal*, 138 F.T.C. at 5.

53. *See id.* at 5–6.

54. *See id.* at 6; Gasoline Fuel, U.S. Patent No. 5,288,393 (issued Feb. 22, 1994).

55. *See Unocal*, 138 F.T.C. at 7.

56. *Id.* para. 64, at 110 (complaint).

57. *See id.* para. 10, at 96.

58. Mueller, *supra* note 18, at 628 (internal quotations and footnote omitted); *see also* Scott H. Segal, *Fuel for Thought: Clean Gasoline and Dirty Patents*, 51 Am. U. L. Rev. 2, 71–81 (2001); Cook, *supra* note 18, at 109–11.

Unocal's ploy roiled the industry.[59] Three months after Unocal's press release, six major oil refiners brought suit in an attempt to invalidate Unocal's lead patent.[60] California's attorney general, incensed by Unocal's attempt to "hijack and distort the state regulatory process by claiming a patent on gasoline formulas,"[61] filed an *amicus curiae* brief joined by 33 other states and the District of Columbia arguing that Unocal's actions "distorted and abused California's administrative regulatory process, and provides a model for similar mischief in a variety of important environmental and consumer protection contexts."[62] Seven members of Congress also filed a brief arguing that upholding the patent would "inflict[] substantial collateral damage on [] important federal policies,"[63] and the U.S. solicitor general also expressed "concern about possible misuse of the regulatory process by a patent applicant."[64] Nevertheless, the Federal Circuit upheld Unocal's patent and the Supreme Court denied certiorari; despite Unocal's reprehensible behavior, the courts found no defect in the patent itself.[65]

With Unocal's patents unscathed and reaping large royalties,[66] attention turned to the competition laws as a possible remedy to Unocal's stranglehold on the gasoline industry. In 2003, the FTC charged Unocal with unfair methods of

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59. *See, e.g.*, Michael Parrish, *Unocal Plan to Sell Clean-Fuel Formulas Has Rivals Angry*, L.A. TIMES, Feb. 1, 1995, at D2; Nancy Rivera Brooks, *In Patent Suit, Unocal's Gain Would Prove Motorists' Pain*, L.A. TIMES, Sept. 24, 1997, at D1; Julie Tamaki, *Unocal Patent on Clean Fuel Stirs Outrage*, L.A. TIMES, Oct. 9, 2000, at A3, https://www.latimes.com/archives/la-xpm-2000-oct-09-mn-33920-story.html.

60. *See Unocal*, 138 F.T.C. ¶ 68, at 111.

61. *See* Press Release, *Attorney General Bill Lockyer Files "Friend of Court" Brief over Unocal Gasoline Patent* (Sept. 14, 2000), https://oag.ca.gov/news/press-releases/attorney-general-bill-lockyer-files-friend-court-brief-over-unocal-gasoline.

62. *Amici Curiae* Brief of Alabama et al. in Support of Petition for Writ of Certiorari at 1, Atl. Richfield Co. v. Union Oil Co. of Cal., 531 U.S. 1183 (Sept. 14, 2000) (No. 00-249) (cert. denied).

63. Motion for Leave to File Brief and Brief for Members of Congress Dennis J. Kucinich et al. as *Amici Curiae* in Support of Petitioners at 2, *Atl. Richfield*, 531 U.S. 1183 (Sept. 14, 2000) (No. 00-249).

64. Brief for the United States as Amicus Curiae at 9, *Atl. Richfield*, 531 U.S. 1183 (Jan. 1, 2001) (No. 00-249).

65. Indeed, they found that Unocal had acted in good faith at least before the patent examiner. *See* Union Oil Co. of Cal. v. Atl. Richfield Co. ("*Unocal v. ARCO*"), 208 F.3d 989, 1002 (Fed. Cir. 2000); Union Oil Co. of Cal. v. Atl. Richfield Co., 34 F. Supp. 2d 1208, 1222 (C.D. Cal. 1998), *aff'd*, 208 F.3d 989.

66. *See Unocal*, 138 F.T.C. 1, paras. 70–72, at 111–12 (2004) (describing Unocal's patent licensing activities).

competition.[67] Ultimately—eleven years after the patent issued—the FTC would prevail, with Unocal entering a consent decree to disclaim its patents and not collect further royalties.[68] Yet the competition authority's pathway to victory was narrow, with Unocal winning resoundingly before the administrative law judge that was only overturned by a lengthy and complex Commission reversal, on a difficult First Amendment question.[69]

C. Safe Handling of Drugs

To many, thalidomide (Thalomid) is an essential drug used to treat a wide variety of cancers and diseases.[70] Thalidomide also causes traumatic birth defects, and the FDA famously made a name for itself when its drug reviewer Frances Kelsey refused to approve it over safety concerns.[71] Thalidomide can be used safely as long as it is not prescribed to patients who are or are likely to become pregnant, prompting a need for a regulatory framework for safe use of thalidomide and other drugs that, used wrongly, could be harmful.

The regulatory framework in question is called "risk evaluation and mitigation strategies," or REMS.[72] Such strategies, developed in coordination between the FDA and a drug's sponsor firm, may include training requirements, monitoring systems, dispensing limitations, and other safety measures.[73] The thalidomide REMS, for example, require the drug's manufacturer Celgene to operate an online system that enrolls patients, assigns them to risk categories based on gender and likelihood of becoming pregnant, and provides authorization numbers for dispensing prescriptions based on those risk categories.[74]

REMS has given rise to two lines of anticompetitive strategies for blocking generic competition. First, firms have cited REMS on their drugs as a reason to

67. Federal Trade Commission Act (FTC Act) § 5, 15 U.S.C. § 45; *see Unocal*, 138 F.T.C. at 92.

68. *Unocal II*, 140 F.T.C. 123, 160–61 (2005).

69. *See Unocal*, 138 F.T.C. at 2; *infra* text accompanying notes 293–302.

70. *See* World Health Org., Model List of Essential Medicines 31 (22d ed. 2021), https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.02; Michael E. Franks et al., *Thalidomide*, 363 Lancet 1802, 1805–08 (2004).

71. *See* Franks et al., *supra* note 70, at 1808; Bridget M. Kuehn, *Frances Kelsey Honored for FDA Legacy*, 304 J. Am. Med. Ass'n 2109, 2110 (2010).

72. *See* Federal Food, Drug, and Cosmetics Act (FFDCA) § 505-1, 21 U.S.C. § 355-1.

73. *Id.* § 505-1(f)(3), 21 U.S.C. § 355-1.

74. *See* Risk Evaluation and Mitigation Strategy (REMS) Document: THALIDOMID REMS Program 9–10 (FDA July 2021), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Thalomid_2021_08_05_REMS_Full.pdf.

refuse to sell samples to potential generic manufacturers.[75] Approval of a new generic requires proof of bioequivalence to an approved drug,[76] which in turn requires testing against samples of the approved drug, so the refusal to provide samples is a full stop to competition.

The second line is the patenting of REMS themselves. REMS often lay out a process for managing distribution of the drug,[77] and processes are patentable.[78] If the FDA required generics to share REMS with the listed drug, as was the default until 2019,[79] then patents on the REMS would produce mandatory infringement. Congress knew of this possibility, providing prior to 2019 that a generic could devise its own REMS if "an aspect . . . is claimed by a patent"[80] and after 2019 allowing the generic to propose its own REMS for any reason.[81]

But what if a patent on a safety protocol for a drug is so broad that it covers all REMS that the FDA might require? This was arguably the case for the patents that Celgene obtained on its thalidomide REMS.[82] Celgene admitted that broad reach in an FDA filing opposing a generic thalidomide entrant, writing that "[i]t is inconceivable that [a] generic applicant would be allowed to market a generic thalidomide product without being required to use the same type of restricted distribution program that was so essential to the approval of Thalomid and is so integral to its labeling."[83]

Both the withholding of samples based on REMS and patents on REMS have attracted substantial public outcry.[84] Multiple scholars criticized Celgene's REMS

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75. *See* Jordan Paradise, *REMS as a Competitive Tactic: Is Big Pharma Hijacking Drug Access and Patient Safety?*, 15 Hous. J. Health L. & Pol'y 43, 64–65 (2015).

76. *See* FFDCA § 505(j)(2)(A)(iv), 21 U.S.C. § 355.

77. *See id.* § 505-1(f)(4)(A), 21 U.S.C. § 355-1.

78. *See* 35 U.S.C. § 101; Bilski v. Kappos, 561 U.S. 593, 607 (2010).

79. *See* Federal Food, Drug, and Cosmetics Act (2019 FFDCA) § 505-1(i)(1)(C), 21 U.S.C. § 355-1 (2019) (equivalent drugs "shall use a single, shared system" of REMS unless the FDA waives the requirement). The CREATES Act amended FFDCA § 505-1(i)(1)(C) to let the generic entrant choose whether to use its own REMS, unless the FDA finds that "no different, comparable aspect . . . could satisfy the requirements" of safety. *See* § 505-1(i)(1)(C)(ii), 21 U.S.C. § 355-1.

80. 2019 FFDCA § 505-1(i)(1)(C)(ii), 21 U.S.C. § 355-1.

81. *See* FFDCA § 505-1(i)(1)(C)(ii), 21 U.S.C. § 355-1.

82. *See, e.g.*, U.S. Patent No. 6,315,720 (issued Nov. 13, 2001); Paradise, *supra* note 75, at 71–72.

83. Citizen Petition of Celgene Corp., No. FDA-2007-P-0113, at 17 (Food & Drug Admin. Sept. 20, 2007).

84. *See, e.g.*, Ameet Sarpatwari et al., *Using a Drug-Safety Tool to Prevent Competition*, 370 New Eng. J. Med. 1476 (2014); Alison Kodjak, *How a Drugmaker Gamed the System to Keep Generic*

patent as potentially invalid and certainly anticompetitive. [85] U.S. Department of Health and Human Services Secretary Alex Azar, at his confirmation hearing, promised to look into "how REMS programs could be abused to block entry,"[86] and in 2017 Congress held a hearing to discuss the anticompetitive use of REMS.[87] Congress did ultimately remedy the sample-sharing problem in 2019,[88] but patents on REMS can still block generic drug competition.

D. Technical Interoperability Standards

Interoperability is the ability of systems and devices to work together to produce a desired result: an electrical or USB plug fitting into a compatible socket, a word processor opening a document produced by another program, or a computer sending the right commands to a distant web server.[89] To do so, those systems must comply with a shared set of specifications, often called "technical standards."[90] For example, a WiFi-capable laptop must issue coded commands about authentication, data transmissions, and signal strength—commands that are defined in and thus copied from the detailed WiFi technical standard.[91] Standards facilitate competition by avoiding fragmentation of the market: A world of incom-

Competition Away, NPR (May 17, 2018), https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.

85. *See* Michael A. Carrier & Brenna Sooy, *Five Solutions to the REMS Patent Problem*, 97 B.U. L. REV. 1661, 1669–71 (2017); Paradise, *supra* note 75, at 69–72; Sarpatwari et al., *supra* note 84, at 1478.

86. *See Nomination of Alex Azar to Serve as Secretary of Health and Human Services: Hearing Before the S. Comm. on Health, Education, Labor, and Pensions*, 115th Cong. 20 (Nov. 29, 2017).

87. *See Antitrust Concerns and the FDA Approval Process: Hearing Before the Subcomm. on Regulatory Reform, Commercial and Antitrust Law of the H. Comm. on the Judiciary*, 115th Cong. (July 27, 2017).

88. *See* Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (CREATES Act), *in* Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, § 610, 133 STAT. 2534, 3130 (2019).

89. *See generally* JOHN PALFREY & URS GASSER, INTEROP: THE PROMISE AND PERILS OF HIGHLY INTERCONNECTED SYSTEMS 1–18 (2012); Samuelson, *supra* note 19, at 193–94; Charles Duan, *A Tale of Two Interoperabilities; Or, How Google v. Oracle Could Become Social Media Legislation*, 2021 CARDOZO L. REV. DE•NOVO 246, 251–59 [hereinafter Duan, *Interoperabilities*].

90. *See* Duan, *Interoperabilities*, *supra* note 89, at 258–61.

91. *See* IEEE-SA STANDARDS BD., IEEE STD. 802.11-2016, WIRELESS LAN MEDIUM ACCESS CONTROL (MAC) AND PHYSICAL LAYER (PHY) SPECIFICATIONS 638 (2016), http://ieeexplore.ieee.org/document/7786995/; Charles Duan, *Internet of Infringing Things: The Effect of Computer Interface Copyrights on Technology Standards*, 45 RUTGERS COMPUTER & TECH. L.J. 1, 18–20 (2019).

patible phone dock connectors, for example, locks consumers into the Android or iOS ecosystem.[92] But interoperability commands and other specifications could be protected by IP rights, the enforcement of which could give the IP holder powerful control to suppress competition among those using the standard.[93]

Technical interoperability standards thus give rise to a difficult tension between IP rights and competition.[94] Even when a standard is not legally mandatory but widely used, this tension has been central to major disputes.[95] In the decade-long feud between Oracle and Google,[96] commentators and computer scientists repeatedly warned that well-known programming language commands and syntaxes could be *de facto* interoperability standards, such that Oracle's claim of copyright protection over those commands and syntaxes could create widespread monopolistic lock-in across the software industry.[97] Worried that copyright protection could be "a lock limiting the future creativity of new programs," the Supreme Court held Google's actions to be noninfringing fair use.[98]

Patents on standards are no less contentious. In an attempt to prevent anticompetitive use of patents essential to a technical standard, the industry consortia that create those standards often obligate their members to license those patents on fair, reasonable, and non-discriminatory ("FRAND") terms.[99] But what satisfies

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92. *See, e.g.,* Jon Porter, *EU Proposes Mandatory USB-C on All Devices, Including iPhones*, The Verge (Sept. 23, 2021), https://www.theverge.com/2021/9/23/22626723/eu-commission-universal-charger-usb-c-micro-lightning-connector-smartphones; Ericsson, Inc. v. D-Link Sys., Inc., 773 F.3d 1201, 1207 (Fed. Cir. 2014); Microsoft Corp. v. Motorola, Inc., 795 F.3d 1024, 1030 (9th Cir. 2015).

93. *See Microsoft*, 795 F.3d at 1030–31.

94. *See, e.g.,* Mark A. Lemley, *Intellectual Property Rights and Standard-Setting Organizations*, 90 Cal. L. Rev. 1889, 1901–03 (2002); A. Douglas Melamed & Carl Shapiro, *How Antitrust Law Can Make FRAND Commitments More Effective*, 127 Yale L.J. 2110, 2116–17 (2018); Josh Lerner & Jean Tirole, *Standard-Essential Patents*, 123 J. Pol. Econ. 547, 549 (2015).

95. *See generally* Jonathan Band, Interfaces on Trial 3.0: Google v. Oracle America and Beyond 5–13 (2021), https://www.policybandwidth.com/interfaces-on-trial-3-0 (describing history of interoperability litigation).

96. *See* Google LLC v. Oracle Am., Inc., 141 S. Ct. 1183, 1194–95 (2021).

97. *See, e.g.,* Jonathan Band, *Broad Support for Google in the First Round of Supreme Court Briefing*, Disruptive Competition Project (Jan. 14, 2020), https://www.project-disco.org/intellectual-property/011420-broad-support-for-google-in-the-first-round-of-supreme-court-briefing/ (discussing *amicus* briefs filed in *Google*).

98. *See Google*, 141 S. Ct. at 1208–09.

99. *See* Ericsson, Inc. v. D-Link Sys., Inc., 773 F.3d 1201, 1207 (Fed. Cir. 2014); Microsoft Corp. v. Motorola, Inc., 795 F.3d 1024, 1031 (9th Cir. 2015).

the FRAND obligation[100] depends very much on one's view of the relative merits of competition and IP protection, as seen in the extensive and contentious bodies of case law[101] and literature.[102] The Department of Justice ("DOJ") has flip-flopped on its interpretation of FRAND three times in the last three administrations, owing to its changing views on competition in the interoperability standards space.[103]

The cases above have dealt with "*de facto* mandatory infringement," insofar as pressure to comply with a technical standard comes from the two-sided nature of interoperability markets. But the same controversies arise when the government mandates interoperability standards. As the agency tasked with regulating communication technologies, the Federal Communications Commission ("FCC") has

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100. The FRAND obligation is intentionally vague to avoid the appearance of anticompetitive collusion among industry competitors. *See* Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 500–01 (1988); U.S. Dep't of Justice & Fed. Trade Comm'n, Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition 50–52 (2007), http://www.usdoj.gov/atr/public/hearings/ip/222655.pdf.

101. *See, e.g.*, *Microsoft*, 795 F.3d at 1045–47; Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 314 (3d Cir. 2007); Rambus Inc. v. Infineon Techs. AG, 318 F.3d 1081, 1102 (Fed. Cir. 2003).

102. *See, e.g.*, J. Gregory Sidak, *The Meaning of FRAND, Part II: Injunctions*, 11 J. Competition L. & Econ. 201 (2015); Anne Layne-Farrar, A. Jorge Padilla & Richard Schmalensee, *Pricing Patents for Licensing in Standard-Setting Organizations: Making Sense of FRAND Commitments*, 74 Antitrust L.J. 671 (2007); Herbert J. Hovenkamp, *FRAND and Antitrust*, 105 Cornell L. Rev. 1683 (2020), https://scholarship.law.upenn.edu/faculty_scholarship/2093; Jorge L. Contreras, *A Brief History of FRAND: Analyzing Current Debates in Standard Setting and Antitrust Through a Historical Lens*, 80 Antitrust L.J. 39 (2015).

103. *See* U.S. Dep't of Justice & U.S. Patent & Trademark Office, Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments 6–8 (Jan. 8, 2013), https://www.justice.gov/atr/page/file/1118381/download ("A patent owner's voluntary F/RAND commitments may also affect the appropriate choice of remedy . . . ."); U.S. Patent & Trademark Office, U.S. Dep't of Justice & Nat'l Inst. of Standards & Tech., Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments 4 (Dec. 19, 2019), https://www.justice.gov/atr/page/file/1228016/download (withdrawing 2013 statement) (finding that special approach to FRAND patents would "result[] in harm to innovation and dynamic competition"); U.S. Patent & Trademark Office, U.S. Dep't of Justice & Nat'l Inst. of Standards & Tech., Draft Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments 4 (Dec. 6, 2021), https://www.justice.gov/opa/press-release/file/1453826/download ("seeking injunctive relief" based on a FRAND patent can "ultimately harm consumers and small businesses"). The agencies ultimately withdrew from any FRAND statement. *See* U.S. Patent & Trademark Office, U.S. Dep't of Justice & Nat'l Inst. of Standards & Tech., Withdrawal of 2019 Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments (June 8, 2022), https://www.uspto.gov/sites/default/files/documents/SEP2019-Withdrawal.pdf.

dealt with IP and interoperability standards many times.[104] The most prominent, long-running clash has been over digital television broadcast signals, for which since 1996 the FCC has adopted standards developed by the Advanced Television Systems Committee ("ATSC"), a private industry consortium.[105] In that 1996 rulemaking and a subsequent one in 2008, the agency acknowledged the potentially problematic role of patents on the mandatory ATSC standard but declined to take action because ATSC had already required FRAND licensing.[106]

But are ATSC patent holders living up to their FRAND commitments? ATSC royalties are reportedly several times higher in the United States compared to other nations.[107] Especially following allegations of a cozy relationship between a key ATSC patent holder and the former FCC chair,[108] the agency's inaction on patents has come under fire from commentators and members of Congress.[109] Nevertheless, as recently as 2020 the FCC has maintained its no-action policy, though over two commissioners' dissents.[110]

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104. *See, e.g.*, Donahue et al., *supra* note 17, at 3–12 (discussing standards on enhanced 911 services, hard-of-hearing accommodations, and cable set-top boxes); Narechania, *supra* note 17, at 1514–15 (telephone interconnection patents); Cook, *supra* note 18, at 111–15 (television V-chip).

