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## Mandatory Infringement

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## MANDATORY INFRINGEMENT

*Charles Duan*\*

### Abstract

In 2005, the Food and Drug Administration required the use of chlorofluorocarbon-free propellants in albuterol inhalers. But 3M held patents on the only U.S.-approved chlorofluorocarbon-free inhaler. The agency's regulations forced multiple generic albuterol manufacturers to choose between infringing 3M's patents or 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 intellectual property 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 the effect of regulations and intellectual property rights on competition. It further enables passing the buck between regulators and courts, encourages rent-seeking rather than innovation, and induces government offloading of licensing costs onto regulated entities that produces a principal-agent disconnect. These phenomena explain why regulators and courts applying antitrust or intellectual property 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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\* © 2023 Charles Duan. Assistant Professor of Law (starting fall 2023). American University Washington College of Law; Postdoctoral Associate, Cornell Tech. I would like to thank especially my postdoctoral advisor, James Grimmelman, for his unparalleled guidance, as well as Jon Band, Sarah Burstein, Mike Carrier, Bernard Chao, Zach Graves, Matthew Lane, Mike

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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.<sup>1</sup> Certain there was a mistake, I asked the pharmacist to dispense the generic I had received many times in the past,<sup>2</sup> 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 (CFCs) as their propellant gas, and the FDA had agreed.<sup>3</sup> 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.<sup>4</sup> 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.<sup>5</sup>

The asthma inhaler dispute was no one-off: in a wide range of industries, there are similar conflicts between legal mandates and intellectual property (IP) rights. Statutes on generic drugs and pesticides expect competitors to duplicate copyrighted labeling text.<sup>6</sup> Vehicle emissions standards have unwittingly required use of a patented

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

2. In 2006, there were four generic albuterol inhalers. See FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS 3–12 (26th ed. 2006), <https://www.drugpatentwatch.com/p/fda-orange-book/edition/26/annual/> [<https://perma.cc/L6AP-MFZ7>].

3. See Use of Ozone-Depleting Substances; Removal of Essential-Use Designations, 70 Fed. Reg. 17168, 17168, 17192 (Apr. 4, 2005) [hereinafter Albuterol V] (codified at 21 C.F.R. pt. 2); National Cooperative Research Notice; see also International Pharmaceutical Aerosol Consortium for Toxicology Testing, 55 Fed. Reg. 36710, 36710 (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); FDA, *supra* note 2, at ADA2 (listing patents for 3M's product Proventil-HFA). The assignee of the patent, Riker Laboratories, Inc., is owned by 3M. See Gerd Wilcke, *3M Agrees to Buy Riker Labs, Dart Industries' Drug Division*, N.Y. TIMES, July 9, 1969, at 55.

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.

composition of gasoline.<sup>7</sup> The FDA and state governments mandate patented drug formulations for safety, quality, and other reasons.<sup>8</sup> Telecommunications regulators require television broadcasters to comply with highly patented digital standards.<sup>9</sup> Official codes of law, even binding ones, are frequently copyrighted.<sup>10</sup> And Senator Thom Tillis recently introduced a bill that 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.<sup>11</sup> 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.

This Article terms this class of situations “mandatory infringement.”<sup>12</sup> It requires two ingredients: (1) a regulation; and (2) IP rights, such as patents or copyrights.<sup>13</sup> 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.<sup>14</sup> Yet the vigorous debates and striking outcomes in cases of mandatory infringement suggest that the phenomenon is

7. See *infra* Section I.B.

8. See *infra* Section I.A.

9. See *infra* Section I.D.

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

11. See SMART Copyright Act of 2022, S. 3880, 117th Cong. § 3(a) (2022); Josh Landau, *Why SMART Isn't Smart—Importing FRAND's Flaws Into Copyright*, DISRUPTIVE COMPETITION PROJECT (Mar. 24, 2022), <https://www.project-disco.org/intellectual-property/032422-why-smart-isnt-smart-importing-frands-flaws-into-copyright/> [<https://perma.cc/ASB3-CEJ4>].