105. *See* Advanced Television Systems and Their Impact Upon the Existing Television Broadcast Service, 11 F.C.C. Rcd. 17771, 17798 (Fed. Commc'ns Comm'n Dec. 27, 1996) [hereinafter ATSC 1996] (codified as amended at 47 C.F.R. § 73.682(d)) (fourth report and order).

106. *See id.* paras. 54–55 ("We reiterate that adoption of this standard is premised on reasonable and nondiscriminatory licensing of relevant patents, but believe that greater regulatory involvement is not necessary at this time."); Digital Television Distributed Transmission System Technologies, 23 F.C.C. Rcd. 16731, 16760 (Fed. Commc'ns Comm'n Nov. 3, 2008) (report and order) ("In cases where stations choose to use a patented technology, we expect that such use will be offered on RAND terms.").

107. *See* Zack Christenson, *Abuse from Patent Pools*, Forbes (May 14, 2014), https://www.forbes.com/sites/realspin/2014/05/14/abuse-from-patent-pools/; Kim Hart, *Consumer Group Petitions FCC to Lower Costs of Digital TV Sets*, Wash. Post (Jan. 2, 2009), http://www.washingtonpost.com/wp-dyn/content/article/2009/01/01/AR2009010101789.html.

108. *See* Cecilia Kang, *F.C.C. Link to Sinclair Is Explored*, N.Y. Times, Feb. 15, 2018, at B1, https://www.nytimes.com/2018/02/15/technology/fcc-sinclair-ajit-pai.html.

109. *See* Letter from Frank Pallone, Jr., House of Representatives, et al., to Ajit V. Pai, Fed. Commc'ns Comm'n 5–6 (Aug. 14, 2017), https://docs.fcc.gov/public/attachments/DOC-346883A2.pdf; Letter from Mike Pompeo, House of Representatives, to Tom Wheeler, Fed. Commc'ns Comm'n (Oct. 27, 2014), https://docs.fcc.gov/public/attachments/DOC-330841A2.pdf; Cook, *supra* note 18, at 119; Becky Chao & Amir Nasr, TV Royalty: How Patents Could Help Sinclair Rule the Broadcasting Market 10–11 (2018), https://www.newamerica.org/oti/reports/tv-royalty/.

110. *See* FCC Addresses Pending ATSC 3.0 Matters and Petitions, 35 F.C.C. Rcd. 6793, paras. 60–61, at 6823–24 (Fed. Commc'ns Comm'n June 16, 2020) (report and order) (affirming FCC Authorizes

E. Product Labeling

Competing products sometimes must use the same text or materials on their packaging labels or advertising. The classic example is generic drugs, for which approval is governed by the Hatch–Waxman Act ("Hatch–Waxman").[111] Since the generic must be equivalent to an already approved one (called the "listed drug"[112]), Hatch–Waxman requires any labeling or marketing materials for the generic to be "the same as the labeling approved for the listed drug."[113] The same-labeling requirement simplifies the approval process for the FDA since the agency need not analyze the generic label extensively, and the requirement avoids leaving patients and physicians wondering whether differences in label text imply differences in the generic's safety or efficacy.[114] Accordingly, both Congress and the FDA have contemplated only minor, trivial exceptions to the expectation that generic and listed drug labels be the same.[115]

Next Gen TV Broadcast Standard, 32 F.C.C. Rcd. 9930, para. 100, n.300, at 52 (Fed. Commc'ns Comm'n Nov. 20, 2017) (report and order) ("We will also use this period to monitor how the marketplace handles patent royalties for essential patents, but we will not require reasonable and non-discriminatory (RAND) licensing at this time.")); *id.* at 6842 (Rosenworcel, Comm'r, dissenting) ("That means the agency is authorizing billions for essential patent holders that will be paid for by consumers who will need to purchase ATSC 3.0 equipment just to continue to watch television."); *id.* at 6845 (Starks, Comm'r, dissenting) ("[I]n this case, a single broadcaster holds the essential ATSC 3.0 patents and thus can set pricing and terms for any other broadcaster seeking to transition.").

111. *See* Federal Food, Drug, and Cosmetics Act (FFDCA) § 505(j), 21 U.S.C. § 355.

112. *See id.* § 505(j)(2)(A)(i), 21 U.S.C. § 355. The listed drug is often informally called the "brand-name drug." *See, e.g.*, Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 404 (2012).

113. *See* FFDCA § 505(j)(1)(A)(v), 21 U.S.C. § 355.

114. *See* Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17950, 17961 (Food & Drug Admin.) (final rule) ("Consistent labeling will assure physicians, health professionals, and consumers that a generic drug is as safe and effective as its brand-name counterpart."); Brief for the United States as *Amicus Curiae* at 11–15, SmithKline Beecham Consumer Healthcare, LP v. Watson Pharm., Inc., 211 F.3d 21 (2d Cir. Jan. 19, 2000) (No. 99-9501), https://www.copyright.gov/rulings-filings/briefs/smithkline-beecham-consumer-healthcare-l-p-v-watson-pharm-inc-211-f-3d-21-2d-cir-2000.pdf (explaining government's understanding of same-labeling requirement). By analogy, lawyers frequently apply the canon of statutory construction that "a material variation in terms suggests a variation in meaning." *See* Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 170 (2012); Russello v. United States, 464 U.S. 16, 23 (1983) ("[I]t is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (quoting United States v. Wong Kim Bo, 472 F.2d 720, 722 (5th Cir. 1972)).

115. *See* Drug Price Competition and Patent Term Restoration Act of 1984, H.R. Rep. No. 98-857, at 22 (1984) (suggesting address corrections and pill color changes as exemplary reasons why "the proposed labeling for the generic drug may not be exactly the same"); 21 C.F.R.

But what happens if the listed drug's labeling text is copyrighted?[116] In *SmithKline Beecham Consumer Healthcare, LP v. Watson Pharmaceuticals, Inc.*, the manufacturer of Nicorette gum asserted copyright protection in its labels and user guides against generic entrants required to use those labels and guides in the FDA approval process.[117] If successful, the copyright claim would have blocked generic competition on Nicorette even after the patents on the gum had expired.[118] The competing injustices of frustrating generic competition on an off-patent drug on the one hand, and ignoring the "more than one million dollars" spent on developing Nicorette labeling on the other, unusually forced the district court and the FDA into tense negotiations and led the Second Circuit to alter the scope of copyright law in light of Hatch–Waxman.[119]

SmithKline is just one of many cases involving mandatory labels. The Environmental Protection Agency ("EPA") has similar authority to expedite approval of generic pesticides that are "identical or substantially similar in composition and labeling to a currently-registered pesticide."[120] In two cases, courts have held that this same-labeling requirement does not conflict with copyright law on the grounds that the statutory command "does not require a me-too applicant to ensure that its product label is identical to a registered label."[121] The courts essentially put the ball in the EPA's court to figure out how to interpret "identical or substantially similar in . . . labeling" without treading on copyright law's prohibition on substantial similarity.[122]

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§ 314.94(a)(8)(iv) (listing permissible labeling changes); Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28884 (Food & Drug Admin.) (proposed rule) ("The [FDA] will not accept ANDA's for products with significant changes in labeling . . . .").

116. On copyrightability of product labels, see generally Zvi Rosen, *Reimagining Bleistein: Copyright for Advertisements in Historical Perspective*, 59 J. Copyright Soc'y USA 347 (2011).

117. *See* 211 F.3d at 24.

118. *See id.*

119. *See id.*; *infra* Section II.B.

120. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) § 3(c)(3)(B)(i)(I), 7 U.S.C. § 136a.

121. Syngenta Crop Prot., LLC v. Willowood, LLC, 944 F.3d 1344, 1357 (Fed. Cir. 2019); *see also* FMC Corp. v. Control Sols., Inc., 369 F. Supp. 2d 539, 558 (E.D. Penn. 2005).

122. *See Syngenta*, 944 F.3d at 1357 ("FIFRA's similarity requirement does not foreclose expedited review for an independently composed label that relies solely on unprotected facts, concepts, and methods derived from the registered label."); *FMC*, 369 F. Supp. 2d at 558 (finding that the EPA is capable of "approving a me-too label application that consisted of language drafted . . . without being a near-verbatim copy").

Lest these cases suggest the problem is limited to copyright law, consider the recent *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA* decision.[123] There, a divided Federal Circuit panel held that a generic drug maker's FDA-approved label could induce infringement of a patent on a method of using a drug based on fragments of text in the label's section on dosing and administration.[124] The fragmentary nature of the infringement analysis is what makes the decision so pernicious: Generics ought to be able to enter since the drug compound itself is off patent, but the majority opinion suggests that those generics may need to pepper their label with edits to avoid later method-of-use patents—despite the same-labeling requirement.[125] To be sure, generics can carve out parts of the label to avoid method-of-use patents, but not at the expense of safety or efficacy.[126] Modifications to dosage and administration would seem to strike at the heart of safety,[127] leaving generics in the dark about how to comply with both Hatch–Waxman and patents. "The only clear thing now," wrote Judge Prost in dissent, "is that no generic can know until hit with the bill whether it's staying within the confines of the law."[128]

Mandatory label IP cases have repeatedly raised public ire. *GlaxoSmithKline*, for example, theoretically allows a drug maker to block generic competition forever by sequentially obtaining new method-of-use patents; commentators panned the Federal Circuit's decision as having "opened the floodgates for induced infringement for years to come."[129] The government itself has vigorously opposed

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123. *See* 7 F.4th 1320 (Fed. Cir. 2021) (per curiam) (petition for certiorari filed July 11, 2022).

124. *See id.* at 1328 (relying on testimony that "the Dosage and Administration section of the partial label disclosed administering particular dosages that satisfied" elements of the method-of-use patent).

125. *See id.* at 1328–29; Brief of 14 Professors of Law as *Amici Curiae* in Support of the Petition for Rehearing En Banc at 3–5, *GlaxoSmithKline*, 7 F.4th 1320 (Oct. 27, 2021) (Nos. 2018-1976, -2023).

126. *See* Federal Food, Drug, and Cosmetics Act (FFDCA) § 505(j)(2)(A)(viii), 21 U.S.C. § 355 (permitting method-of-use carve-outs); 21 C.F.R. § 314.127(a)(7) (requiring that differences in labeling "do not render the proposed drug product less safe or effective than the listed drug for all remaining, nonprotected conditions of use); Ctr. for Drug Evaluation & Research, FDA, ANDA Submissions—Refuse-to-Receive Standards 13 (2d rev. Dec. 2016), https://www.fda.gov/media/86660/download ("FDA will [refuse to receive] an ANDA on a case-by-case basis if the ANDA contains differences in packaging and/or labeling from the [listed drug] that may be associated with safe/effective use of the drug product.").

127. *See* Theophrast von Hohenheim [Paracelsus], Sieben Defensiones [Seven Defenses] 25 (Karl Sudhoff ed., 1915) (1538), https://catalog.hathitrust.org/Record/100160006 ("[A]llein die Dosis macht, daß ein Ding kein Gift ist." ["The dose alone makes a thing not a poison."]).

128. *GlaxoSmithKline*, 7 F.4th at 1361 (Prost, J., dissenting).

129. Sara W. Koblitz, *Ding Dong Is the Skinny Label (Effectively) Dead?*, FDA L. Blog (Sept. 7, 2021), https://www.thefdalawblog.com/2021/09/ding-dong-is-the-skinny-label-effectively-dead/;

copyright assertion in mandatory labels, saying of the pesticide cases that "copyright liability on me-too manufacturers would thwart FIFRA's expedited-review scheme for generic pesticides."[130] That controversy is unsurprising, as these cases show the cost of mandatory IP: high monopoly prices for drugs and other products that are off patent and ought to be subject to competition.

F. The Text of the Law

To comply with the law, one must read its words. Yet words are copyrightable subject matter, setting the stage for sharp clashes among IP holders, scholars, and public advocates that have traversed all three branches of government and numerous judicial opinions.

Copyright in the text of the law was largely a settled problem when judges and legislators wrote it: the Supreme Court long ago held that neither could hold copyrights in official works.[131] But as the administrative state developed during the 20th century, legislatures and agencies increasingly relied on external experts as drafters of laws. Consortia such as the Uniform Law Commission and the International Code Council developed model codes on subjects such as commercial law and safe building construction, and states or agencies adopted these model codes by reprinting them in statutes or, as the model codes became larger and more unwieldy to reprint, by "incorporation by reference."[132] The latter technique is ubiquitous today: The National Institute of Standards and Technology reports

see also David Wallace, *Blow for Industry as GSK–Teva "Skinny Label" Decision Upheld*, Pink Sheet (Aug. 6, 2021), https://pink.pharmaintelligence.informa.com/PS145125/Skinny-Label-Case-Gives-Brands-A-Blueprint-To-Alter-Use-Codes-In-Patent-Litigation; Ian Lopez, *Teva "Skinny Label" Ruling Comes Amid Lawmaker Drug Cost Fight*, Bloomberg L. (Aug. 6, 2021), https://news.bloomberglaw.com/health-law-and-business/teva-skinny-label-ruling-comes-amid-lawmaker-drug-cost-fight; Kevin Dunleavy, *GSK Again Scores $235M in "Skinny Label" Case, but Court Admits It's "Unclear What Teva Even Did Wrong"*, Fierce Pharma (Aug. 6, 2021), https://www.fiercepharma.com/pharma/court-reaffirms-235m-judgement-for-gsk-against-generic-manufacturer-teva-skinny-label-case.

130. Brief for the United States as Amicus Curiae in Support of Appellees at 13, Syngenta Crop Prot., LLC v. Willowood, LLC, 944 F.3d 1344 (Fed. Cir. June 13, 2018) (No. 2018-1614); *see also* Brief for the United States as *Amicus Curiae* at 8, SmithKline Beecham Consumer Healthcare, LP v. Watson Pharm., Inc., 211 F.3d 21 (2d Cir. Jan. 19, 2000) (No. 99-9501), https://www.copyright.gov/rulings-filings/briefs/smithkline-beecham-consumer-healthcare-l-p-v-watson-pharm-inc-211-f-3d-21-2d-cir-2000.pdf.

131. *See* Wheaton v. Peters, 33 U.S. (8 Pet.) 591 (1834); Banks v. Manchester, 128 U.S. 244 (1888); Callaghan v. Myers, 128 U.S. 617 (1888).

132. *See generally* Peter L. Strauss, *Private Standards Organizations and Public Law*, 22 Wm. & Mary Bill Rts. J. 497, 524–25 (2013).

over 24,000 standards incorporated by reference in federal regulations,[133] and the National Technology Transfer and Advancement Act of 1995 in fact requires agencies to use privately developed standards in regulations by default.[134] Are these legally mandated model codes and standards protected by copyright? The standards developers vigorously argue that they are, but the implication is that the developers, like any other copyright holder, can charge whatever they want for—or even withhold access to—the text of mandatory law.

Unsurprisingly, copyrights in mandatory legal texts have raised many eyebrows.[135] In 2011, the Administrative Conference of the United States expressed concerns that copyright in incorporated legal texts was "particularly problematic" and recommended that agencies make greater efforts to require public access.[136] In 2012, Congress required that incorporated-by-reference pipeline safety standards be "made available to the public, free of charge," apparently in response to one congressional office being asked to pay $1000 for a copy of a mandatory standard.[137] The same year, a coalition of scholars and practitioners petitioned the Office of the Federal Register ("OFR") to require free online publication of any text incorporated into a regulation and having the force of law.[138] The petition attracted at least 162 comments, many in support of increasing access to incorporated standards.[139] Yet the OFR refused to impose the requirement, in part claiming that the agency lacked the resources and authority to overcome copyright interests.[140]

Several courts have considered whether copyright law can preclude access to mandatory legal texts. *Building Officials & Code Administrators v. Code Technol-*

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133. *Standards Incorporated by Reference (SIBR) Database*, Nat'l Inst. Standards & Tech. (last updated Aug. 16, 2016), https://sibr.nist.gov/.

134. *See* Pub. L. No. 104-113, § 12(d)(1), 110 Stat. 775, 783 (1996); Emily S. Bremer, *Incorporation by Reference in an Open-Government Age*, 36 Harv. J.L. & Pub. Pol'y 131, 134–35 (2013) [hereinafter Bremer, *Incorporation*].

135. *See, e.g.*, Strauss, *supra* note 132; Lawrence A. Cunningham, *Private Standards in Public Law: Copyright, Lawmaking and the Case of Accounting*, 104 Mich. L. Rev. 291, 294 (2005).

136. *See* Adoption of Recommendations, 77 Fed. Reg. 2257, 2258 (Admin. Conference of the U.S. Jan. 17, 2012).

137. 49 U.S.C. § 60102(p); *see* Bremer, *Incorporation*, *supra* note 134, at 175.

138. *See* Letter from Peter L. Strauss et al. to Office of the Fed. Register 4–5 (Feb. 10, 2012), https://downloads.regulations.gov/NARA-12-0002-0002/content.pdf, *reprinted in* Incorporation by Reference, 77 Fed. Reg. 11414 (Office of the Fed. Register Feb. 27, 2012); Strauss, *supra* note 132, at 530.

139. *See* Strauss, *supra* note 132, at 531–36.

140. *See* Incorporation by Reference, 79 Fed. Reg. 66267, 66273 (Office of the Fed. Register Nov. 7, 2014).

ogy, Inc. expressed strong skepticism about the compatibility of the mandatory nature of incorporated model codes with "the exclusivity afforded a private copyright holder," but declined to declare the code at issue uncopyrightable.[141] By contrast, *Practice Management Information Corp. v. American Medical Ass'n* permitted a copyright in a system of medical codes even where a federal agency had made use of the coding system mandatory, finding the "economic incentive" of copyright a necessary driver of creation of such systems.[142] In *Veeck v. Southern Building Code Congress International, Inc.*, the Fifth Circuit held incorporated model building codes to be uncopyrightable "facts" once they had been adopted as law.[143] The court sharply divided, with the majority finding it "difficult to reconcile the public's right to know the law with the statutory right of a copyright holder to exclude,"[144] and the dissent fearing that the majority's decision would "imping[e] on the financial incentive and ability to continue creating and revising [] model codes."[145]

Most recently, the organization Public.Resource.Org engaged in collecting and distributing federally incorporated private standards on an expectation that *Veeck* protected such activity.[146] Public Resource nevertheless triggered high-profile copyright infringement lawsuits in 2013 and 2014.[147] The case, *American Society for Testing & Materials v. Public.Resource.Org, Inc.* ("*ASTM*"), attracted dozens of *amici curiae*[148] and a strident concurring opinion comparing the use of copyright to the evils of the Roman emperor Caligula.[149] Yet the question remains unresolved: The D.C. Circuit in *ASTM* remanded the case to the district court for

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141. 628 F.2d 730, 736 (1st Cir. 1980).

142. 121 F.3d 516, 518–19 (9th Cir. 1997), *amended by* Practice Mgmt. Info. Corp. v. Am. Med. Ass'n, 133 F.3d 1140 (9th Cir. 1998). The court nevertheless found that the copyright holder had engaged in copyright misuse based on anticompetitive exclusive-dealing provisions in its agreement with the agency. *See id.* at 521.

143. *See* 293 F.3d 791, 801 (5th Cir. 2002).

144. *Id.* at 799.

145. *Id.* at 816–17 (Wiener, J., dissenting).

146. *See The Scope of Copyright Protection: Hearing Before the Subcomm. on Courts, Intellectual Property, and the Internet of the H. Comm. on the Judiciary*, 113th Cong. 90–91 (Jan. 14, 2014), https://www.govinfo.gov/app/details/CHRG-113hhrg86344/CHRG-113hhrg86344 (statement of Carl Malamud, Public.Resource.Org).

147. *See* Am. Soc'y for Testing & Materials v. Pub.Res.Org, Inc. ("*ASTM*"), 896 F.3d 437, 441, 444 (D.C. Cir. 2018).

148. *See, e.g.,* Brief of 66 Library Associations et al. as *Amici Curiae* in Support of Defendant-Appellant, *ASTM*, 896 F.3d 437 (Sept. 25, 2017) (Nos. 17-7035, -7039).