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 234.

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, 1003–05 (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 CALIF. L. REV. 493, 533 (2021) (explaining how the FDA can promulgate a rule that allows for the disclosure of trade secrets without violating the Trade Secrets Act). 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 overlaps between patents and regulations 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 generally, for example, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 141–43 (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. ENV'T. L.J. 237, 240–41 (2011); Jacob E. Gersen, *Overlapping and Underlapping Jurisdiction in Administrative Law*, 2006 SUP. CT. REV. 201, 211–16.

distinct and warrants further exploration and specialized treatment in the law.<sup>15</sup>

Scattered scholarship has sought to characterize possible solutions to mandatory infringement. Environmental law commentators describe regulation–IP overlaps simply as a “super-monopoly” to be avoided in laws or regulations.<sup>16</sup> More detailed studies characterize the problem as a conflict between IP law and government policy to be resolved through agency expertise and authority,<sup>17</sup> eminent domain,<sup>18</sup> or realignment of IP doctrine.<sup>19</sup> 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.<sup>20</sup>

This Article aims to discern how mandatory infringement transcends IP and regulatory regimes to affect the behaviors and incentives of regulators, courts, innovators, and industry participants. This Article first identifies the heart of the problem with mandatory infringement: competition. IP 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

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15. See *infra* Section I.H.

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, Dialogue, *Patent Law and the Environment/Technology Paradox*, 20 ENV'T. L. REP. 10171, 10173 (1990); Antonio G. Fraone, Note, *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> [<https://perma.cc/MS6U-T6UT>] (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); see also Brian Cook, Note, *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. ENV'T. 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”); see also 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”).

competition outside.<sup>21</sup> 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:

- *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.<sup>22</sup>
- *Rent-seeking*: Mandatory infringement detaches the IP holder's profits from the societal value of their work.<sup>23</sup> 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.<sup>24</sup>
- *Cost-offloading*: In mandating the 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.<sup>25</sup> Among other things, this creates a principal-agent problem.<sup>26</sup>

Critically, 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; buck-passing undermines the private-action nature of IP infringement; rent-seeking challenges IP as an innovation incentive; and cost-offloading questions technology transfer efficiency. 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: (1) the agency or legislature<sup>27</sup> imposing the mandate, which could mitigate the market power problem *ex ante*; and (2) the courts, which *ex*

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21. See *infra* Part II.

22. See *infra* Section II.B.

23. See *infra* Section II.C.

24. *Id.*

25. See *infra* Section II.D.

26. *Id.*

27. 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.

*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 markets.<sup>28</sup> But no less often, agencies and courts fail to act, leaving mandatory infringement intact. Agencies overlook IP holders and their own incentive distortions and pass the buck to courts.<sup>29</sup> 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 how IP and antitrust law usually interact.<sup>30</sup> And courts considering IP infringement cases fall back to standard IP theory, ignoring rent-seeking and cost-offloading behavior.<sup>31</sup>

A new approach to mandatory infringement is needed—one that transcends boundaries of IP regimes and 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, this Article proposes a judicial defense to infringement when the law mandates use of the IP.<sup>32</sup> At the same time, the IP holder should receive compensation for use of its works, not from regulated entities but from the government itself.<sup>33</sup> The government IP-use statute already provides a workable vehicle for providing such compensation in most situations,<sup>34</sup> 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.

These case studies reveal the deep divisions and often manifest injustices that accompany almost every mandatory infringement situation, as IP holders wield power that intuitively seems excessive or

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28. See *infra* Section I.C.; see also *In re Union Oil Co. of Cal. (Unocal II)*, 140 F.T.C. 123, 160–61 (2005) (resolution by competition authority [consent decree & not to collect further royalties]); see also *Veck v. S. Bldg. Code Cong. Int'l, Inc.*, 293 F.3d 791, 801 (5th Cir. 2002) (resolution by court applying IP law—laws are facts, which are uncopyrightable). These cases are discussed *infra* Part I.