149. *See ASTM*, 896 F.3d at 458 (Katsas, J., concurring).

further factfinding, which as of this writing is still ongoing.[150] Without resolution, authors of incorporated model codes and standards will continue to wield powerful copyrights over citizens needing access to the text of the law.

G. Texts in Legal Proceedings

Copyrightable works are often used as evidence or argument in an adjudicatory proceeding.[151] If the work is both copyright-protected and necessary to secure or vindicate legal rights in the proceeding, then using the work is mandatory infringement. In *Jartech, Inc. v. Clancy*, for example, members of a city council surreptitiously photographed a showing of a pornographic film in order to shut down the theater per the city's nuisance abatement ordinance.[152] The film producers (who also owned the theater) sued the city council for copyright infringement on the basis of the photographs.[153] Because the photographs were made "not for subsequent use and enjoyment, but for evidence to be used in the nuisance abatement proceedings," the Ninth Circuit held the city council's actions to be fair use and thus noninfringing.[154] Courts have also found no infringement based on copying works for preparing expert testimony,[155] to investigate defenses during litigation,[156] or to prove a parent's unsuitability for child custody.[157] A leading copyright treatise finds it "inconceivable" that reproduction of a work in the course of a judicial proceeding would constitute copyright infringement,[158] and

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150. In March 2022, the district court on remand granted almost complete summary judgment to Public Resource, holding that reproduction of most of the standards in the case was permissible fair use. *See* Am. Soc'y for Testing & Materials v. Pub.Res.Org, Inc., No. 1:13-cv-01215, at 36 (D.D.C. Mar. 31, 2022) (mem.). The decision will be appealed.

151. *See generally* David Kluft et al., *"The Weakest Infringement Claims of All Time"??? Patent Prosecution and the Physics of Fair Use*, Trademark & Copyright L. (Apr. 30, 2012), https://www.trademarkandcopyrightlawblog.com/2012/04/the-weakest-infringement-claims-of-all-time-patent-prosecution-and-the-physics-of-fair-use/.

152. *See* 666 F.2d 403, 405–06 (9th Cir. 1982).

153. *See id.* at 405.

154. *Id.* at 407.

155. *See* Religious Tech. Ctr. v. Wollersheim, 971 F.2d 364, 367 (9th Cir. 1992).

156. Healthcare Advocates, Inc. v. Harding, Earley, Follmer & Frailey, 497 F. Supp. 2d 627, 636–37 (E.D. Pa. 2007).

157. *See* Bond v. Blum, 317 F.3d 385, 395 (4th Cir. 2003).

158. *See* Melville B. Nimmer & David Nimmer, Nimmer on Copyright § 13.05[D][2] (2021) [hereinafter Nimmer].

one might wonder why there is not a simple doctrinal path for dismissing cases like these quickly.

Copyright-protected texts also are sometimes required for regulatory compliance. *Gulfstream Aerospace Corp. v. Camp Systems International, Inc.* held that copyright law could not preclude an aircraft maintenance business from making copies of the airplane manufacturer's manuals in order to perform government-mandated repairs.[159] The court feared that enforcing copyright in the manuals would let the manufacturer "gain a judicially enforced monopoly" in the repair market.[160] In 2012, several publishing houses sued patent law firms for copyright infringement committed when the firms submitted technical articles to patent examiners, as U.S. and foreign patent laws require them to do; patent attorneys breathed a sigh of relief when the courts found no infringement.[161]

Sometimes the mandate is not so obvious. *Georgia v. Public.Resource.Org, Inc.* considered whether state-authored annotations to the official code of laws were subject to copyright protection, such that reproducing the official code entirely was prohibited.[162] The courts sharply divided on this question: A 5–4 Supreme Court majority and the Eleventh Circuit found that no copyright protection inhered,[163] while the district court and dissenting justices disagreed.[164]

Mandatory infringement offers one way to understand *Public.Resource.Org*. The dissents primarily focused on the fact that the official annotations, being nonbinding, "do not even purport to embody the will of the people because they are not law."[165] Chief Justice Roberts for the majority replied that the dissents' un-

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159. *See* 428 F. Supp. 2d 1369, 1371–73 (S.D. Ga. 2006).

160. *Id.* at 1380.

161. *See, e.g.*, Am. Inst. of Physics v. Schwegman, Lundberg & Woessner, P.A., No. 0:12-cv-528, at 22 (D. Minn. July 30, 2013) (magistrate recommendations) ("[A] reasonable jury could only conclude that Schwegman's purpose in downloading and making internal copies of the Articles was to ultimately comply with the legal requirement to provide prior art to the USPTO and to represent its clients' interests in obtaining patents in Europe and Japan."), *aff'd mem.*, No. 0:12-cv-528 (D. Minn. Aug. 30, 2013); David Kluft et al., *Finally Dismissed: Were They the "Weakest Infringement Claims of All Time"?*, Trademark & Copyright L. (Mar. 31, 2014), https://www.trademarkandcopyrightlawblog.com/2014/03/copyright-claims-based-on-submission-of-prior-art-to-patent-office-finally-dismissed-were-they-the-weakest-infringement-claims-of-all-time/.

162. *See* 140 S. Ct. 1498, 1503–04 (2020).

163. *See id.* at 1504–05.

164. *See id.* at 1505 (describing district court opinion); *id.* at 1517 (Thomas, J., dissenting).

165. *Id.* at 1517 (Thomas, J., dissenting); *see also id.* at 1523 (Ginsburg, J., dissenting) (noting that annotations "do not rank as part of the Georgia Legislature's lawmaking process") (emphasis omitted).

derstanding of the annotations "undersells their practical significance."[166] What significance? A good interpretation is that the annotations are mandatory incidents of legal advocacy: Unless one adheres to rigid textualism, the pronouncements of legislators are necessary for making arguments about the interpretation of laws. Even Justice Scalia, noted skeptic of legislative history, conceded that "[s]ince most judges use legislative history, . . . you must use legislative history as well."[167] Thus, Roberts observes that nonbinding annotations "illuminate the law" such that "first-class readers with access to the annotations will be assured" that their legislators understand that, for example, certain statutes have been held unconstitutional.[168] Justice Thomas's rejoinder that one could glean the same information from the case reports does not answer Roberts's point under this interpretation.[169] The case law alone cannot make citizens "assured" that the *legislature* has accepted the unconstitutionality of its laws.[170] Nonbinding legislative works are mandatory to citizens who, to participate effectively in the legal process, must be able to make legislative intent arguments.

While most of the examples of mandatory infringement have affected limited populations of regulated entities—asthma patients, oil refineries, technology developers, pharmaceutical manufacturers—the *Public.Resource.Org* case emphasizes how far the mandatory infringement problem reaches. All citizens are expected to understand the laws, advocate for themselves in court, and engage with the political process. Those who hold IP rights to texts mandatory for executing the duties of citizenship thus become gatekeepers to constitutional government itself.

H. Themes and Questions

Despite the vast differences in subject matter and IP rights involved in these case studies, several common themes emerge. First and foremost is a theme of potential harms to consumers and the public. Monopoly pricing is the starting point of the harm in many cases: costly albuterol inhalers and product-hopped drugs that some patients cannot afford,[171] billions of dollars of raised gas prices,[172]

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166. *Id.* at 1512 (majority op.).

167. Antonin Scalia & Bryan A. Garner, Making Your Case: The Art of Persuading Judges 49 (2008).

168. *Pub.Res.Org*, 140 S. Ct. at 1513, 1512.

169. *See id.* at 1517–18 (Thomas, J., dissenting).

170. *See id.* at 1512 (majority op.).

171. *See supra* Section I.A.

172. *See Unocal*, 138 F.T.C. 1, paras. 70–72, at 111–12 (2004); *supra* Section I.B.

inflated prices for out-of-date building codes and standards.[173] And the value of the mandatory, IP-protected work often seems incommensurate with the power the IP holder wields: SmithKline Beecham using drug label text to keep generics off the market,[174] and Celgene's database patent of questionable inventiveness having similar anticompetitive effect.[175] The disproportionality between IP and power indeed transcends economics at times, as when copyright hands a legal publisher the reins of justice and the democratic process.[176]

On the flip side, the case studies reveal often-intense desires among creators and firms to become the holders of mandatory patents or copyrights. IP holders like the American Medical Association will lobby intensely and exploit political connections in order to secure regulatory mandates on their holdings.[177] Indeed, IP holders have engaged in extreme—even criminal—behavior to secure mandates on their holdings.[178]

A publicly harmful yet privately tantalizing phenomenon would seem a straightforward target for lawmakers to fix, and yet the case studies show mandatory infringement to be anything but easy to resolve. Courts deciding copyright cases on mandatory texts reach results in all directions.[179] The dueling judicial opinions on legal text copyrights and drug-label patent infringement reveal similar uncertainty.[180] Nor does the commentary reach consensus. In environmental law, for example, some scholars have described the possibility of a mandate to

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173. *See* Strauss, *supra* note 132, at 509–10; *cf.* Emily S. Bremer, *On the Cost of Private Standards in Public Law*, 63 KAN. L. REV. 279, 326–27 (2015) (noting substantial cost of mandatory standard, but arguing that free access may diminish overall access to safety standards). Bremer's study is discussed *infra* text accompanying notes 422–426.

174. *See* SmithKline Beecham Consumer Healthcare, LP v. Watson Pharm., Inc., 211 F.3d 21, 24 (2d Cir. 2000); *supra* text accompanying notes 116–119.

175. *See supra* note 85 and accompanying text.

176. *See supra* Section I.G.

177. *See supra* note 142 (discussing Practice Mgmt. Info. Corp. v. Am. Med. Ass'n, 121 F.3d 516, 521 (9th Cir. 1997)); *see also supra* notes 107–110 and accompanying text (discussing close relationship of IP holder and regulatory agency).

178. *See supra* text accompanying notes 47–50 (criminal fraud in product hopping).

179. *Compare SmithKline*, 211 F.3d at 24, *with* Syngenta Crop Prot., LLC v. Willowood, LLC, 944 F.3d 1344, 1357 (Fed. Cir. 2019).

180. *Compare* Am. Soc'y for Testing & Materials v. Pub.Res.Org, Inc., No. 1:13-cv-1215, slip op. at 33–39 (D.D.C. Feb. 2, 2017), *vacated*, 896 F.3d 437 (D.C. Cir. 2018), *and* GlaxoSmithKline LLC v. Teva Pharm. USA, 7 F.4th 1320, 1327 (Fed. Cir. 2021) (per curiam) (petition for certiorari filed July 11, 2022), *with ASTM*, 896 F.3d at 448–54, *and GlaxoSmithKline*, 7 F.4th at 1342–43 (Prost, J., dissenting).

use patented technology as a "doomsday scenario," while others envision it as a "catalyst for innovation."[181]

What gives the case studies of mandatory infringement these common themes of public harm, private attractiveness, and decisional uncertainty? It may be tempting simply to lay blame on particular bad actors, but the case studies do not support this idea: Mandatory infringement seems harmful even where there are no illegal acts.[182] A more general explanation of these themes, beyond particular cases or actors, seems warranted.

To explain these themes of public harm, private temptation, and decisional uncertainty, it is necessary first to understand the mechanics of mandatory infringement—what it does to markets and incentives. It is to that question that I now turn.

II. A Theory of Harm

The harmfulness, attractiveness, and undecidability observed in mandatory infringement are best explained as consequences of the regulation–IP overlap's mechanics. While there is nothing inherently incompatible between regulation

181. *Compare* Gollin, *supra* note 16, at 219 n.128, Paul Gormley, Comment, *Compulsory Patent Licenses and Environmental Protection*, 7 Tul. Envtl. L.J. 131, 143–45 (1993) (describing IP holders' incentives to withhold access to environmental technologies), *and* Adam Gunderson, *Protecting the Environment by Addressing Market Failure in Intellectual Property Law: Why Compulsory Licensing of Green Technologies Might Make Sense in the United States Institutional Religious Exemptions: A Balancing Approach*, 2014 BYU L. Rev. 671, 672 (expressing concern about "patent suppression" of desirable environmental technologies), *with* Ofer Tur-Sinai, *Patents and Climate Change: A Skeptic's View*, 48 Envtl. L. 211, 258 (2018), Derzko, *supra* note 20, at 21 (arguing that mandate to use patented technology can make it "advantageous to develop a new environmental technology"), *and* Magat, *supra* note 20, at 18 (predicting that mandatory technology standards will generally discourage innovation except insofar as the mandate "creates a widely-expanded market for [a] firm's innovation"). Curiously, these positions do not correlate with the authors' views on patents generally: Those finding mandatory infringement potentially desirable are skeptical of patents to varying degrees, and the critics are generally favorable to patents. *See, e.g.*, Tur-Sinai, *supra*, at 214–15; Derzko, *supra* note 20, at 41 (noting how patents can interfere with environmental technology diffusion); Gollin, *supra* note 16, at 212; Gunderson, *supra*, at 676.

182. None of the product labeling cases, for example, appeared to involve illegal activity. *See supra* Section I.E.

and IP rights,[183] and indeed IP law itself is in a sense a regulatory system,[184] mandatory infringement is distinctly problematic in four ways that other overlapping regulations typically are not.

The first and most important is its tendency to produce durable market power that shuts down competition even beyond what might be expected of IP rights. That power arises out of a unique interaction between IP and regulation that does not afflict other overlaps of legal regimes: IP exclusivity shuts off the safety valve that regulation leaves open for competition, and vice versa. The remaining three problems flow, to an extent, from this anticompetitive consequence: buck passing between courts and agencies, incentives toward rent-seeking behavior, and government offloading of IP acquisition costs to regulated entities.

A. Market Power

To see how IP rights and regulation interact when mandatory infringement occurs, consider the space of competition as shown in Figure 1. In the absence of regulation or IP (top left), a free market permits for competition across the entire space, such that consumers may enjoy diverse choice among products or services that meet their needs.[185] The space is not infinite, but rather is bounded by a market definition of "commodities reasonably interchangeable by consumers for the same purposes."[186]

IP rights demarcate a region of the competitive space and give the IP holder a temporary exclusivity there (Figure 1, bottom left).[187] Patents contain textual claims that specify their boundaries and exclude others from acting within those

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183. Indeed, then-Professor Stephen Breyer viewed the two as reinforcing each other, as both regulation and IP encourage dissemination of information. *See* Stephen Breyer, Regulation and Its Reform 27 (1982).

184. *Cf.* Stuart Minor Benjamin & Arti K. Rai, *Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law*, 95 Geo. L.J. 269, 273–74 (2006) (proposing treatment of patent law akin to other regulatory regimes).

185. Economists have used "spatial competition" models in other contexts. *See, e.g.,* Harold Hotelling, *Stability in Competition*, 39 Econ. J. 41, 45 (1929); Christopher S. Yoo, *Copyright and Product Differentiation*, 79 N.Y.U. L. Rev. 212, 241–46 (2004) (citing sources).

186. United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 395 (1956); United States v. Microsoft Corp., 253 F.3d 34, 51–52 (D.C. Cir. 2001) (en banc) (per curiam). *See generally* 2 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 533 (4th ed. 2020).

187. *See* 17 U.S.C. § 106 ("[T]he owner of copyright under this title has the exclusive rights . . . ."); 35 U.S.C. § 271(a) ("Whoever without authority makes, uses, offers to sell, or sells any patented invention . . . infringes the patent."); Mark A. Lemley, *Economics of Improvement in Intellectual Property Law*, 75 Tex. L. Rev. 989, 1004 fig.1 (1997).

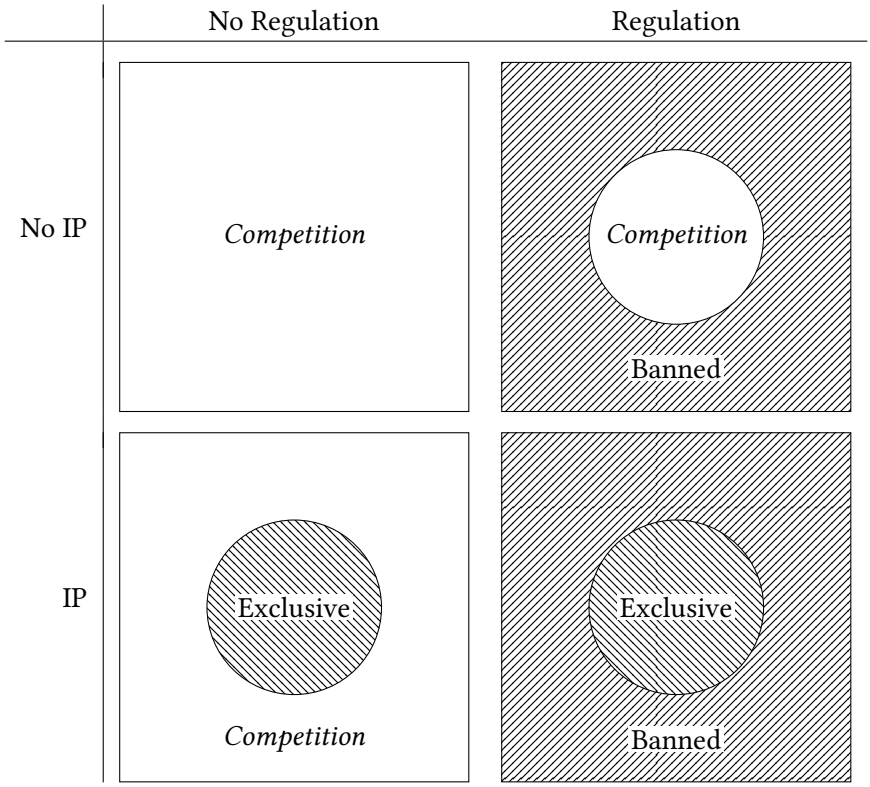

Figure 1: Depiction of competition in markets with regulation, intellectual property, and both. Shaded areas represent portions of the market that are rendered uncompetitive by IP exclusivity and/or regulation depending on the quadrant, and unshaded areas indicate the product space where competition is permitted.

boundaries.[188] Copyright protection does not define a boundary explicitly, but excludes exact copies as well as derivative works that are often determined by a test of substantial similarity.[189] IP rights thus exclude competitors from perfect or close substitutes to the protected work or technology, but permit imperfect substitutes in the form of noninfringing products or services.

Imperfect-substitute competition is the foundation of the celebrated tenet that IP rights are not inherent economic monopolies.[190] "Although the intellectual property right confers the power to exclude with respect to the specific product, process, or work in question," the DOJ has reasoned, "there will often be sufficient actual or potential close substitutes for such product, process, or work to prevent the exercise of market power."[191] Similarly, Congress amended the patent laws in 1988 to reject a presumption of market power in patent cases,[192] on the grounds that the presumption "prevents courts from considering whether there are substitute products for a patented product."[193] These views led the Supreme Court in *Illinois Tool Works Inc. v. Independent Ink, Inc.* to hold that "Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not necessarily confer market power upon the patentee."[194] Imperfect-substitute competition effectively acts as a safety valve, ensuring that IP rights do not presumptively create market power.

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188. *See* 35 U.S.C. § 112(b); 35 U.S.C. § 271(a)–(c).

189. *See* 17 U.S.C. § 106(1), (3); Walker v. Time Life Films, Inc., 784 F.2d 44, 48 (2d Cir. 1986). *See generally* Jeanne C. Fromer, *Claiming Intellectual Property*, 76 U. Chi. L. Rev. 719, 731–52 (2009).

190. *See, e.g.*, Edmund W. Kitch, *Elementary and Persistent Errors in the Economic Analysis of Intellectual Property*, 53 Vand. L. Rev. 1727, 1730–38 (2000); Mark A. Lemley, *Economics of Improvement in Intellectual Property Law*, 75 Tex. L. Rev. 989, 996 n.26 (1997); Yoo, *supra* note 185, at 220; 3 Areeda & Hovenkamp, *supra* note 186, ¶ 704a. *But see* Ariel Katz, *Making Sense of Nonsense: Intellectual Property, Antitrust, and Market Power*, 49 Ariz. L. Rev. 837, 891–903 (2007) (finding a presumption of market power from an IP right justified in some situations).