29. See *infra* Section III.A.

30. See *infra* Section III.B.

31. See *infra* Section III.C.

32. See *infra* Section IV.A.

33. See *infra* Section IV.B.

34. See 28 U.S.C. § 1498.



unjustified. The case studies 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.<sup>35</sup> 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.<sup>36</sup> For example, the pharmaceutical firm Reckitt Benckiser's regulatory exclusivity over the opioid addiction treatment drug buprenorphine (Suboxone) expired in 2009.<sup>37</sup> 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.<sup>38</sup> Product hopping forces patients and the health care system to pay monopoly prices for a treatment that ought to have been competitive.<sup>39</sup> This has attracted widespread criticism from patient advocates, healthcare experts, legal scholars, competition authorities, and lawmakers.<sup>40</sup>

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35. See, e.g., KEVIN T. RICHARDS ET AL., CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 20 (2020), <https://www.everycrsreport.com/reports/R46221.html> [<https://perma.cc/9FL7-UWAB>]; see also Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 171 (2016) (defining product hopping as “reformulating the 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”).

36. See Carrier & Shadowen, *supra* note 35, at 181–82.

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

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

39. See ALEX BRILL, MATRIX GLOB. ADVISORS, THE COST OF BRAND DRUG PRODUCT HOPPING 2 (Sept. 2020), <https://getmga.com/wp-content/uploads/2022/04/CostofProductHoppingSept2020.pdf> [<https://perma.cc/T7UE-C7W5>] (estimating health care system cost of product hopping at \$4.7 billion per year).

40. See, e.g., Vikram Iyengar, *Should Pharmaceutical Product Hopping Be Subject to Antitrust Scrutiny?*, 97 J. PAT. & TRADEMARK OFF. SOC'Y 663, 666 (2015) (“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 US State Laws Allowing Pharmacist Substitution of Generic Drugs*, at 2–3, BRITISH MED. J. (June 23, 2020), <https://www.bmj.com/content/369/bmj.m2236> [<https://perma.cc/ND3P-K87J>]; MARKUS H. MEIER ET AL., FED. TRADE COMM'N, OVERVIEW OF FTC ACTIONS IN PHARMACEUTICAL PRODUCTS AND DISTRIBUTION 83–84 (2019), [https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview\\_pharma\\_june\\_2019.pdf](https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_june_2019.pdf) [<https://perma.cc/ZX48-5MPX>]

For product hopping to work, the drug maker must switch patients using the old, soon-to-be-generic drug over to the new formulation.<sup>41</sup> 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”).<sup>42</sup> These tactics can be forceful, but they are not dispositive because the switch relies on doctors’ prescription pads or patient inertia to disfavor the old formulation.<sup>43</sup>

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, which drew opposition from almost 10,000 public comments,<sup>44</sup> was featured in a heated congressional hearing,<sup>45</sup> and generated contention in the popular, legal, and medical literature.<sup>46</sup> Similarly, Purdue Pharma hopped its extended-release oxycodone (Oxycontin) product to a new formulation and then, on safety grounds,

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(describing Federal Trade Commission’s (FTC) efforts on product hopping); Diane Bartz, *U.S. House Panel Approves Three Bills Aimed at Tackling High Drug Prices*, REUTERS (Sept. 29, 2021, 6:44 PM), <https://www.reuters.com/business/healthcare-pharmaceuticals/us-house-panel-approves-three-bills-aimed-tackling-high-drug-prices-2021-09-29/> [<https://perma.cc/A6AX-QE5J>] (discussing congressional product hopping bill); Daniel Burke, Note, *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).

41. See Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 711–12 (2009); Carrier & Shadowen, *supra* note 35, at 176–78.