191. Antitrust Guidelines for the Licensing of Intellectual Property 4 (U.S. Dep't of Justice & Fed. Trade Comm'n 2017), https://www.justice.gov/atr/IPguidelines/download (citing Ill. Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28, 45–46 (2006)).

192. *See* Act of Nov. 19, 1988, Pub. L. No. 100-703, sec. 201, 102 Stat. 4674, 4676 (codified at 35 U.S.C. § 271(d)(5)).

193. The Intellectual Property Antitrust Protection Act of 1988, S. Rep. No. 100-492, at 12 (Aug. 25, 1988).

194. 547 U.S. at 45; *see also* Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136, 162 (2013) (Roberts, C.J., dissenting) (finding antitrust relevant only when patentee's "actions go beyond the monopoly powers conferred by the patent").

Regulation also carves a region within this competitive space, but it excludes conduct *outside* (Figure 1, top right).[195] Hatch–Waxman forces all generic drugs to share common labeling,[196] for example, and the FCC's adoption of the ATSC standard precludes television manufacturers from choosing competing broadcast protocols.[197] Activities permitted under a regulation will generally be similar in some aspects, placing them close together in the competitive space.[198]

Despite constraining the competitive space, the expectation is that regulatory mandates still leave open a safety valve for competition and do not inherently produce monopolies.[199] The FDA repeatedly accounted for concerns about generic competition in implementing the albuterol ban,[200] and the FCC specifically concluded that mandating a digital television standard "will encourage technological innovation and competition."[201] Agencies are likely attuned to the competitive consequences of their actions because of a long line of economic criticism that firms can capture agencies in order to exclude competition, which has led to close scrutiny and oversight.[202] And where administrative agencies know that their ac-

195. *See* 2 Areeda & Hovenkamp, *supra* note 186, ¶ 572b ("To the extent that regulation limits substitution, it may define the extent of the market."). To be sure, excluded conduct also has an outer bound defined by the regulator's jurisdiction. The assumption here, which will be true for most administrative agencies, is that the jurisdictional scope of a regulation is at least as wide as the relevant market definition, such that the exclusionary zone reaches the edges of the competitive space. *See supra* note 186.

196. *See supra* Section I.E.

197. *See supra* Section I.D.

198. An contrary example is FDA regulatory exclusivity, which excludes approval of similar drugs or biologics for a period of time and thus permits only dissimilar products. *See* Yaniv Heled, *Patents v. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both*, 18 Mich. Telecomm. & Tech. L. Rev. 419, 427–30 (2012). That makes regulatory exclusivities more like IP in this model, and unsurprisingly commentators have described these exclusivities as quasi–IP rights. *See id.* at 424; Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 Mich. Telecomm. & Tech. L. Rev. 345, 359 (2007) (describing exclusivities as "pseudo-patents").

199. *See* 2 Areeda & Hovenkamp, *supra* note 186, ¶ 572b ("In general, the ongoing cost of regulatory compliance is not an entry barrier when equally applicable to old and new firms.").

200. *See infra* note 250.

201. ATSC 1996, *supra* note 105, para. 39, at 17789.

202. *See* George J. Stigler, *The Theory of Economic Regulation*, 2 Bell J. Econ. & Mgmt. Sci. 3, 5 (1971) ("We propose the general hypothesis: every industry or occupation that has enough political power to utilize the state will seek to control entry."); 2 Alfred E. Kahn, The Economics of Regulation: Principles and Institutions 1 (1971) ("[T]he decision to regulate is, typically, a decision also to restrict competition . . . ."); Jean-Jacques Laffont & Jean Tirole, A Theory of Incentives in Procurement and Regulation 550 (1993) ("A regulated firm is adversely

tions will produce monopolies, they often turn to tools of economic regulation such as rate regulation and franchise bidding, to temper the deadweight losses of monopoly control.[203] Social-regulation agencies like the FDA and the EPA do not have these economic regulation tools,[204] suggesting that Congress did not envision them eliminating competition through their activities. Regulation preserves competition in a market but limits that competition to close, sometimes perfect substitutes.

Neither regulatory mandates nor IP rights alone fully stymie competition, but when the two of them intersect (Figure 1, bottom right), something unexpected happens. When the IP right is at least coextensive with that of the regulation, the two swallow up the entire competitive space. Put another way, the IP right closes off the safety valve that the regulation leaves for competition, and the regulation closes off the safety valve that the IP right leaves for competition. The IP holder can thus realize monopoly profits either by excluding competitors or licensing as a gatekeeper to the market.

Other overlaps of exclusionary regimes do not have the same effect, as Figure 2 shows. IP rights alone would need to be numerous to stamp out an entire space of competition, insofar as competitors can practice in parts of the market outside the scope of all IP rights (left figure).[205] Two regulations could overlap to exclude an entire market—one requires what the other prohibits—but chances are, an agency or court would be alerted to the conflict and fix it.[206] So long as overlapping regulations do not create an impossibility, they may constrain competition to closer and closer substitutes but will not preclude it entirely (right figure).[207] It

affected by entry and therefore has an incentive to induce the agency to prevent new firms from entering the industry."); BREYER, *supra* note 183, at 115 ("The added cost of compliance with a standard automatically raises barriers to entering the industry."); W. KIP VISCUSI ET AL., ECONOMICS OF REGULATION AND ANTITRUST 48–50 (4th ed. 2005).

203. *See* VISCUSI ET AL., *supra* note 202, at 358–62.

204. *See, e.g., Antitrust Concerns and the FDA Approval Process*, *supra* note 87, at 8 (testimony of Scott Gottlieb, the FDA) ("FDA doesn't oversee any aspect of drug pricing as part of our regulatory mandate . . . ."). On the difference between economic and social regulation, see generally VISCUSI ET AL., *supra* note 202, at 5–8.

205. *See* Erik Hovenkamp & Herbert Hovenkamp, *Buying Monopoly: Antitrust Limits on Damages for Externally Acquired Patents*, 25 TEX. INTELL. PROP. L.J. 39, 51–56 (2017) (considering difficulties in distinguishing procompetitive and anticompetitive patent aggregation).

206. *Cf.* Nat'l Ass'n of Home Builders v. Defs. of Wildlife, 551 U.S. 644, 666 (2007) ("We must therefore read [a regulation-authorizing statute] against the statutory backdrop of the many mandatory agency directives whose operation it would implicitly abrogate or repeal . . . .").

207. For example, *Pom Wonderful LLC v. Coca-Cola Co.* considered the overlap between the FFCDA and the Lanham Act. *See* 573 U.S. 102, 106 (2014). Though the latter law is part of an IP statute

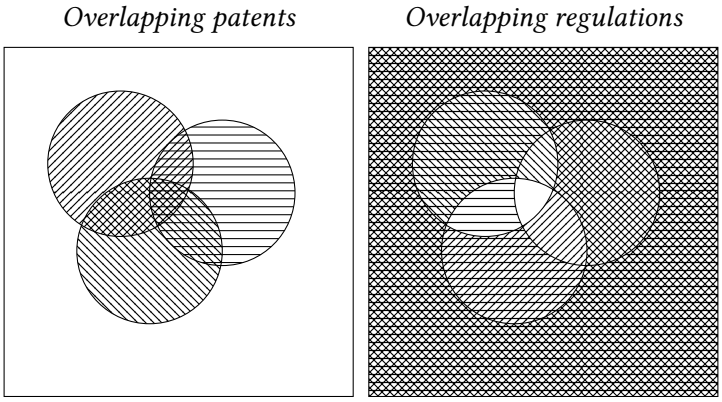

Figure 2: Competition in markets with overlapping patents or regulations. Shaded areas represent portions of the market that are rendered uncompetitive by IP exclusivity and/or regulation, and unshaded areas indicate the product space where competition is permitted.

is the inverse relationship between IP and regulation that makes that combination an especially potent threat to competition.

Importantly, the IP-protected work is never coextensive with the captured market. In some cases, it is just one product that would have faced substitutes absent regulation—HFA-134a inhalers, for example, or ATSC-compliant televisions. In others, the relevant market is wholly unrelated to the IP. Celgene's REMS patent monopolized the market for thalidomide, not the market for patient tracking databases; SmithKline's copyrights on labels and marketing materials were similarly not the relevant market to Nicorette gum consumers. Melville and David Nimmer's copyright treatise characterizes a subset of mandatory infringement cases as ones where "the purpose of a copyright suit is to hinder a rival from lawful, non-copyright competition."[208] They optimistically predict that "there is

(on trademarks), the provision at issue was not IP protection but a prohibition on misleading advertising, so like a regulation it cut off competition outside a sphere of truthful advertising. *See id.* at 107. The Court held that both regulations could be enforced because the two regulations "complement each other" by each precluding different ranges of conduct, and there was no evidence that "there will be any difficulty in fully enforcing each statute according to its terms." *Id.* at 117–18.

208. Nimmer, *supra* note 158, § 1.19[A][2].

scant reason to be hospitable to the claim" of IP infringement[209]—whether their assessment is correct is the subject of Section III.

B. Buck Passing

When market power from mandatory infringement arises, it is hard to pin down responsibility at both institutional and doctrinal levels. An agency, even when aware that its regulations will require use of IP rights, can press forward with those regulations on the argument that IP protection and scope questions are not agency matters.[210] Yet when courts are asked to account for mandatory regulations in assessing IP cases, they often assume that the agency will resolve mandatory infringement market power in the rulemaking process.[211] Regulatory law passes responsibility to IP law for the harms of mandatory infringement and vice versa; the agency passes the buck to courts to resolve the harms and vice versa.

The district court proceedings in *SmithKline* are perhaps the starkest reflection of this buck-passing problem. After the FDA ordered the generic entrant to use a label virtually identical to SmithKline's, the district court took unusually held a conference with the FDA (which was not a party to the litigation) to persuade the agency to "revisit" its decision and accommodate copyright concerns.[212] The FDA refused, saying that it "had never been directed by Congress to consider potential copyright rights in approving generic drug labeling."[213] By contrast, the court thought that the FDA "surely has a duty to address the apparent conflict" between copyright and Hatch–Waxman, and indeed was "tempted" to order the agency to do so if it had jurisdiction.[214] Simply put, the agency expected the court to solve

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209. *Id.*

210. *See, e.g.*, Incorporation by Reference, 79 Fed. Reg. 66267, 66273 (Office of the Fed. Register Nov. 7, 2014); Albuterol V, *supra* note 3, at 17178.

211. *See, e.g.*, Practice Mgmt. Info. Corp. v. Am. Med. Ass'n, 121 F.3d 516, 519 (9th Cir. 1997) (predicting that federal agency "would no doubt exercise its right to terminate its agreement" to use copyrighted medical coding system if copyright holder restricted public access); Syngenta Crop Prot., LLC v. Willowood, LLC, 944 F.3d 1344, 1357–58 (Fed. Cir. 2019) (anticipating that the EPA would interpret statutory requirement for "substantially similar" labeling to accommodate labeling rewritten to avoid copyright infringement, despite the EPA having rejected such rewrites).

212. *See* SmithKline Beecham Consumer Healthcare, LP v. Watson Pharm., Inc., 2000 Copyright L. Dec. (CCH) ¶ 28036, at 32149, 32152.

213. *Id.* (quoting FDA letter to court) (internal alternations omitted).

214. *Id.* at 32154 & n.3.

the problem by bending IP law, while the court expected the agency to solve it by bending regulations.

That the regulator and court confronted each other directly was unusual to *SmithKline*, and observing the FDA passing the buck perhaps forced the district court's hand not to pass it back: The court reversed its prior grant of a preliminary injunction, which the Second Circuit affirmed.[215] In the usual case where the agency and court do not confront each other, mandatory infringement conflict could easily go unresolved.

Buck passing explains, among other things, the absence of challenges under the Administrative Procedure Act ("APA") to agency actions mandating use of intellectual property. Ordinarily, a court may set aside any arbitrary or capricious agency action, which can include an action that has "entirely failed to consider an important aspect of the problem."[216] An agency's failure to deal with mandated IP infringement would seem to fit this test, and yet the only APA challenge I find to the agency actions in the case studies is a lawsuit over the FCC's adoption of digital television standards—a lawsuit that does not raise IP issues.[217] The FCC's approach to those standards highlights why an APA challenge might face difficulty: The agency deferred to patent law and practice for setting licensing costs, rather than making explicit cost–benefit findings that could have served as the basis for judicial review.[218] In other words, buck passing to IP law seemingly allows agencies to avoid evaluating the costs of mandatory IP licensing without fear of judicial scrutiny.[219]

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215. *See* 211 F.3d 21, 24 (2d Cir. 2000).

216. Motor Vehicle Mfrs. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); *see* 5 U.S.C. § 706(2)(A); Citizens to Pres. Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971) (noting need for agency to "consider[] the relevant factors"); Nat'l Audubon Soc'y v. Hoffman, 132 F.3d 7, 17–18 (2d Cir. 1997).

217. Consumer Elecs. Ass'n v. FCC, 347 F.3d 291, 302–04 (D.C. Cir. 2003) (focusing on costs of digital tuners); *see supra* text accompanying notes 104–110.

218. *See supra* note 106. To be sure, the FRAND licensing obligations that the FCC relied upon in its rulemakings are private contracts, not intrinsically part of patent law. *See* Microsoft Corp. v. Motorola, Inc., 795 F.3d 1024, 1052 (9th Cir. 2015) (though noting that such contracts involve public-interest considerations). Nevertheless, negotiations over FRAND royalties are conducted against a backdrop of patent case law. *See* Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 314 n.8 (3d Cir. 2007) (noting applicability of patent reasonable-royalty test to construction of FRAND obligation).

219. Buck passing also explains why "Mandatory Infringement" is the proper title of this Article. "Mandatory Licensing" would imply that regulators explicitly call for licensing or permission to use IP in the course of complying with regulations. However, the typical mandatory-

C. Rent Seeking

Mandatory infringement disrupts the traditional theory of IP incentives, shifting firms' incentives away from valuable innovation and toward rent seeking. Absent regulation, competition with noninfringing imperfect substitutes disciplines monopoly IP pricing, limiting it to the improvement encapsulated in the IP holder's products *vis á vis* the competition: "the greater the usefulness the greater the reward."[220] A marginal improvement to a drug, for example, would command no market share even when patented because patients could still opt for the unpatented, unimproved version.[221] Knowing this, an innovator would ordinarily not invest in marginal improvements that do not provide consumers with value.

But making use of IP mandatory increases the market value of the IP regardless of the inherent value of the innovation, because consumers are compelled to use and thus pay for IP licenses regardless of the technical merits.[222] In the context of *de facto* mandatory interoperability standards, this value-increase phenomenon

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infringement regulation only specifies the mandatory conduct and does not address licensing. In other words, the mandatory conduct is infringing, and not licensed, activity.

220. 2 John Stuart Mill, Principles of Political Economy 498 (1848), https://catalog.hathitrust.org/Record/001308505 (justifying preference for patents over government rewards); *see, e.g.,* Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 Yale L.J. 544, 327–28 (2019); Carrier & Shadowen, *supra* note 33, at 182 & nn.69–71; *cf.* Steven Shavell & Tanguy van Ypersele, *Rewards Versus Intellectual Property Rights*, 44 J.L. & Econ. 525, 529–30 (2001) (comparing monopoly IP pricing to government rewards).

221. *See* Walgreen Co. v. AstraZeneca Pharm. LP, 534 F. Supp. 2d 146, 151 (D.D.C. 2008) ("New products are not capable of affecting competitors' market share unless consumers prefer the new product . . . ") (discussing Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 287 (2d Cir. 1979)); Dennis W. Carlton et al., *Does the FTC's Theory of Product Hopping Promote Competition?*, 12 J. Competition L. & Econ. 495, 504 (2016); *cf.* Timothy J. Muris & Jonathan E. Nuechterlein, *Generic Drugs, Used Textbooks, and the Limits of Liability for Product Improvements*, 4 Criterion J. on Innovation 207 (2019) (noting that "a generic company *could* . . . market its own products" but observing complications).

222. *See, e.g.,* Apple, Inc. v. Motorola, Inc., 869 F. Supp. 2d 901, 913 (N.D. Ill. 2012) (Posner, J.) (distinguishing "value conferred by the patent itself as distinct from the additional value—the hold-up value—conferred by the patent's being designated as standard-essential"); Joseph Farrell, *Standard Setting, Patents, and Hold-Up*, 74 Antitrust L.J. 603, 607 (2007) (describing "fundamental transformation" of standardized IP's value) (quoting Oliver Williamson, The Economic Institutions of Capitalism: Firms, Markets, Relational Contracting 61–63 (1985)); Mark A. Lemley & Carl Shapiro, *A Simple Approach to Setting Reasonable Royalties for Standard-Essential Patents*, 28 Berkeley Tech. L.J. 1135, 1139–40 (2013) (distinguishing "ex ante value of the patented technology" from "ex post value resulting from the standardization itself") (citing Carl Shapiro & Hal R. Varian, Information Rules: A Strategic Guide to the Network Economy 241 (1999)); Lerner & Tirole, *supra* note 94, at 548.

is often called "hold-up" and is well-known.[223] But *de jure* mandates exacerbate the distortion. Unlike legal mandates, *de facto* standards are still subject to market forces that may or may not select them.[224] Market forces give private standard-setting organizations incentives to select technologies and IP to standardize based on costs and quality; the government lacks such incentives.[225] And in many cases, the regulatory scheme associated with mandatory infringement also mandates the creation of the work in the first place—the FDA requiring drug companies to produce label texts and REMS systems—such that IP incentives may be unnecessary for the production of mandatory works.[226]

The IP value increase resulting from a mandate triggers several changes to innovators' behavior. Firms are more likely "to invest in persuading governments to mandate use of their standards" rather than in higher-quality innovation itself.[227] Thus, Reckitt Benckiser lobbied heavily for states to mandate use of its buprenorphine sublingual film, despite that product being potentially worse than the tablet formulation.[228] Furthermore, the promise of inflated royalties diminishes mandatory IP creators' incentives to invest in high-quality innovation, since even a valueless innovation will reap profits. As Bernard Chao explains in the context of *de facto* compatibility standards, detaching IP value from technical merit can encourage "horizontal innovations" that offer no consumer benefit, such as incompatible razor blade cartridge connectors or different-shaped computer connectors.[229]

In particular, mandatory infringement can encourage overinvestment in research and development in low-value improvements: The value of the mandate can make million-dollar investments worthwhile even if the resulting improvement offers little or no public welfare benefit. In the case of albuterol inhalers, for example, 3M and other pharmaceutical companies claimed that their research and

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223. *See* references cited *supra* note 222 (patents); Google LLC v. Oracle Am., Inc., 141 S. Ct. 1183, 1208 (2021) (describing how copyright on popular programming language command set can be "a lock limiting the future creativity of new programs"); Duan, *supra* note 91.

224. *See* Shapiro & Varian, *supra* note 222, at 261–96 (describing "standards wars").

225. *See infra* Section II.D.

226. *See Antitrust Concerns and the FDA Approval Process*, *supra* note 87, at 34 (testimony of Prof. David Olson) ("[T]here is no additional incentive that is given by granting REMS patents that is needed, because there is already an incentive to create the REMS in ETASU systems . . . .").

227. *See* Samuelson, *supra* note 19, at 223.

228. *See supra* Section I.A.

229. Bernard Chao, *Horizontal Innovation and Interface Patents*, 2016 Wis. L. Rev. 287, 295–307.

development costs were "between $250 and $400 million per firm,"[230] even though experts estimated that the environmental benefit was so small that, by one expert's estimate, any environmental damage from not enforcing the CFC ban would be repaired in "roughly another week.[231] And consider SmithKline Beecham's "more than one million dollars" spent on developing mandatory Nicorette labeling.[232] And the development of copyrighted safety standards in which one commentator observes that "there has been over-production in quantity and under-production in quality."[233] In all of these cases, it is unlikely that the IP-protected improvements greatly influenced consumer demand—patients do not seek out Nicorette for its mellifluous label text—suggesting that the costs of developing those improvements are driven by the potential value of a mandate and not the inherent market value of the improvements.