42. See Carrier & Shadowen, *supra* note 35, at 168.

43. See RICHARDS ET AL., *supra* note 35, at 20–21; Dogan & Lemley, *supra* note 41, at 712; Darrow et al., *supra* note 40, at 3. *But see* CHARLES DUAN, R ST. INST., POL’Y STUDY NO. 227, PRODUCT HOPPING: FEDERAL AND STATE APPROACHES 6 (2021), <https://www.rstreet.org/2021/03/31/product-hopping-federal-and-state-approaches/> [<https://perma.cc/E7DX-P83V>] (arguing that legal requirements for prescriptions are a sort of regulatory mandate to use certain drugs over others).

44. See Use of Ozone-Depleting Substances; Essential Use Determinations, 64 Fed. Reg. 47719, 47723 (Sept. 1, 1999) [hereinafter Albuterol II].

45. See generally *Regulatory Efforts to Phaseout Chlorofluorocarbon-Based Metered Dose Inhalers: Hearing Before the Subcomm. on Health and Env’t of the H. Comm. on Com.*, 105th Cong. (1998) [hereinafter *Metered Dose Inhaler Phaseout*], <https://catalog.hathitrust.org/Record/007605070> [<https://perma.cc/5XY3-5XLL>] (providing a transcript of the hearing).

46. See Una C. Fan, Note, *Capture Your Breath: FDA Regulations Can Incentivize the Recapture of Off-Patent Drug Products*, 43 AIPLA Q.J. 189, 210–11 (2015); Erik R. Swenson, Letter to the Editor, *The True Environmental Cost of Chlorofluorocarbon-Based Inhalers*, 175 JAMA INTERNAL MED. 1867, 1867 (2015), <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2467743> [<https://perma.cc/EKX8-ZB8Q>]; Redberg, *supra* note 1; Joseph S. Ross & Rita F. Redberg, *On Chlorofluorocarbon Bans and Inhaled Albuterol Prices*, 175 JAMA INTERNAL MED. 1179, 1179 (2015), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2293074> [<https://perma.cc/BY2U-36GA>].

convinced the FDA to withdraw approval of the older form.<sup>47</sup> 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.<sup>48</sup> With that claim, the companies convinced state insurers, such as Massachusetts's Medicaid program, MassHealth, to make the sublingual film the preferred formulation.<sup>49</sup> 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.<sup>50</sup> Adding to that concern is that product-hop reformulations often are not actual improvements.<sup>51</sup> Buprenorphine is a dramatic example: the sublingual film formulation was actually more dangerous to children because it dissolved and took effect instantly, unlike the tablet that could be spit out.<sup>52</sup> 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.<sup>53</sup> 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 formulations.<sup>54</sup> In response, CARB initiated several

47. 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).

48. See Plea Agreement, Exhibit B, ¶¶ 22–26, *United States v. Indivior Sols., Inc.*, No. 1:19-cr-00016-JPJ-PMS (W.D. Va. July 27, 2020).

49. *Id.*

50. Noah, *supra* note 47, 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.

51. See Noah, *supra* note 47, at 178 (“For legitimate patients, OxyContin OP represents no improvement over the original formula.”).

52. Plea Agreement, Exhibit B, ¶¶ 12, 22–26, *Indivior*, No. 1:19-cr-00016-JPJ-PMS.

53. See *id.* at 1; Rebecca L. Haffajee & Richard G. Frank, *Generic Drug Policy and Suboxone to Treat Opioid Use Disorder*, 47 J.L. MED. & ETHICS 43, 48 (2019); Alison Knopf, *Indivior CEO Sentenced to Prison over Marketing Schemes*, 32 ALCOHOLISM & DRUG ABUSE WKLY., Nov. 9, 2020, at 6–7.