Even when firms continue to innovate, the distortive effect of mandatory infringement can lead to seemingly bizarre commercialization decisions. Peter L. Strauss identified "market distortion and monopoly pricing" in the cost of the American Herbal Products Association ("AHPA") reference text *Herbs of Commerce*: In 2013, a largely improved 2000 edition sold for under $100, while an outdated 1992 edition sold for $250 by virtue of being mandatorily incorporated by the FDA.[234] But why did AHPA not push the FDA to update its regulations? It would seem that an updated, "must-have edition"[235] would command an even higher price if incorporated by reference, giving AHPA an incentive to lobby the FDA. Yet mandatory infringement makes the work's economic value irrelevant: If demand for *Herbs of Commerce* is largely driven by regulatory compliance, then that demand (and the price AHPA could charge) is independent of the work's quality, so AHPA arguably has no incentive to push adoption of its newer edition. The problem of outdated standards in regulations, which many have attributed to

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230. Use of Ozone-Depleting Substances, 69 Fed. Reg. 33602, 33615 (Food & Drug Admin. June 16, 2004) [hereinafter Albuterol IV].

231. Swenson, *supra* note 44, at 1867; *see also* Albuterol IV, *supra* note 230, at 33614 ("We believe that the direct benefits of this proposed regulation are small relative to the overall benefits of the Montreal Protocol.") (citing United Nations data).

232. *See* SmithKline Beecham Consumer Healthcare, LP v. Watson Pharm., Inc., 211 F.3d 21, 24 (2d Cir. 2000); *supra* Section I.E.

233. Cunningham, *supra* note 135, at 311 & n.98.

234. *See* Strauss, *supra* note 132, at 509–10.

235. *See id.* at 510 (quoting AHPA's online bookstore).

rulemaking process inefficiencies,[236] may in part also be an effect of mandatory infringement distorting incentives to commercialize innovation.

The incentive distortions resulting from this rent-seeking phenomenon are surprisingly pernicious. For example, it is commonly argued that an author's copyright protection in a novel or treatise should not be affected if the work is placed on a public school's required reading list.[237] It may seem difficult to imagine copyright incentives being distorted in this situation. And yet for one class of school-required reading, this distortion is apparent. School textbook publishers frequently issue new editions with often nominal changes, forcing students to buy new, high-priced copies rather than cheaper used ones.[238] Even the seemingly innocuous mandate of a school reading list can lead to distortions of the incentive structures that underlie intellectual property theory.

D. Cost Offloading

Besides distorting incentives for innovators, mandatory infringement distorts incentives for the government by allowing regulators to offload the costs of IP acquisition onto regulated entities. Absent regulation, IP theory generally holds that users of IP-protected works derive value from the quality of the works, and IP protection enables the author or inventor to recapture at least a portion of that

236. *See, e.g.*, Office of the Fed. Register ("OFR"); Adoption of Recommendations, 77 Fed. Reg. 2257, 2258 (Admin. Conference of the U.S. Jan. 17, 2012); Bremer, *Incorporation*, *supra* note 134, at 183–90.

237. *See* Brief of Amici Curiae American Society for Testing and Materials et al. at 24, Georgia v. Pub.Res.Org, Inc., 140 S. Ct. 1498 (Aug. 30, 2019) (No. 18-1150) ("[N]obody suggests that song lyrics quoted in a judicial opinion or a book designated as required reading in a school district suddenly become 'government edicts' [that] lose their private authorship"); Email from John Noble, *Veeck vs. SBCCI (US 5th Circuit Ct Appeals)* (Feb. 19, 2001), https://www3.wcl.american.edu/cni/0102/27972.html ("What if Nimmer on Copyright is the required text for a copyright course. . . . Is that reason enough to deny copyright protection to Nimmer on Copyright?").

238. *See* Kaitlyn Vitez, Student PIRGs, Open 101: An Action Plan for Affordable Textbooks 7 (2018), https://www.studentpirgs.org/textbooks.

value from those users.[239] IP law thus effects a Coasean allocation of property rights that enables bargaining between creators and users of works.[240]

Yet where regulation mandates use of IP, there are two more players in the value equation: the public and the government itself, both of which take a share of the IP's value. Consider, for example, the Unocal gasoline patents.[241] Without regulation, competing refineries would have licensed Unocal's patented gasoline technology only if it would increase their profits by more than the license cost. California's mandate changes that equation in two ways: The public enjoys some value from Unocal's technology in the form of cleaner air; and California extracts some value from the patent, as its regulators need not expend effort on researching emissions standards. Nevertheless, neither the public nor the government pays the IP holder for that value—the entire cost is borne by competing refineries in the form of infringement liability.

The public's share could be justified as redistributive policy,[242] though sometimes puzzlingly—why should albuterol-using patients bear the cost of the cost of a cleaner environment, intermediated by pharmaceutical industry profits?[243] But the government's unpaid share is the troubling one. It is odd enough that that the government obtains the benefits of valuable IP rights on someone else's dime. But offloading IP liability onto regulated entities also creates a principal–agent problem: The government lacks incentives to evaluate the costs and benefits of mandatory IP since it does not bear the costs.[244] In *Practice Management*, for example, a

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239. *See, e.g.*, Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* The Rate and Direction of Inventive Activity: Economic and Social Factors 609, 619 (Nat'l Bureau of Econ. Research ed., 1962); Heidi L. Williams, *Intellectual Property Rights and Innovation: Evidence from Health Care Markets*, *in* 16 Innovation Policy and the Economy 53, 54 (Josh Lerner & Scott Stern, Nat'l Bureau of Econ. Research eds., 2016); *cf.* Ted Sichelman, *Commercializing Patents*, 62 Stan. L. Rev. 341, 358–62 (2010) (discussing but critiquing this "reward" theory of IP).

240. *See, e.g.*, Robert P. Merges, *Of Property Rules, Coase, and Intellectual Property*, 94 Colum. L. Rev. 2655, 2657 (1994).

241. *See generally supra* Section I.B.

242. *See* Theodore J. Lowi, *Four Systems of Policy, Politics, and Choice*, 32 Pub. Admin. Rev. 298, 300 tbl.1 (1972).

243. *See infra* notes 262–265 and accompanying text; *cf.* Louis Kaplow & Steven Shavell, *Why the Legal System Is Less Efficient than the Income Tax in Redistributing Income*, 23 J. Legal Stud. 667, 669 (1994) (favoring tax system over legal rules to achieve redistribution). Further research on the redistributive nature of mandatory infringement may be worthwhile.

244. This is related to the economic theory that regulators have incentives to collude with industry in reporting what regulations are necessary. *See* Jean Tirole, *Hierarchies and Bureaucracies: On the Role of Collusion in Organizations*, 2 J.L. Econ. & Org. 181, 184–87 (1986).

health care regulator made massive concessions to the American Medical Association, agreeing to use its copyrighted medical coding system to the exclusion of all others, to advertise the AMA's copyright, and to "use its regulatory powers as a federal agency to require the use" of the system—all of which impose little cost on the agency but tremendous costs on physicians and patients.[245] An agency that incorporates a copyrighted model code into law similarly pays nothing for the privilege, but lawyers and regulated entities who must comply with the law pay instead.[246] As with other principal–agent problems, the disconnect between regulatory benefits and IP licensing costs can lead regulators to give insufficient attention to cost or value—a problem that mandatory infringement market power only exacerbates.

III. Contemporary Approaches

A. Agencies: Ex Ante *Action*

Ideally, agencies or lawmakers would resolve mandatory infringement problems when drawing up regulations. Besides the general benefits of early action, regulators have more options for avoiding mandatory infringement: choosing IP-agnostic performance standards, negotiating for licensing concessions, and mandating fair IP licensing. Some agencies such as the EPA have statutory authorization to compulsorily license patent rights,[247] and ancillary authority as a general matter might enable any agency to regulate patents affecting its domain.[248]

Yet the nature of mandatory infringement leads agencies to fail to address it even knowing of the relevant IP rights and their statutory authority. This is illustrated well in the albuterol inhaler regulation, so that situation is used as a case study here.[249]

Buck passing. — The presence of overlapping patents enabled the FDA to sidestep concerns about destruction of the generic albuterol industry by blaming the patent laws and Hatch–Waxman. The FDA was not deaf to concerns about

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245. Practice Mgmt. Info. Corp. v. Am. Med. Ass'n, 877 F. Supp. 1386, 1388–89 (C.D. Cal. 1994), *rev'd sub nom.* Practice Mgmt. Info. Corp. v. Am. Med. Ass'n, 121 F.3d 516 (9th Cir. 1997).

246. The dissent in *Veeck* shows how easy this problem is to overlook, positing that incorporating a private building code into law comes at "no expense" to taxpayers. 293 F.3d 791, 817 (5th Cir. 2002) (Wiener, J., dissenting).

247. *See* Clean Air Act (CAA) § 308, 42 U.S.C. § 7608; 40 C.F.R. § 95.3.

248. *See* Narechania, *supra* note 17, at 1488–89.

249. The OFR's rulemaking on incorporation by reference is a second useful case study on these three phenomena, so I discuss it in the footnotes.

competition,[250] but nevertheless asserted that it was "bound by existing patent and exclusivity laws with regard to the approval of generic versions of innovator products."[251] Generic availability was controlled not by the FDA, but "by U.S. patent laws" and other external forces.[252] Instead, the agency characterized its sole duty as implementing clean air laws that "mandate the phaseout of non-essential uses of CFC's" regardless of how "the phaseout . . . may affect the availability of generic products."[253] Because of that duty, the FDA refused even to conduct a cost-benefit study despite calls to do so.[254]

Importantly, the FDA did not argue that it lacked *authority* to avoid mandating a patented technology; it could have delayed its regulation until a generic HFA inhaler was available.[255] The agency's appeals to its statutory duties and its lack of patent capacity are better understood as directing critics of the ban to the patent laws, not regulatory power.[256]

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250. *See, e.g.*, Albuterol II, *supra* note 42, at 47724 (committing to "consider the cost of alternative products" in view of public comments); *Regulatory Efforts to Phaseout Chlorofluorocarbon-Based Metered Dose Inhalers*, *supra* note 43, at 49 (statement of Jenkins) ("Many of the comments . . . have centered on the issue of generic competition for non-CFC products. The agency acknowledges these concerns . . . ."); Albuterol V, *supra* note 3, at 17187–91 (criticizing industry-funded economic analysis). Indeed, the agency took several steps to address these concerns. It waited until there were two approved CFC-free inhalers that "should provide downward pressure on prices," though recognizing that any price reduction from competition "may be small until generic albuterol MDIs are reintroduced into the market."Albuterol V, *supra* note 3, at 17176, 17188. And it pressured HFA-134a inhaler manufacturers into concessions on pricing and free giveaways. *See* Albuterol IV, *supra* note 230, at 33616; Albuterol V, *supra* note 3, at 17174–75.

251. *Regulatory Efforts to Phaseout Chlorofluorocarbon-Based Metered Dose Inhalers*, *supra* note 43, at 49.

252. Albuterol II, *supra* note 42, at 47733; *accord* Use of Ozone-Depleting Substances, 67 Fed. Reg. 48370, 48380 (Food & Drug Admin. July 24, 2002) [hereinafter Albuterol III] (same); *see also* Albuterol V, *supra* note 3, at 17178 ("[W]e do not have the institutional expertise to evaluate patents").

253. Albuterol II, *supra* note 42, at 47736; *see* Albuterol V, *supra* note 3, at 17176.

254. Albuterol II, *supra* note 42, at 47733.

255. *Cf.* Albuterol III, *supra* note 252, at 48374 (requiring two approved products as prerequisite to dedesignation).

256. *See also* Letter from Janet Woodcock, Food & Drug Admin., to William Franzblau, Prometheus Labs., Inc., *Docket No. FDA-2013-P-0572* 6 (Oct. 7, 2013), https://downloads.regulations.gov/FDA-2013-P-0572-0003/attachment_1.pdf (instructing petitioner complaining of REMS abuse to "consult with the FTC"), *quoted in* Michael A. Carrier, *Sharing, Samples, and Generics: An Antitrust Framework*, 103 Cornell L. Rev. 1, 37 (2017) [hereinafter Carrier, *Sharing*]; Paradise, *supra* note 75, at 69. The OFR passed the buck on copyright issues as well. In declining to require public access to those legally mandatory texts, the OFR instead encouraged other agencies to "work with copyright holders" to "ensure that the public does have reasonable access to the

Rent seeking. — In justifying the increased costs of albuterol inhalers, the FDA cited claims by 3M and other pharmaceutical firms that the research and development costs of HFA-134a inhalers was "between $250 and $400 million per firm."[257] Because of those investments, the agency found that monopoly pricing on albuterol inhalers "not only reward the developers of the HFA technology, but would also serve as a signal to potential developers of other environmentally benign technologies."[258]

Yet the facts before the agency did not bear out either those investments or the level of reward. The environmental harms of generic albuterol inhalers were minimal: Additional ozone hole damage resulting from delaying the ban until the HFA-134a patents' expiration would have been repaired in, by one expert's estimate, "roughly another week."[259] It is difficult to square that minimal harm with a $400 million solution. The better explanation is that the investment was worthwhile because of the monopoly profits that the albuterol ban would produce—an estimated $850 million per year over twelve years of generic-free patent exclusivity.[260] The FDA's assumption of traditional patent incentives in a distorted mandatory-infringement market led the agency to credit 3M with orders of magnitude more innovative merit than it deserved.[261]

Cost offloading. — In banning generic albuterol, the FDA imposed tremendous costs on asthma patients. Immediately after the ban, average out-of-pocket costs for insured asthma patients rose $11, with some patients paying over $40 more according to a 2015 study.[262] That cost bump outpriced an estimated 5% of adults and 3% of children with insurance—to say nothing of uninsured patients.[263] And

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referenced documents." *See* Incorporation by Reference, 79 Fed. Reg. 66267, 66273 (Office of the Fed. Register Nov. 7, 2014).

257. Albuterol IV, *supra* note 230, at 33615.

258. *Id.* at 33614.

259. Swenson, *supra* note 44, at 1867; *see also* Albuterol IV, *supra* note 230, at 33614 ("We believe that the direct benefits of this proposed regulation are small relative to the overall benefits of the Montreal Protocol.") (citing United Nations data).

260. *See* Albuterol IV, *supra* note 230, at 33615.

261. In dismissing comments to make incorporated legal texts available to the public, the OFR argued that those comments "did not address costs associated with creating the standard or providing free access to it," implicitly appealing to the need for private copyright control to compensate for those costs. *See* 79 Fed. Reg. at 66273.

262. *See* Jena et al., *supra* note 5, at 1176 & fig.2.

263. *See id.* at 1176.

despite the FDA's predictions that competition would return as early as 2010,[264] HFA-134a generics did not enter until 2020, costing patients and insurance payers an estimated $1.2 billion a year largely to the benefit of patent-holding pharmaceutical companies.[265]

Yet consistent with the principal–agent dynamic of cost-offloading, the FDA gave little attention to these costs. Regarding insured asthma patients' premiums and copays, the agency argued that "[t]hese increased expenditures represent primarily transfers . . . to branded pharmaceutical manufacturers; they are, therefore, not net costs to society."[266] It thus solely focused on uninsured patients.[267] For them, the agency predicted that free samples, coupons, and other concessions by the patent holders would minimize the number of uninsured low-income patients who would go without medication, despite evidence that similar programs had minuscule effect.[268]

The buck-passing, rent-seeking, and cost-offloading problems all hinder agencies' ability to respond to mandatory infringement. Yet there is reason for hope: To the extent that agencies can recognize these distortive effects of mandatory infringement, they may better be able to respond to them and craft regulations that mitigate undesirable market power.

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264. *See* Albuterol IV, *supra* note 230, at 33610 (expecting generic entry on HFA-134a inhalers in 2010–2015); Albuterol V, *supra* note 3, at 17183 n.12 (pushing estimates out until 2017 due to new patents).

265. *See* Rebecca Voelker, *Generic Albuterol Inhaler Approved*, 323 J. Am. Med. Ass'n 1887 (2020); Albuterol V, *supra* note 3, at 17191; Albuterol IV, *supra* note 230, at 33615 (estimating $850 million a year in revenues for HFA-134a inhaler manufacturers due to generic ban).

266. Albuterol V, *supra* note 3, at 17187.

267. *See* Albuterol IV, *supra* note 230, at 33610 ("Our estimates of reductions in canisters are based primarily on a response among the uninsured . . . ."); Albuterol V, *supra* note 3, at 17188 (estimating "number of albuterol MDIs not sold" based on predictions about uninsured patients).

268. Albuterol V, *supra* note 3, at 17189. In the incorporation-by-reference rulemaking, the OFR received numerous comments that access to copyrighted standards was cost-prohibitive and inconvenient. *See* Incorporation by Reference, 79 Fed. Reg. 66267, 66272 (Office of the Fed. Register Nov. 7, 2014). Nevertheless, the agency refused to address those costs. *See id.* at 66273. Similarly, in 2000, the EPA proposed emissions standards for small handheld engine devices that, given current engine technology, would effectively have mandated John Deere's patented "compression wave technology." *See* Phase 2 Emission Standards for New Nonroad Spark-Ignition Handheld Engines At or Below 19 Kilowatts and Minor Amendments to Emission Requirements Applicable to Small Spark-Ignition Engines and Marine Spark-Ignition Engines, 65 Fed. Reg. 24267, 24276 (Envtl. Prot. Agency Apr. 25, 2000). The EPA agreed with competitors that John Deere's proposed licensing fees were too high, but nevertheless assumed that either John Deere would lower its rates or that other satisfactory technologies would emerge at some point in the future. *See id.* at 24277.

B. Courts: Competition Law

A second approach to dealing with mandatory infringement is to find impropriety in the IP holder's actions that lead to or exploit the government's mandate. Since mandatory infringement creates market power, the most obvious remedial doctrines would be the federal antitrust laws, FTC authority, and related unfair competition laws.[269] The patent and copyright misuse doctrines similarly prohibit anticompetitive use of IP rights.[270] These competition laws would seem relevant to mandatory infringement as a species of what leading commentators have called "predation by abuse of governmental procedures,"[271] "regulatory gaming,"[272] or "cheap exclusion."[273] And these laws have successfully resolved mandatory infringement cases.[274] In *Practice Management*, for example, the Ninth Circuit found copyright misuse where a federal agency's arrangement with the American Medical Association to mandate a copyrighted medical coding system "gave the AMA a substantial and unfair advantage over its competitors," and held that these "adverse effects" meant that "The AMA had used its copyright in a manner violative of the public policy embodied in the grant of a copyright."[275]

Yet the competition laws face challenges in dealing with mandatory infringement, challenges that are illuminated—and potentially resolved—by the framework of mandatory infringement phenomena.[276]

IP as antitrust exception. — Traditionally, IP has been treated as "an exception to the general rule against monopolies" under the competition laws.[277] In a sense, this traditional exception passes the buck from competition law to IP law. Nevertheless there are at least two reasons why the traditional exception is inapplicable to mandatory infringement. First, the exception depends on imperfect substitute

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269. *See generally* 2 Areeda & Hovenkamp, *supra* note 186, ¶¶ 300–302.

270. *See, e.g.*, C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1372 (Fed. Cir. 1998); Lasercomb Am., Inc. v. Reynolds, 911 F.2d 970, 976–77 (4th Cir. 1990).

271. Robert H. Bork, The Antitrust Paradox 159 (1978).

272. Dogan & Lemley, *supra* note 39, at 687.

273. Susan A. Creighton et al., *Cheap Exclusion*, 72 Antitrust L.J. 975, 990–92 (2005).

274. *See also Unocal II*, 140 F.T.C. 123 (2005); *In re* Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 684–85 (E.D. Pa. 2014).

275. 121 F.3d 516, 521 (9th Cir. 1997) (internal quotations omitted) (quoting 911 F.2d at 977).

276. *See supra* Section II.

277. Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965) (quoting Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945)); *see supra* note 190 (citing sources).

competition,[278] but regulation closes off that avenue of competition in mandatory infringement cases.[279] Second, courts justify the exception on the grounds that antitrust enforcement against IP rights might diminish incentives to innovate.[280] The rent-seeking distortion of mandatory infringement lessens this concern.[281]

Indeed, the competition-excluding nature of mandatory infringement arguably triggers the essential facilities doctrine of antitrust law, which can require a dominant firm to share a critical resource, including IP rights.[282] Courts and commentators have been skeptical of the doctrine as inconsistent with firms' general right of refusal to deal with rivals,[283] but have nevertheless suggested that antitrust law could require a monopolist to share, in some conditions, facilities that competitors cannot practically or reasonably duplicate.[284] Mandatory infringement could satisfy these conditions, since the IP right wholly excludes rivals despite the regulator's intent not to frustrate competition in the regulated market.[285] Courts faced with competition law claims would thus be well-advised at least to consider this doctrine in light of the unique features of mandatory infringement.

Antitrust and regulation. — Next, the challenger of mandatory infringement would have to overcome the possibility that the regulatory mandate itself weighs against competition law enforcement—buck passing to the regulator. In a number of cases, the Supreme Court has held that "a regulatory structure designed to deter and remedy anticompetitive harm" can make it "less plausible that the an-

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278. *See supra* text accompanying notes 190–194.

279. *See supra* Section II.A; *cf.* 2 Areeda & Hovenkamp, *supra* note 186, ¶ 518e ("[O]n some occasions a single patent or copyright *does* confer market power . . . .").

280. *See, e.g.*, Image Tech. Servs., Inc. v. Eastman Kodak Co., 125 F.3d 1195, 1218 (9th Cir. 1997) (worrying that cost of unilateral-conduct antitrust suits "will reduce a patent holder's incentive to risk the often enormous costs in terms of time, research, and development") (quoting Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974)) (internal quotations and alterations omitted).

281. *See supra* Section II.C.

282. *See* Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 599 (1985); *Image Tech. Servs.*, 125 F.3d at 1218 (quoting Data Gen. Corp. v. Grumman Sys. Support Corp., 36 F.3d 1147, 1187 (1st Cir. 1994)); 3 Areeda & Hovenkamp, *supra* note 186, ¶ 771a.

283. *See, e.g.*, Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 407–11 (2004).

284. MCI Commc'ns Corp. v. Am. Tel. & Tel. Co., 708 F.2d 1081, 1132–33 (7th Cir. 1983); 3 Areeda & Hovenkamp, *supra* note 186, ¶ 773a.

285. *See supra* Section II.A; *cf.* Nikolas Guggenberger, *The Essential Facilities Doctrine in the Digital Economy: Dispelling Persistent Myths*, 23 Yale J.L. & Tech. 301, 307–11 (2021); Joshua D. Sarnoff, *The Patent System and Climate Change*, 16 Va. J.L. & Tech. 301, 333 (2011).

titrust laws contemplate . . . additional scrutiny" in the regulated space.[286] Since mandatory infringement by definition involves a regulatory structure, these principles could superficially weigh against antitrust enforcement, as some courts have held.[287]

Again, mandatory infringement cases ought to be distinguishable. The preclusion of antitrust enforcement typically depends on anticompetitive practices being "clearly within the agency's regulatory jurisdiction" with the agency being "active in exercising its jurisdiction in that area, taking competitive concerns into account."[288] The buck-passing and cost-offloading problems, however, suggest that agencies may not be diligent about managing competition.[289] As Michael A. Carrier has argued, if an effective regulatory scheme obviates the need for antitrust enforcement, then an *ineffective* regulatory scheme should permit antitrust enforcement to compensate.[290]

Petitioning immunity. — Perhaps the most significant barrier to challenging mandatory infringement is the *Noerr–Pennington* doctrine, which immunizes government lobbying and litigation activities as protected under the First Amendment.[291] To the extent that an IP holder lobbies a regulator to mandate use of its intellectual property, this doctrine would preclude treatment of that lobbying as grounds for a competition law violation.[292]

Noerr–Pennington was central to the Unocal gasoline regulation situation.[293] In its complaint of unfair competition, the FTC alleged that Unocal had made

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286. *Trinko*, 540 U.S. at 412; Credit Suisse Sec. (USA) LLC v. Billing, 551 U.S. 264, 275–76 (2007) (holding that "existence of regulatory authority" can preclude application of antitrust laws that, if simultaneously enforced, "would produce conflicting guidance, requirements, duties, privileges, or standards of conduct") (discussing Gordon v. N.Y. Stock Exch., Inc., 422 U.S. 659 (1975); United States v. Nat'l Ass'n of Sec. Dealers, Inc., 422 U.S. 694 (1975)). *See generally* 1 Areeda & Hovenkamp, *supra* note 186, ¶ 243d.

287. *See In re* Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 687 (E.D. Pa. 2014) (FDA's authority over REMS "actually diminishes the need for antitrust scrutiny"); Carrier, *Sharing*, *supra* note 256, at 38 & n.262.

288. 1 Areeda & Hovenkamp, *supra* note 186, ¶ 243d.

289. *See supra* Section II.B; *supra* Section II.D.

290. *See, e.g.*, Michael A. Carrier, *Of Trinko, Tea Leaves, and Intellectual Property*, 31 J. Corp. L. 357, 113–14 (2005); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 70 (2009).

291. *See* E.R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 136 (1961); United Mine Workers of Am. v. Pennington, 381 U.S. 657, 669–72 (1965).

292. *See* Dogan & Lemley, *supra* note 39, at 719–21.

293. *See Unocal*, 138 F.T.C. 1, 2 (2004); *supra* Section I.B.

misrepresentations to California regulators that its proposed gasoline standards were "non-proprietary," despite knowing it had pending patent applications on those standards.[294] Unocal rebutted on factual grounds—it claimed that "non-proprietary" merely meant not confidential[295]—but more importantly on a *Noerr–Pennington* assertion that its representations before regulators were First Amendment–protected government petitioning activities.[296] The administrative law judge agreed with Unocal, holding that even taking the company's representations as untrue, the Supreme Court's "broad view of Noerr–Pennington immunity" shielded Unocal's representations from FTC scrutiny.[297]

Over sixty-two pages of analysis, the FTC reversed the administrative law judge.[298] Initially, the Commission recognized that Supreme Court jurisprudence "has left key questions unanswered" on when a misrepresentation before the government qualifies for immunity under *Noerr–Pennington*.[299] Misrepresentations may be "condoned in the political arena" but "not immunized when used in the adjudicatory process,"[300] or before the Patent Office.[301] Based on these and other cases and considerations, the FTC found that Unocal's misrepresentations were not immunized under *Noerr–Pennington*.[302]

Although the FTC found *Noerr–Pennington* overcome, its decision reveals the competition laws' limits for mandatory infringement. For one thing, the Commission opinion reveals questions about the doctrine that may not be resolved as the FTC anticipated.[303] More importantly overcoming *Noerr–Pennington* required an act of misrepresentation. If Unocal had been forthright about its patent activity before CARB, *Noerr–Pennington* likely would have precluded the case. Other cases have similarly required an external bad act to find a mandatory IP holder in

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294. *See Unocal*, 138 F.T.C. at 6.

295. *See* Anwer Resp't Union Oil Co. California 1–2, Mar. 1, 2003, https://www.ftc.gov/sites/default/files/documents/cases/2003/03/030321unocalanswer.pdf.

296. *See id.* at 3.

297. *Unocal*, 138 F.T.C. at 165 (initial decision).

298. *See id.* at 17–78.

299. *Id.* at 22.

300. *Id.* at 23 (quoting Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 513 (1972)).

301. *Id.* at 23–24 (citing Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172 (1965)).

302. *Id.* at 51, 57.

303. *See* Dogan & Lemley, *supra* note 39, at 719 (discussing *Unocal*'s inconsistency with Rambus Inc. v. Fed. Trade Comm'n, 522 F.3d 456, 464–65 (D.C. Cir. 2008)).

violation of a competition law.[304] For IP holders that do not go beyond lobbying, *Noerr–Pennington* could be a significant barrier to the competition laws remedying mandatory infringement.

The competition laws present a mixed bag for mandatory infringement. On the one hand, substantial barriers to successful assertion of those laws arise from the IP exemption from antitrust, the presence of a regulatory authority, and *Noerr–Pennington*. On the other hand, many of these barriers are based on assumptions about IP and competition that fail for mandatory infringement. This suggests the possibility of doctrinal evolution such that the competition laws can better deal with mandatory infringement. More importantly, it shows the importance of recognizing mandatory infringement as a unique class of issues that cannot be lumped together with other IP or competition law questions.

C. Courts: IP Law

Mandatory infringement can also be overcome with doctrines of IP law. Limitations on IP rights are constitutionally required[305] and often designed to prevent IP rights from overly encroaching on competition.[306] As a result, those doctrines could mitigate mandatory infringement's detrimental effects on competition. Yet courts frequently find IP limiting doctrines inapplicable and allow mandatory infringement to persist untrammeled. These failures stem from the distinctive fea-

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304. *See, e.g., In re* Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 682–83 (E.D. Pa. 2014) (requiring "coercive measures" such as fabricated safety concerns); Practice Mgmt. Info. Corp. v. Am. Med. Ass'n, 121 F.3d 516, 521 (9th Cir. 1997) (relying on copyright holder's exclusive dealing contracts with agency). Strangely, the Ninth Circuit justified non-application of *Noerr–Pennington* in part because the copyright holder "did not lobby" the agency—suggesting that a few lobbying meetings might have evaporated the misuse holding. *See Practice Mgmt.*, 121 F.3d at 521.

305. *See* U.S. Const. art. I, § 8, cl. 8; Golan v. Holder, 565 U.S. 302, 329 (2012) (holding that "speech-protective purposes and safeguards embraced by copyright law" avoid conflict with the First Amendment) (quoting Eldred v. Ashcroft, 537 U.S. 186, 219 (2003)) (internal quotations omitted); Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., 499 U.S. 340, 346 (1991) ("Originality is a constitutional requirement."); Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 6 (1966) ("[P]atent validity requires reference to a standard written into the Constitution.") (quoting Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 154 (1950) (Douglas, J., concurring)) (internal quotations omitted).

306. *See, e.g.*, Lear, Inc. v. Adkins, 395 U.S. 653, 670 (1969) (noting "the important public interest in permitting full and free competition in the use of ideas"); Ariel Katz, *Copyright and Competition Policy*, *in* Handbook of the Digital Creative Economy 209, 209 (Ruth Towse & Christian Handke eds., 2013); Marcel Boyer, *Efficiency Considerations in Copyright Protection*, 1 Rev. Econ. Res. on Copyright Issues 11, 19 (2004).

tures of mandatory infringement:[307] Courts pass the buck to agencies, overvalue innovation incentives despite rent-seeking, and/or ignore the government's offloading of costs.

1. Unprotectability

Both patent and copyright law include strict requirements on what subject matter is protectable—broadly speaking, what works are sufficiently original to merit copyrights[308] or what technologies are sufficiently inventive to merit patents.[309] These doctrines can forcefully stop mandatory infringement by eliminating the IP right that gives rise to market power.

Copyright protectability involves two overlapping principles. First, protection extends to only "original" subject matter.[310] Second, ideas are not protectable; only specific expressions of those ideas are.[311] If there is only one or a limited number of ways to express an idea, then the merger doctrine renders those expressions unprotectable as necessary to use the idea.[312] Similarly, the doctrine of *scènes à faire*, precludes copyright in "expressions that are standard, stock, or common to a particular topic."[313] Courts and leading commentators have considered the applicability of these doctrines to mandatory infringement cases.[314] Most notably,

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307. *See supra* Section II.

308. *See Feist*, 499 U.S. at 345–46.

309. *See Graham*, 383 U.S. at 17–18.

310. *See Feist*, 499 U.S. at 345.

311. *See* 17 U.S.C. § 102(b).

312. *See* Baker v. Selden, 101 U.S. 99, 104 (1880); Comput. Assocs. Int'l, Inc. v. Altai, Inc., 982 F.2d 693, 707–10 (2d Cir. 1992).

313. *See Comput. Assocs.*, 982 F.2d at 709; Gates Rubber Co. v. Bando Chem. Indus., Ltd., 9 F.3d 823, 838 (10th Cir. 1993).

314. *See, e.g.*, Practice Mgmt. Info. Corp. v. Am. Med. Ass'n, 121 F.3d 516, 520 n.8 (9th Cir. 1997); Am. Soc'y for Testing & Materials v. Pub.Res.Org, Inc., No. 1:13-cv-1215, slip op. at 29–31 (D.D.C. Feb. 2, 2017); *cf. Feist*, 499 U.S. at 363 (finding telephone book's selection unoriginal in part because book's author "was required to do so by the Kansas Corporation Commission as part of its monopoly franchise"); Samuelson, *supra* note 19, at 221 (arguing that legally mandatory standards "may be unprotectable by copyright law under the scenes a fair or merger doctrines"); Pamela Samuelson, *Reconceptualizing Copyright's Merger Doctrine*, 63 J. Copyright Soc'y USA 417, 462 (2016) [hereinafter Samuelson, *Reconceptualizing*] ("Merger has quite often been found when laws or regulations limit the range of expressive alternatives."); Bremer, *Incorporation*, *supra* note 134, at 170–71; Cunningham, *supra* note 135, at 307–08; Justin Hughes, *Created Facts and the Flawed Ontology of Copyright Law*, 83 Notre Dame L. Rev. 43, 45 (2007) (proposing that mandatory model codes are "facts created by original expression").

Veeck relied on merger to hold private building codes uncopyrightable.[315] *Veeck* presents one possible pathway for responding to mandatory infringement generally: The Fifth Circuit held that a legal mandate to use a copyrighted work rendered the idea of legal compliance coextensive with the expression of the work, precluding copyright protection.[316]

The difficulty with applying protectability doctrines like merger to mandatory infringement is that it appears to strip the author of much value and to diminish incentives to create further candidate works for public benefit.[317] The dissenting judges in *Veeck* expressed concern that applying the merger doctrine would cause the model code author to "lose significant revenue, in turn substantially impinging on the financial incentive and ability to continue creating and revising its model codes."[318] Other courts have refused to apply copyright protectability doctrines to mandatory infringement in part to "limit[] the economic consequences that might result."[319]

The nature of mandatory infringement, however, qualifies this economic concern. The rent-seeking phenomenon suggests that the correlation between copyright protection and high-quality works may not be straightforward: A private author may overinvest in producing a mediocre code, as Lawrence A. Cunningham finds, if the author expects the code to be made mandatory.[320] That qualification is compounded by the cost-offloading problem:[321] It is unclear why regulated entities should pay the costs of the work when the government receives its benefits. The economic criticisms of applying protectability doctrines to mandatory

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315. *See* 293 F.3d 791, 800–02 (5th Cir. 2002).

316. *See id.* at 802.

317. *See, e.g.*, Michael Abramowicz & John F. Duffy, *The Emergence of Intellectual Property for Legal Innovation*, *in* Mapping Legal Innovation: Trends and Perspectives 113, 122–23 (Antoine Masson & Gavin Robinson eds., 2021); Katie M. Colendich, Note, *Who Owns "the Law"? The Effect on Copyrights when Privately-Authored Works Are Adopted or Enacted by Reference into Law*, 78 Wash. L. Rev. 589, 613 (2003); Hughes, *supra* note 314, at 92 ("[C]reated fact works may need the incentive of copyright . . . .").

318. 293 F.3d at 816–17 (Wiener, J., dissenting).

319. *ASTM*, 896 F.3d 437, 447 (D.C. Cir. 2018); *see also* Google LLC v. Oracle Am., Inc., 141 S. Ct. 1183, 1197 (2021) (opting to decide case based on fair use rather than copyrightability so as to "not answer more than is necessary to resolve the parties' dispute"); *Practice Mgmt.*, 121 F.3d at 519 ("Non-profit organizations that develop these model codes and standards warn they will be unable to continue to do so if the codes and standards enter the public domain when adopted by a public agency.").

320. *See* Cunningham, *supra* note 135, at 311 & n.98; *supra* Section II.C.

321. *See supra* Section II.D.

copyrights, then, are not necessarily as strong as their proponents make them out to be.

Patent law also contains a variety of protectability doctrines: subject matter eligibility,[322] novelty,[323] nonobviousness,[324] and sufficiency of written description.[325] There are similarities to be found, particularly between the prohibition on patenting abstract ideas[326] and copyright's idea–expression dichotomy.[327] But while copyright protectability doctrines can arguably account for post-creation events such as a legal mandate,[328] patent's protectability doctrines are explicitly measured from the time of patent filing.[329] As a result, patent protectability doctrines generally cannot account for legal mandates in the same way that copyright protectability doctrines can.

Nevertheless, it is worth observing that many mandatory patents are in fact invalid or at least questionable. Celgene's thalidomide REMS patents were held unpatentably obvious[330] and likely were ineligible for patenting as well.[331] Many patents involved in product hopping, including those on buprenorphine, have been invalidated.[332] Unocal's mandatory patents on gasoline formulations were also forcefully (though unsuccessfully) challenged based on Unocal's hasty revi-

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322. *See* 35 U.S.C. § 101; Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 216–18 (2014).

323. *See* 35 U.S.C. § 102.

324. *See* § 103.

325. *See* § 112.

326. *See Alice*, 573 U.S. at 218.

327. *See, e.g.*, Lateef Mtima, *The Idea Exclusions in Intellectual Property Law*, 28 Tex. Intell. Prop. L.J. 343, 347–49 (2020).

328. *See* Veeck v. S. Bldg. Code Cong. Int'l, Inc., 293 F.3d 791, 802 (5th Cir. 2002) (incorporation into law "transformed" model codes' copyrightability). To be sure, there is some debate as to whether post-creation events can affect copyrightability. *Compare* Samuelson, *Reconceptualizing*, *supra* note 314, at 445–46, *with* Oracle Am., Inc. v. Google Inc., 750 F.3d 1339, 1361 (Fed. Cir. 2014) ("It is well-established that copyrightability and the scope of protectable activity are to be evaluated at the time of creation, not at the time of infringement."), *rev'd on other grounds sub nom.* Google LLC v. Oracle Am., Inc., 141 S. Ct. 1183 (2021), *and* Colendich, *supra* note 317, at 613–14.

329. *See, e.g.*, 35 U.S.C. § 102(a)(1) (novelty of patent is based on "the effective filing date of the claimed invention").

330. *See* Celgene Corp. v. Peter, 931 F.3d 1342, 1355 (2019).

331. *See* Paradise, *supra* note 75, at 75–76; Carrier & Sooy, *supra* note 85, at 1686—1695.

332. *See* Indivior UK Ltd. v. Dr. Reddy's Labs. SA, Nos. 20-2073, -2142, slip op. at 2 (Fed. Cir. Nov. 24, 2021) (petition for en banc rehearing filed Jan. 26, 2022); Indivior Inc. v. Dr. Reddy's Labs., SA, 930 F.3d 1325, 1330–31 (Fed. Cir. 2019); BioDelivery Scis. Int'l, Inc. v. RB Pharm. Ltd., No.

sions to make its patents match California's emissions standards.[333] This questionability is likely no coincidence, but rather results from mandatory infringement shifting incentives away from innovation and toward rent-seeking, suggesting a need for close scrutiny of mandatory patents' validity.[334]

2. Noninfringement

A second IP-based approach involves doctrines that permit otherwise-infringing uses of IP. In copyright law, fair use under 17 U.S.C. § 107 excuses certain uses of copyrighted materials such as academic quotations and parodies.[335] Patent law, by contrast, only includes only a few irrelevant exceptions to infringement.[336] To the extent that fair use successfully deals with mandatory copyrights, the asymmetry with patents perhaps bolsters the argument for a patent fair use doctrine.[337]

IPR2014-00325, slip op. at 2 (P.T.A.B. June 30, 2015) (final written decision), *aff'd mem.*, 667 F. App'x 997 (Fed. Cir. 2016).

333. *See Unocal v. ARCO*, 208 F.3d 989, 997–1001 (Fed. Cir. 2000); *cf. id.* at 1002 (Lourie, J., dissenting) (arguing that patents failed § 112 because they described only general ranges of gasolines, not the specific mandated one); Mueller, *supra* note 18, at 626–27.