54. See *Union Oil Co. of Cal. (Unocal I)*, 138 F.T.C. 1, 4 (2004). Although these facts are taken largely from the FTC complaint and thus are not proven assertions, they are also allegations that Unocal did not deny. See generally Answer of Respondent, *Unocal I*, 138 F.T.C. 1 (No. 9305), 2004 WL 2458850.

rulemakings in which it took input from industry groups and members of the public on what gasoline formulation standards to mandate.<sup>55</sup> Among other participants in the rulemaking process was the oil refiner Unocal, which proposed adoption of its T50 gasoline standard.<sup>56</sup> Unbeknownst to CARB or the other rulemaking participants, Unocal was simultaneously prosecuting a patent application involving that same T50 standard.<sup>57</sup> CARB issued its final regulations in June 1994, which included the T50 standard and other properties recited in Unocal's patent application.<sup>58</sup> Although its patent was 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.<sup>59</sup>

Between the patent and the CARB mandates, Unocal had brazenly created 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, an amount almost entirely passed onto consumers.<sup>60</sup> Commentators sharply criticized this "capture of an industry standard."<sup>61</sup>

Unocal's ploy roiled the industry.<sup>62</sup> Three months after Unocal's press release, six major oil refiners brought suit in an attempt to invalidate Unocal's lead patent.<sup>63</sup> California's attorney general was incensed by Unocal's attempt to "hijack and distort the state regulatory process by

55. See *Unocal I*, 138 F.T.C. at 5.

56. See *id.* at 5–6.

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

58. See *Unocal I*, 138 F.T.C. at 7.

59. *Id.* at 110.

60. See *id.* at 96.

61. 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. 49, 71–81 (2001) (arguing that the Unocal patent is inconsistent with a broad range of public policies); Cook, *supra* note 18, at 111 (highlighting the negative characterizations of Unocal's activities by commentators).

62. See, e.g., Michael Parrish, *Unocal Plan to Sell Clean-Fuel Formulas Has Rivals Angry*, L.A. TIMES (Feb. 1, 1995), <https://www.latimes.com/archives/la-xpm-1995-02-01-fi-26883-story.html> [<https://perma.cc/FE7G-TKPZ>]; Nancy Rivera Brooks, *In Patent Suit, Unocal's Gain Would Prove Motorists' Pain*, L.A. TIMES (Sept. 24, 1997, 12:00 AM), <https://www.latimes.com/archives/la-xpm-1997-sep-24-fi-35476-story.html> [<https://perma.cc/Q4QU-4Y2D>]; Julie Tamaki, *Unocal Patent on Clean Fuel Stirs Outrage*, L.A. TIMES (Oct. 9, 2000, 12:00 AM), <https://www.latimes.com/archives/la-xpm-2000-oct-09-mn-33920-story.html> [<https://perma.cc/2UNH-ZEUT>].

63. See *Unocal*, 138 F.T.C. at 111.

claiming a patent on gasoline formulas.”<sup>64</sup> He filed an amicus curiae brief joined by thirty-three 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.”<sup>65</sup> Seven members of Congress also filed a brief arguing that upholding the patent would “inflict[] substantial collateral damage on . . . important federal policies,”<sup>66</sup> and the U.S. Solicitor General expressed “concern about possible misuse of the regulatory process by a patent applicant.”<sup>67</sup> Nevertheless, the U.S. Court of Appeals for the Federal Circuit upheld Unocal’s patent, and the U.S. Supreme Court denied certiorari; despite Unocal’s reprehensible behavior, the courts found no defect in the patent itself.<sup>68</sup>

With Unocal’s patents unscathed and reaping large royalties,<sup>69</sup> 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 competition.<sup>70</sup> Ultimately—eleven years after the patent was issued—the FTC prevailed, with Unocal entering a consent decree to disclaim its patents and not collect further royalties.<sup>71</sup> Yet the competition authority’s pathway to victory was narrow—Unocal resoundingly won before the administrative law judge and the decision was only overturned after a lengthy and complex Commission reversal on a difficult First Amendment question.<sup>72</sup>

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64. Press Release, *Attorney General Bill Lockyer Files “Friend of Court” Brief over Unocal Gasoline Patent* (Sept. 14, 2000) (internal quotations omitted), <https://oag.ca.gov/news/press-releases/attorney-general-bill-lockyer-files-friend-court-brief-over-unocal-gasoline> [<https://perma.cc/HH8D-D58D>].