334. *See supra* Section II.C.

335. Another potentially relevant infringement-excuse approach is the implied license doctrine, which is a defense to infringement based on the IP holder's conduct. *See, e.g.,* Effects Assocs., Inc. v. Cohen, 908 F.2d 555, 558–59 (9th Cir. 1990) (finding implied license to use film footage based on contract for its production) (discussing Oddo v. Ries, 743 F.2d 630, 634 (9th Cir. 1984)); Orit Fischman Afori, *Implied License: An Emerging New Standard in Copyright Law*, 25 Santa Clara Computer & High Tech. L.J. 275, 279–87 (2008). In *SmithKline*, the FDA proposed that the implied license doctrine permitted use of copyrighted drug labels. *See* Brief for the United States as *Amicus Curiae* at 21–26, SmithKline Beecham Consumer Healthcare, LP v. Watson Pharm., Inc., 211 F.3d 21 (2d Cir. Jan. 19, 2000) (No. 99-9501), https://www.copyright.gov/rulings-filings/briefs/smithkline-beecham-consumer-healthcare-l-p-v-watson-pharm-inc-211-f-3d-21-2d-cir-2000.pdf. However, an IP holder can expressly override any implied license, likely making the doctrine not generally useful. *See, e.g.,* Field v. Google Inc., 412 F. Supp. 2d 1106, 1116 (D. Nev. 2006); Christopher M. Newman, *What Exactly Are You Implying: The Elusive Nature of the Implied Copyright License*, 32 Cardozo Arts & Ent. L.J. 501, 541–42 (2013).

336. *See* 35 U.S.C. § 287(c) (doctors' use of patented surgical methods); *see also* Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002) (describing research exemption to patent infringement as "very narrow and strictly limited").

337. *See, e.g.*, Katherine J. Strandburg, *Patent Fair Use 2.0*, 1 U.C. Irvine L. Rev. 265, 295–97 (2011) (proposing patent fair use to deal with refusals to license and holdup issues); Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 Colum. L. Rev. 1177, 1205–09 (2000).

Courts have often used fair use to deal with mandatory copyrights.[338] This seems reasonable because where a regulated entity uses another's IP to comply with a regulatory mandate, that entity's use is intuitively "fair."[339] The second of the four statutory factors for fair use addresses "the nature of the copyrighted work," a natural place for considering a work's mandatory status.[340] And fair use only excuses particular uses of copyrighted works rather than condoning all uses, as a finding of unprotectability would.[341] To courts concerned with the economic incentives fallout of resolving a mandatory infringement case against the IP holder, fair use's more limited effect may be attractive over resolution by protectability doctrines like merger.[342]

Yet fair use is "is notoriously fact sensitive and often cannot be resolved without a trial," as Chief Justice Roberts observed, which could leave the "less bold among us" vulnerable to the harms of mandatory infringement.[343] If fair use unambiguously excused mandatory infringement, then this fact-sensitive nature might be tolerable. But the doctrine, developed largely in the context of literary works,[344] produces counterintuitive results in mandatory infringement cases.

For one thing, fair use typically turns on whether the accused infringer has recontextualized the work or copied it wholesale. The third statutory factor under § 107 is "the amount and substantiality of the portion used."[345] Under the first factor that inquires into the "purpose and character of the use,"[346] courts frequently consider Judge Leval's "transformativeness" test, which asks whether a use is "pro-

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338. *See, e.g., ASTM*, 896 F.3d 437, 447 (D.C. Cir. 2018); Gulfstream Aerospace Corp. v. Camp Sys. Int'l, Inc., 428 F. Supp. 2d 1369, 1380–81 (S.D. Ga. 2006); Jartech, Inc. v. Clancy, 666 F.2d 403, 407 (9th Cir. 1982); Religious Tech. Ctr. v. Wollersheim, 971 F.2d 364, 367 (9th Cir. 1992).

339. *See* Lloyd L. Weinreb, *Fair's Fair: A Comment on the Fair Use Doctrine*, 103 HARV. L. REV. 1137, 1150 (1990) ("Fair use does not exclude consideration of . . . social values or, more simply, fairness."). Professor Weinreb, who passed away recently, was my copyright law professor, and I remember him discussing this point about fairness in class.

340. 17 U.S.C. § 107(2).

341. *See* Campbell v. Acuff-Rose Music, Inc., 510 U.S. 569, 577 (1994) (requiring "case-by-case analysis" of fair use).

342. *See supra* note 319 (citing cases).

343. Georgia v. Pub.Res.Org, Inc., 140 S. Ct. 1498, 1513 (2020).

344. Of the five modern Supreme Court decisions on fair use, four dealt with literary works. *See Campbell*, 510 U.S. 569; Stewart v. Abend, 495 U.S. 207 (1990); Harper & Row Publishers, Inc., v. Nation Enters., 471 U.S. 539 (1985); Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417 (1984). The fifth was Google LLC v. Oracle Am., Inc., 141 S. Ct. 1183 (2021).

345. 17 U.S.C. § 107(3).

346. *Id.* § 107(1).

ductive" and employs the copyrighted work "in a different manner or for a different purpose from the original."[347] For traditional fair uses such as parodies and academic quotations, these inquiries can work well.[348] But with respect to mandatory infringement, would-be competitors typically must make complete and exact copies for purposes identical to the copyright holder's: A generic drug maker uses almost the entire listed drug's label to market the generic in the same manner as the listed drug, for example.[349] Courts have weighed these factors against mandatory infringement being fair use.[350] Even *ASTM*, which largely suggested that it was fair use to republish mandatory copyrighted standards, nevertheless held the third factor to weigh against fair use and the first factor to support it only on the narrow grounds that use "to facilitate public debate" could be considered transformative.[351] Courts finding mandatory infringement to be fair use must take a broad (but not uncommon) view that total copying can be permissible for "legitimate objectives."[352]

Additionally, fair use typically favors non-competitive uses over competitive ones. Another consideration under the first § 107 factor is "whether such use is of a commercial nature or is for nonprofit educational purposes."[353] And the fourth factor, sometimes called "undoubtedly the single most important element of fair use,"[354] considers "the effect of the use upon the potential market for or value of the copyrighted work."[355] If the fair use doctrine is to overcome market power caused by mandatory infringement and restore competition, then these considerations

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347. Pierre N. Leval, *Toward a Fair Use Standard*, 103 HARV. L. REV. 1105, 1111 (1990); *see Campbell*, 510 U.S. at 579 ("The central purpose of this investigation is to see . . . whether the new work . . . adds something new, with a further purpose or different character, altering the first with new expression, meaning, or message . . . ") (citing Leval, *supra*, at 1111).

348. *See* 17 U.S.C. § 107 (listing exemplary fair uses); *Campbell*, 510 U.S. at 578–79.

349. *See supra* Section I.E.

350. *See, e.g.,* Am. Soc'y for Testing & Materials v. Pub.Res.Org, Inc., No. 1:13-cv-1215, slip op. at 33–34 (D.D.C. Feb. 2, 2017) (characterizing republication of copyrighted mandatory standards as tantamount to "offer[ing] them for free in competition").

351. 896 F.3d 437, 450, 453 (D.C. Cir. 2018).

352. Google LLC v. Oracle Am., Inc., 141 S. Ct. 1183, 1205 (2021); *see also* Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417, 449–50 (1984) (holding complete copying of television broadcasts to be fair use when done for purposes of time-shifting).

353. 17 U.S.C. § 107(1).

354. *Harper & Row*, 471 U.S. 539, 566 (1985); *see* Stewart v. Abend, 495 U.S. 207, 238A (1990).

355. 17 U.S.C. § 107(4).

would seem to work directly contrary to that objective.[356] Indeed, in *ASTM*, the D.C. Circuit agreed that "there may be some adverse impact on the market for the copyrighted works" and remanded to the district court to find how much the copyright holders' markets were worth and whether they could make money on derivative works.[357] Should the district court find those markets highly valuable and the derivative works markets insufficient compensation,[358] then *ASTM* might be taken to suggest that fair use ought to tolerate mandatory infringement more when the monopoly profits are highest.

Google LLC v. Oracle America, Inc. offers a better route for applying market considerations to mandatory infringement. Justice Breyer for the Court agreed that Google's use of Oracle's assumed-copyrightable Java commands harmed Oracle's market, but observed that "a potential loss of revenue is not the whole story."[359] In particular, he pointed to "the public benefits the copying will likely produce" as weighing strongly in favor of fair use.[360] Google's use of the Java commands opened up a new smartphone platform to programmers locked into that API's commands, which "allows creative new computer code to more easily enter the market."[361]

Breyer's analysis accommodates many of the unique features of mandatory infringement. It weighs monopolization of markets beyond the copyrighted work as favoring fair use.[362] Its consideration of "public benefits of copying" could give courts further opportunity to consider the rent-seeking and cost-offloading effects

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356. *See, e.g.*, Am. Soc'y for Testing & Materials v. Pub.Res.Org, Inc., No. 1:13-cv-1215, slip op. at 39 (D.D.C. Feb. 2, 2017) (making "logical presumption" that duplication of copyrighted standards "negatively impacts the potential market").

357. *See* 896 F.3d 437, 453 (D.C. Cir. 2018).

358. In its March 2022 decision on remand, the district court found no plausible evidence of market harm. *See* Am. Soc'y for Testing & Materials v. Pub.Res.Org, Inc., No. 1:13-cv-01215, at 35 (D.D.C. Mar. 31, 2022) (mem.). This is unsurprising given the substantial profits that standards development organizations earn even absent copyright protection in legally mandatory codes. *See* Brief of 66 Library Associations et al. as *Amici Curiae* in Support of Defendant-Appellant at 22, *ASTM*, 896 F.3d 437 (Sept. 25, 2017) (Nos. 17-7035, -7039).

359. 141 S. Ct. 1183, 1206 (2021).

360. *Id.* at 1206, 1208.

361. *See id.* at 1208.

362. *See id.* (expressing concern about copyright being "a lock" on a wide market of programmers); *see also* Gulfstream Aerospace Corp. v. Camp Sys. Int'l, Inc., 428 F. Supp. 2d 1369, 1380 (S.D. Ga. 2006) (weighing monopolization resulting from copyright protection under the fourth factor).

of mandatory infringement.[363] Courts adopting this broader view of market effects will likely apply fair use more realistically to mandatory infringement, rather than applying traditional understandings of IP incentives and value that do not hold in the mandatory infringement context.[364]

3. Remedial Limitations

The third category of IP law approaches for dealing with mandatory infringement involves remedy doctrines. Courts may hold that mandatory IP is valid and infringed, but then cap the recovery that the IP holder can recover in order to limit anticompetitive injury. The two main IP remedies are monetary compensation and injunctive relief; each is discussed below.

Monetary damages. — Intuitively, damages-based approaches are well-suited to dealing with mandatory infringement. Unlike denial of protectability or excusing infringement, adjustment of remedies allows courts to recognize at least some degree of compensation for the IP holder's innovative contributions. At the same time, well-adjusted remedies could account for the rent-seeking incentives that accompany mandatory infringement.

Case law on interoperability standards patents, described as "*de facto* mandatory infringement" previously,[365] suggests a workable pathway for dealing with *de jure* mandatory infringement. In *Ericsson, Inc. v. D-Link Systems, Inc.*, the Federal Circuit considered whether a patent holder's FRAND commitment, made in the course of developing the WiFi standard, affected damages under 35 U.S.C. § 284.[366] Observing that a WiFi patent is widely used "because its use is necessary to comply with the standard" and not necessarily because of technical merit, the Federal Circuit required "apportionment of the value of the patented technology from the value of its standardization."[367] As a result, the traditional damages factors required alteration in view of the FRAND commitment, with several of those factors being "irrelevant."[368]

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363. *See Google*, 141 S. Ct. at 1206 (citing MCA, Inc. v. Wilson, 677 F.2d 180, 183 (2d Cir. 1981) (citing cases on relevance of public benefit)). Importantly, *Google* does not limit the "public benefits" to copyright-related benefits; "copyright's concern for the creative production of new expression" is given only as an "example" of a relevant public benefit. *See id.*

364. *See supra* Section II.C; *supra* Section II.D.

365. *See supra* Section I.D.

366. *See* 773 F.3d 1201, 1229 (Fed. Cir. 2014).

367. *Id.* at 1233 (citing Garretson v. Clark, 111 U.S. 120, 121 (1884)).

368. *Id.* at 1230.

Ericsson informs mandatory infringement in two ways. First, many agencies call for FRAND licensing of mandatory patents,[369] meaning that *Ericsson*'s modifications to § 284 apply. Second, flexibility in § 284 to accommodate FRAND obligations suggests similar flexibility to accommodate mandatory infringement that presents similar holdup and overvaluation problems,[370] even absent explicit FRAND obligations.

Nevertheless, difficulties remain. First, patent damages principles may not translate well to copyright law, which entails a different range of monetary remedies.[371] Second, the methodologies for computing FRAND damages may not map well onto mandatory infringement. The "top-down" approach, which apportions IP value based on the aggregate number of patents on a standard, works well for interoperability standards that cover dozens or thousands of patents[372] but could lead to unreasonable outcomes in mandatory infringement cases involving just a few patents.

Most fundamentally, FRAND methodologies are designed to separate an invention's intrinsic value from the value of standardization, and then allocate that intrinsic value to implementers of the standard.[373] But this allocation ignores cost-offloading, as some of the intrinsic value of a patented technology goes to the government and the public.[374] This is the fundamental problem with all IP-based approaches to mandatory infringement, as they can only allocate value between

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369. *See, e.g., supra* text accompanying notes 104–110 (FCC expecting FRAND licensing of digital television patents); OMB Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities sec. 2(d), at 16 (Office of Mgmt. & Budget Jan. 27, 2016), https://www.whitehouse.gov/wp-content/uploads/2020/07/revised_circular_a-119_as_of_1_22.pdf ("In order to qualify as a 'voluntary consensus standard' . . . a standard that includes patented technology needs to be governed by [FRAND] policies . . . ."); *see also* Clean Air Act (CAA) § 308, 42 U.S.C. § 7608 (permitting compulsory licensing of patents "on such reasonable terms and conditions as the court, after hearing, may determine").

370. *See supra* Section II.C.

371. *See* 17 U.S.C. § 504(b)–(c) (providing for statutory damages and accounting of profits as remedies for copyright infringement). Patent law permits no accounting for the infringer's profits. *See* Aro Mfg. Co. v. Convertible Top Replacement Co., 377 U.S. 476, 505 (1964). *See generally* Pamela Samuelson, John M. Golden & Mark P. Gergen, *Recalibrating the Disgorgement Remedy in Intellectual Property Cases*, 100 B.U. L. Rev. 1999, 2049–50, 2070–71 (2020).

372. *See* Jorge L. Contreras, *Aggregated Royalties for Top-down FRAND Determinations: Revisiting Joint Negotiation*, 62 Antitrust Bull. 690, 692–94 (2017).

373. *See Ericsson*, 773 F.3d at 1233.

374. *See supra* Section II.D.

IP holders and regulated entities, so one of them must pay for public value that neither party receives.

Injunctive relief. — Even if a court can adjust monetary remedies to account for mandatory infringement, market power will persist if injunctive relief also issues.[375] An injunction renders IP protection a property-like right in that the IP holder may set the price for licensing the IP or refuse to license entirely—powers that underlie the exclusion of competition from mandatory infringement.[376]

Ordinarily, courts have discretion over injunctive relief and can take mandatory infringement into account. *eBay Inc. v. MercExchange, LLC* directs courts in IP cases to consider a four-factor test for injunctive relief, the fourth factor of which is whether "the public interest would not be disserved by a permanent injunction."[377] Courts have applied this factor to public concerns such as doctors' access to medical treatments.[378] The strong public interest in competitive markets ought to weigh heavily on this factor.[379] But the tendency of courts to apply traditional IP theory despite its inapplicability to mandatory infringement could lead them to find that the "public interest nearly always weighs in favor of protecting property rights," leaving the problem unresolved.[380]

Courts do not always have discretion over injunctive relief. In patent disputes involving generic drugs under Hatch–Waxman, a finding that a patent is valid and infringed precludes the FDA from approving the generic—effectively an injunction against marketing that generic.[381] In cases involving patents and generic

375. *See* 35 U.S.C. § 283 (injunctions for patents); 17 U.S.C. § 502 (injunctions for copyrights).

376. *See* Guido Calebresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 Harv. L. Rev. 1089, 1092 (1972); Mark A. Lemley & Philip J. Weiser, *Should Property or Liability Rules Govern Information?*, 85 Tex. L. Rev. 783, 784 (2007).

377. 547 U.S. 388, 391 (2006); *see* Salinger v. Colting, 607 F. 3d 68, 77–78 (2d Cir. 2010) (applying *eBay* to copyright cases).

378. *See* Christopher B. Seaman, *Permanent Injunctions in Patent Litigation After eBay: An Empirical Study*, 101 Iowa L. Rev. 1949, 1999 & n.311 (2016) (citing cases).

379. *See* Practice Mgmt. Info. Corp. v. Am. Med. Ass'n, 121 F.3d 516, 519 (9th Cir. 1997) (predicting that "mandatory licensing" via denial of injunctive relief could prevent "great public injury that would result if adequate access to [a copyrighted mandatory standard] were denied") (citing Abend v. MCA, Inc., 863 F.2d 1465, 1479 (9th Cir. 1988)).

380. *See* Apple Inc. v. Samsung Elecs. Co., Ltd., 809 F.3d 633, 647 (Fed. Cir. 2015).

381. *See* Federal Food, Drug, and Cosmetics Act (FFDCA) § 505(j)(5)(B)(iii), 21 U.S.C. § 355; 35 U.S.C. § 271(e)(4)(A); *see also* 35 U.S.C. § 271(e)(4)(D) (courts "shall order a permanent injunction prohibiting any infringement" of a patent in certain litigation over biologic products).

drugs,[382] then, courts simply may lack the discretion necessary to relieve mandatory infringement.

IV. A Proposed Approach

Agency action and judicial application of competition and IP laws all play important roles in resolving mandatory infringement situations, but all of them have limitations and drawbacks.[383] Better would be a unified approach that responds directly to the buck-passing, rent-seeking, and cost-offloading problems. That approach need not operate to the exclusion of existing doctrines or efforts, but should supplement greater awareness of and action toward mandatory infringement by agencies and courts.

Several considerations inform this proposal. First, to the extent that mandatory infringement entails a conflict between IP and regulation, the former ought to yield to the latter. While agencies can avoid mandatory infringement situations by declining to regulate,[384] doing so hampers the agency's ability to execute its statutory functions and protect public welfare; the marginal policy benefits of slightly expanded IP enforcement likely do not outweigh those interests. Second, courts are likely the better locus of reform than the agencies themselves, because courts are institutionally insulated from political and financial pressures including those of the cost-offloading problem. Third, both regulated entities and IP holders should be restored to a proper economic state, such that amounts paid are commensurate with value created or received.

The proposal below consists of two parts. The first is the creation of a transsubstantive doctrine that excuses infringement based on activity required by a regulatory mandate. The second is a mechanism for limited IP holder compensation from the government, along with the possibility of a regulator-mediated royalty paid by regulated entities.

A. Default Royalty-Free Access

By default, I propose that a regulated entity should have royalty-free access to use any IP rights in order to comply with a regulatory or legal mandate. In

382. *See, e.g., supra* Section I.A (patents and product hopping); *supra* Section I.C (REMS patents).

383. *See supra* Section III.

384. *See* Approval and Promulgation of Air Quality Implementation Plans, 80 Fed. Reg. 21176, 21178 (Envtl. Prot. Agency Apr. 17, 2015) (proposing to avoid mandatory infringement by declining to select the best available technology); Narechania, *supra* note 17, at 1498–502 (describing the EPA's declining to regulate chemical emissions).

other words, courts should adopt a trans-substantive judicial doctrine that excuses mandatory infringement.

Trans-substantive doctrines, in the general sense of doctrines that cover multiple legal regimes,[385] are common across IP law. The "historic kinship" between patent and copyright law has been questioned factually,[386] but in practice the two IP schemes share rules on indirect infringement,[387] substantial noninfringing uses,[388] and laches[389] among others. In particular, several trans-substantive IP doctrines are judge-made rules that limit IP infringement in order to avoid encroaching on non-IP interests. The patent exhaustion and copyright first sale doctrines, for example, "mark[] the point where [IP] rights yield to the common law principle against restraints on alienation."[390] Both IP regimes also (inconsistently) disallow extraterritorial assertion of rights in the interest of international comity.[391]

A judicial exception for mandatory infringement is well-justified within this pattern. Compliance with a mandatory regulation is an important non-IP interest that will generally be superior to IP protection in terms of enactment precedence, narrowness of scope, and legislative intent.[392] Such an exception would also be consistent with the overall IP objective of advancing progress and innovation,[393] insofar as the undue restraints on competition posed by mandatory infringement distort innovation incentives.[394] Unlike existing IP doctrines applied to mandatory infringement,[395] a trans-substantive approach avoids the interstices of individual IP regimes, which makes sense since the problem of mandatory infringement de-

385. *See* Peter Lee, *The Supreme Assimilation of Patent Law*, 114 MICH. L. REV. 1413, 1417 n.13 (2016).

386. *See, e.g.*, Peter S. Menell & David Nimmer, *Unwinding Sony*, 95 CAL. L. REV. 941, 944 (2007).

387. *See* Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 936–37 (2005).

388. *See* Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417, 441–42 (1984).

389. *See* SCA Hygiene Prods. AB v. First Quality Baby Prods., LLC, 137 S. Ct. 954, 961 (2017) (applying Petrella v. Metro-Goldwyn-Mayer, Inc., 134 S. Ct. 1962, 1972–73 (2014)).

390. Impression Prods., Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523, 1532 (2017); *accord* Kirtsaeng v. John Wiley & Sons, Inc., 568 U.S. 519, 538–40 (2013).

391. *See* Timothy R. Holbrook, *Is There a New Extraterritoriality in Intellectual Property?*, 44 COLUM. J.L. & ARTS 457, 459 (2021).

392. *See* SmithKline Beecham Consumer Healthcare, LP v. Watson Pharm., Inc., 211 F.3d 21, 28 (2d Cir. 2000).

393. *See* U.S. CONST. art. I, § 8, cl. 8.

394. *See supra* Section II.C.

395. *See supra* Section III.C.

pends only on the general nature of IP protection.[396] And a judicial exception would fit well within existing lines of IP precedent. The Second Circuit found in *SmithKline* that "some new law, essentially judge-made," was warranted in view of the unique conflict between copyright law and Hatch–Waxman, and that new law can be fashioned out of standard principles of statutory construction.[397] That case could broadly point to the general treatment of mandatory infringement as a matter of construction of conflicting statutes, in which case the IP laws, being more amenable to judicial limitation, usually ought to yield.[398]

Although the general principle that the mandate excuses infringement should be generally applicable, that principle could be implemented through a variety of IP-specific doctrines. In copyright cases, the merger doctrine could effect royalty-free access.[399] The government IP use statute, 28 U.S.C. § 1498, also acts as a complete defense to infringement, so a regulated entity could raise a defense on the grounds that the government has authorized any infringing conduct.[400] So while courts could follow the *SmithKline* approach of treating mandatory infringement under new judge-made law, they could also fit the proposed trans-substantive approach within existing doctrinal frameworks.

B. Compensation Via Regulator

In most cases, royalty-free access seems appropriate: Mandatory IP is often of little or no public value, and that value is offset by the tendency of mandatory infringement to encourage anticompetitive rent-seeking behavior and to overinvest in research and development.[401] Cases may arise, however, where it seems appropriate to award the IP holder some return on investment in the development of mandatory technologies or works. In such cases, I propose that compensation be determined as part of the regulatory process. This compensation comprises two components: an award from the government to the mandatory IP holder, and a regulatory charge imposed on regulated entities.

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396. *See supra* Section II.A.

397. 211 F.3d at 25, 29.

398. By analogy, the antitrust laws similarly admit a large degree of judicial interpretation, and they often yield to more focused regulatory regimes. *See* Credit Suisse Sec. (USA) LLC v. Billing, 551 U.S. 264, 271 (2007); Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877, 900 (2007) (describing how antitrust laws "evolve to meet the dynamics of present economic conditions").

399. *See supra* Section III.C.1.

400. *See, e.g.*, Crater Corp. v. Lucent Techs., Inc., 255 F.3d 1361, 1367–70 (Fed. Cir. 2001). The applicability of § 1498 to mandatory infringement is discussed further in *infra* Section IV.B.

401. *See supra* Section II.C.

IP holder compensation. — The government IP use statute, § 1498, epitomizes first component of government IP compensation at least in the federal context. Under that law, the government must pay "reasonable and entire compensation" for unauthorized use of patents or copyrights.[402] Government compensation for mandatory infringement is frequently proposed, though often misunderstood. In cases where courts have held mandated works unprotectable or not infringed, commentators have asserted that the devaluation of the IP right constitutes a Fifth Amendment taking.[403] Others have treated § 1498 as tantamount to eminent domain.[404] These are misstatements: A mandate to use IP is not a taking at least because the government does not "den[y] all economically beneficial or productive use" of the IP,[405] infringement is a tort subject to sovereign immunity and not a taking,[406] and § 1498 provides the sole remedy for government IP use to the exclusion of the Fifth Amendment.[407] The distinction is important in that lawmakers

402. *See* 28 U.S.C. § 1498. *See generally* Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 Yale J.L. & Tech. 275, 298–307 (2016).

403. *See, e.g.*, John C. O'Quinn, *Protecting Private Intellectual Property from Government Intrusion: Revisiting SmithKline and the Case for Just Compensation*, 29 Pepp. L. Rev. 435, 517 (2002); Segal, *supra* note 58, at 88; I. Trotter Hardy, *The Copyrightability of New Works of Authorship: "XML Schemas" as an Example*, 38 Hous. L. Rev. 855, 877 (2001) (enactment of copyrighted model codes falls within the "fact pattern under the heading of 'eminent domain' "); *see also* Ann Bartow, *Open Access, Law, Knowledge, Copyrights, Dominance and Subordination*, 10 Lewis & Clark L. Rev. 869, 876 (2006) (policy of open access to law supports "a *Kelo*-style eminent domain approach to proprietary legal information").

404. *See* Mueller, *supra* note 18, at 662–63; Cook, *supra* note 18, at 121.

405. Lucas v. S.C. Coastal Council, 505 U.S. 1003, 1015 (1992); Palazzolo v. Rhode Island, 533 U.S. 606, 631 (2001) (finding no taking where landowner retained "substantial" use of property). The IP holder retains valuable rights to exclude other private actors making non-mandatory uses. *See* SmithKline Beecham Consumer Healthcare, LP v. Watson Pharm., Inc., 211 F.3d 21, 29 (2d Cir. 2000).

406. *See* Schillinger v. United States, 155 U.S. 163, 169 (1894).

407. *See* Golden v. United States, 955 F.3d 981, 988 (Fed. Cir. 2020); Zoltek Corp. v. United States, 442 F.3d 1345, 1352 (Fed. Cir. 2006) (per curiam), *vacated*, 672 F.3d 1309 (Fed. Cir. 2012) (en banc). *See generally* Jonathan S. Masur & Adam K. Mortara, *Patents, Property, and Prospectivity*, 71 Stan. L. Rev. 963, 991–92 (2019) ("Patent infringement [by the government] is described in terms of eminent domain or takings when that characterization is irrelevant to the resolution of the case at hand."); Christopher J. Morten & Charles Duan, *Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 Yale J.L. & Tech. 1, 48–49 (2020), https://yjolt.org/sites/default/files/23_yale_j.l._tech._1_section_1498_0.pdf.

often characterize eminent domain as repugnantly extraordinary; § 1498, by contrast, is a well-trodden procedural law that the government invokes frequently.[408]

As applied to mandatory infringement, § 1498 has a number of key benefits. By providing the IP holder "reasonable and entire compensation," it solves cost offloading: The government pays for the benefits it receives, and the IP holder is made whole. It overcomes the principal–agent problem since the government now bears its own costs. And § 1498 mitigates rent-seeking incentives, since the IP holder's compensation is determined objectively under a liability rule. And the *ex post* nature of § 1498 litigation addresses buck-passing: Government patent use is automatic regardless of the agency's explicit invocation of the statute.[409]

To be sure, automatic invocation of § 1498 alone will not reach every mandatory infringement situation. It will operate only on mandates that imply "authorization or consent of the Government" for third parties to use the IP;[410] many will qualify[411] but some will not.[412] To the extent necessary, regulators or legislators could invoke § 1498 explicitly to avoid questions of whether the authorization and consent test is satisfied.[413] Also, § 1498 does not apply to state government use; in those cases traditional sovereign immunity applies.[414] Finally, despite § 1498's straightforward applicability to mandatory infringement and the fact that critics

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408. *See* Morten & Duan, *supra* note 407, at 13–33.

409. *See* Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis, 583 F.3d 1371, 1377–78 (Fed. Cir. 2009); Herbert Cooper Co., 38 Comp. Gen. 276, 279 (1958), https://catalog.hathitrust.org/Record/003100408 (any government procurement invitation automatically authorizes patent use under § 1498).

410. 28 U.S.C. § 1498(a)–(b); *see* Madey v. Duke Univ., 413 F. Supp. 2d 601, 607 (M.D.N.C. 2006) (private infringement "in furtherance and fulfillment of a stated Government policy" triggers § 1498) (quoting Riles v. Amerada Hess Corp., 999 F. Supp. 938, 940 (S.D. Tex. 1998)). A regulation requiring use of IP arguably also constitutes inducement of infringement; it is unclear whether § 1498 would apply under that theory. *Compare* Decca Ltd. v. United States, 640 F.2d 1156, 1169 (Ct. Cl. 1980) (§ 1498 applies "only with respect to governmental direct infringement"), *with* Cook, *supra* note 18, at 125 (finding cases following *Decca* to take "a broader interpretation of § 1498").

411. The same-labeling requirement of Hatch–Waxman likely does, insofar as Congress would have intended for generics to copy labels and thus implicitly authorized such copying. *See* SmithKline Beecham Consumer Healthcare, LP v. Watson Pharm., Inc., 211 F.3d 21, 27 (2d Cir. 2000).

412. The generic albuterol ban potentially does not qualify because the FDA did not explicitly direct anyone to use patented HFA-134a inhalers, instead only proscribing alternatives.

413. *Cf.* Brennan, Kapczynski, Monahan & Rizvi, *supra* note 402, at 346 (describing procedure for explicit invocation of § 1498).

414. *See* Allen v. Cooper, 140 S. Ct. 994, 1007 (2020); Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 630 (1999).

of the statute often misapprehend it, many might still deem § 1498 politically too strong a medicine to treat mandatory infringement.

To the extent that § 1498 is legally unusable or politically infeasible, alternatives remain. Legislators and agencies may compensate for mandatory IP by buying a license up front, otherwise known as a patent buyout.[415] The license could also be obtained through a government procurement process. Finally, the government could simply offer no compensation at all, making a zero-royalty license a condition of incorporating IP into a regulation.

IP use charges. — One might worry that a government-liability approach overcharges the government and might even deter agencies from engaging in socially beneficial regulation.[416] One potential solution is to allow the government to defray that liability by imposing user fees on regulated entities that use mandatory IP rights.[417] The assessed fee is essentially an IP royalty, paid to the mandatory IP holder through the regulator.

There are at least three advantages to passing IP licensing costs through the government regulator, rather than leaving courts to assess appropriate compensation. First, it solves the buck-passing problem: The agency is definitively tasked with evaluating the merits of the IP-protected work. Second, it offers an opportunity for resolving the cost-offloading problem. To the extent that the government extracts value from its adoption of another's IP, it can impose on regulated entities a fee that is lower than whatever compensation the regulator pays to the IP holder. Third and most importantly, the proposed procedure enables APA review of the agency's cost determinations.[418] A regulator's assessment of IP royalties against regulated entities is essentially a cost–benefit analysis, of the kind that

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415. *See* Hemel & Ouellette, *supra* note 220, at 565–66 (discussing Michael R. Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q.J. Econ. 1137 (1998)).

416. It is worth noting that some agencies already refrain from rulemakings that would otherwise mandate the use of IP rights. *See* examples cited *supra* note 384. Concerns about the deterrent effect of government compensation must be weighed against this existing deterrence phenomenon.

417. There are several ways in which such a fee could be imposed. An agency could exercise its statutory authority under 31 U.S.C. § 9701(b) to "establish[] the charge for a service or thing of value provided by the agency." *See* Clayton P. Gillette & Thomas D. Hopkins, *Federal User Fees: A Legal and Economic Analysis*, 67 B.U. L. Rev. 795, 826–27 (1987). Narechania proposes that agency ancillary authority can include the establishment of IP licensing regimes, which might offer another pathway for setting royalty rates. *See* Narechania, *supra* note 17, at 1518–19. Of course, Congress could also grant explicit fee-setting authority through legislation.

418. *See* 5 U.S.C. § 706(2)(A).

courts frequently review under the arbitrary-and-capricious standard.[419] If the regulator fails to discount offloaded costs or ignores evidence of an IP-protected improvement's minimal benefit, courts would be well-positioned to set aside that regulator's actions.[420] The royalty-through-regulator approach thus offers several layers of governmental review to overcome the market power and other problems of mandatory infringement.

Likely used infrequently. — Practically speaking, this complex regulator-based compensation approach will likely be exercised rarely. Those who seek to make their IP rights mandatory often have close government relationships that they would not want to damage with a contentious § 1498 lawsuit or high payment demands. Private IP holders likely have ancillary profit opportunities—first-mover advantage, membership fees, training and testing programs, and monetization of derivative works, for example—that may obviate their need for revenues from mandatory IP.[421]

Most importantly, the proposed compensation approach makes the government cost-sensitive to its choice of regulation, which creates competition among IP holders to increase quality and lower "prices" (i.e., demands for § 1498 compensation). On this point, Emily S. Bremer's study of pipeline safety standards is instructive.[422] Following enactment of a statute requiring that mandatory pipeline safety standards be "made available to the public, free of charge, on an Internet

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419. *See* Nat'l Ass'n of Home Builders v. EPA, 682 F.3d 1032, 1040 (D.C. Cir. 2012) ("[W]hen an agency decides to rely on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable.") (citing City of Portland v. EPA, 507 F.3d 706, 713 (D.C. Cir. 2007); Owner-Operator Indep. Drivers Ass'n v. Fed. Motor Carrier Safety Admin., 494 F.3d 188, 206 (D.C. Cir. 2007)).

420. If the agency assesses the fee under 31 U.S.C. § 9701, a second administrative challenge to the fee rate is possible. Under Supreme Court precedent interpreting that statute, an agency-set fee can only be assessed against an "identifiable recipient" of benefits from the agency's actions. Fed. Power Comm'n v. New Eng. Power Co., 415 U.S. 345, 351 (1974). And the fee is limited to the "value to the recipient," as distinguished from any agency costs resulting from "the public policy or interest that is also served." Nat'l Cable Television Ass'n, Inc. v. United States ("*NCTA*"), 415 U.S. 336, 344 (1974). If an agency mandates use of IP at the cost of compensation under § 1498, then regulated entities are the identifiable recipient of a benefit from the agency, namely royalty-free access to that IP. Under *NCTA*, then, the agency can charge a fee commensurate with the value of that IP to the regulated entities, but the fee cannot incorporate value that the public or government receives. In other words, the *NCTA* framework potentially avoids the government cost-offloading problem.

421. *See, e.g.*, Veeck v. S. Bldg. Code Cong. Int'l, Inc., 293 F.3d 791, 805–06 (5th Cir. 2002); Cunningham, *supra* note 135, at 319 ("[C]opyright revenue is not a main reason or motivation for its production of materials.").

422. *See* Bremer, *supra* note 173, at 281.

Web site,"[423] the federal pipeline regulatory agency successfully negotiated free access agreements with seven out of eight developers of active pipeline safety standards, the only holdout being the largest standards developer, ASME International ("ASME").[424] Bremer takes the lack of agreement with ASME as a failure of the free access statute.[425] But an alternate interpretation of events is that the smaller standards developers saw free access as a competitive angle against the incumbent, and had Congress not subsequently relaxed the free access requirement, one wonders whether those smaller developers would have sought to supplant ASME with free competitive standards.[426] Resolving the government cost offloading problem through government IP use or otherwise thus has the potential benefit of enabling this sort of *ex ante* competition.

Conclusion

It seems difficult to believe that the government would compel the use of privately held intellectual property rights, and yet mandatory infringement happens all the time in a wide variety of contexts.[427] These cases are a special class with unique problems: market power arising from the inverse relationship between regulation and IP rights, buck passing between regulatory agencies and courts, distortion of incentives away from innovation and toward rent-seeking, and government offloading of IP value creating a principal–agent disconnect.[428] Agencies face limitations and deterrents to solving these problems *ex ante*, and courts applying competition and IP laws find themselves stymied by doctrinal theory ill-suited to the unusual nature of mandatory infringement.[429] By recognizing that traditional IP and competition theory do not generally apply well to mandatory in-

423. Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011, Pub. L. No. 112-90, sec. 24, 125 Stat. 1904, 1919 (2012) (codified as amended at 49 U.S.C. § 60102); *see* Bremer, *supra* note 173, at 297–98.

424. *See* Bremer, *supra* note 173, at 325. Of the three other pipeline standards developers, two were no longer actively developing standards and one already made them available for free. *See id.*

425. *See id.* at 327–28.

426. *Id.* at 298 (describing subsequent amendments to § 60102). Bremer appears to assume that the pipeline regulator would have had to write its own standards to replace ASME's. *See id.* at 328–29.

427. *See supra* Section I.

428. *See supra* Section II.

429. *See supra* Section III.

fringement, courts and lawmakers can hopefully address these problems head-on, enabling competition alongside the public benefits of well-regulated markets.[430]

Mandatory infringement is a complex area with much more to be explored. Other IP regimes such as trademarks and trade secrets may present important clashes with regulation. The economic and redistributive effects of mandatory infringement could further inform remedy computations.[431] "Semi-mandates" such as industry standards or incentive-based regulations may present similarities and differences. And there are potentially relevant distinctions among types of mandatory infringement—the degree of the government's involvement in creation of mandatory IP, for example,[432] or whether the IP right was defined before or after the mandating regulation.[433]

Further study is warranted if only because mandatory infringement is a growing problem. Many instances are recent or ongoing disputes: the *GlaxoSmithKline* case on labeling,[434] drug product hopping, the REMS question, digital television, and litigation over mandatory copyrighted standards,[435] among others. Nor is environmental protection standing still. In 2015, the EPA issued a long-term plan for phasing out greenhouse gases.[436] Among the chemicals it has designated for phaseout: HFA-134a.[437]

430. *See supra* Section IV.

431. *See supra* text accompanying notes 242–243.

432. *See* Cunningham, *supra* note 135, at 298–99.

433. The Unocal patent, for example, was apparently revised to match CARB's final regulations. *See* Mueller, *supra* note 18, at 626.

434. A petition for certiorari in the case was filed in July 2022.

435. *See* Am. Soc'y for Testing & Materials v. Pub.Res.Org, Inc., No. 1:13-cv-01215 (D.D.C. Mar. 31, 2022) (mem.).

436. *See* Prot. of Stratospheric Ozone: Change of Listing Status for Certain Substitutes Under the Significant New Alternatives Policy Program, 80 Fed. Reg. 42869, 42871 (Envtl. Prot. Agency July 20, 2015), *vacated in part sub nom.* Mexichem Fluor, Inc. v. Envtl. Prot. Agency, 866 F.3d 451 (D.C. Cir. 2017).

437. *See* Protection of Stratospheric Ozone: Listing of Substitutes Under the Significant New Alternatives Policy Program, 86 Fed. Reg. 55549, 42881–83 (Envtl. Prot. Agency Oct. 6, 2021).