65. Brief of the State of Alabama et al. as Amici Curiae in Support of Petition for Writ of Certiorari at 1, *Atl. Richfield Co. v. Union Oil Co. of Cal.*, 531 U.S. 1183 (2001) (No. 00-249).

66. 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 Co.*, 531 U.S. 1183 (No. 00-249).

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

68. *Union Oil Co. of Cal. v. Atl. Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000). Indeed, they found that Unocal had acted in good faith at least before the patent examiner. *See id.*

69. *See Unocal I*, 138 F.T.C. 1, 111–12 (2004) (describing Unocal’s patent licensing activities).

70. Federal Trade Commission Act (FTC Act), § 5, 38 Stat. 717, 719 (codified as amended at 15 U.S.C. § 45); *see Unocal I*, 138 F.T.C. at 92.

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

72. *See Unocal I*, 138 F.T.C. at 2; *infra* text accompanying notes 308–17.

### C. Safe Handling of Drugs

To many, thalidomide (Thalomid) is an essential drug used to treat a wide variety of cancers and diseases.<sup>73</sup> But 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.<sup>74</sup> 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.<sup>75</sup> 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.<sup>76</sup> 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.<sup>77</sup>

REMS have given rise to two lines of anticompetitive strategies for blocking generic competition. First, firms have cited REMS on their drugs as a reason to refuse to sell samples to potential generic manufacturers.<sup>78</sup> Approval of a new generic requires proof of bioequivalence to an approved drug,<sup>79</sup> which in turn requires testing against samples of the approved drug. Thus, 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,<sup>80</sup> and processes are patentable.<sup>81</sup> If the FDA required generics to share REMS with the

73. See WORLD HEALTH ORG., MODEL LIST OF ESSENTIAL MEDICINES 31 (22d ed. 2021); Michael E. Franks et al., *Thalidomide*, 363 LANCET 1802, 1805–08 (2004).

74. See Franks et al., *supra* note 73, at 1808; Bridget M. Kuehn, *Frances Kelsey Honored for FDA Legacy*, 304 JAMA 2109, 2110 (2010).

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

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

77. See FOOD & DRUG ADMIN., THALOMID RISK EVALUATION AND MITIGATION STRATEGY (REMS) DOCUMENT 8–10 (2021), [https://www.accessdata.fda.gov/drugsatfda\\_docs/remis/Thalomid\\_2021\\_08\\_05\\_REMS\\_Full.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/remis/Thalomid_2021_08_05_REMS_Full.pdf) [<https://perma.cc/9Z9C-V2GS>].

78. 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).

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

80. See FFDCA § 505-1(f)(4)(A), 21 U.S.C. § 355-1(f)(4)(A).

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

listed drug, as was the default until 2019,<sup>82</sup> then patents on the REMS would produce mandatory infringement. Congress knew of this possibility: prior to 2019, Congress provided that a generic could devise its own REMS if “an aspect . . . is claimed by a patent.”<sup>83</sup> And after 2019, Congress allowed the generic to propose its own REMS for any reason.<sup>84</sup>

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.<sup>85</sup> 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.”<sup>86</sup>

Both the withholding of samples based on REMS and patents on REMS have attracted substantial public outcry.<sup>87</sup> Multiple scholars criticized Celgene’s REMS patent as potentially invalid and certainly anticompetitive.<sup>88</sup> At his confirmation hearing, U.S. Department of Health and Human Services Secretary Alex Azar promised to look into “how REMS programs could be abused to block entry,”<sup>89</sup> and in 2017,

82. See FFDC Act § 505-1(i)(1)(C), 21 U.S.C. § 355-1(i)(1)(C) (2019) (stating that equivalent drugs “shall use a single, shared system” of REMS unless the FDA waives the requirement). The CREATES Act amended § 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. 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).

83. § FFDC Act 505-1(i)(1)(C)(ii), 21 U.S.C. § 355-1(i)(1)(C)(ii).

84. See CREATES Act, Pub. L. 116-94, § 610(f)(2), 133 Stat. 2534, 3136 (amending 21 U.S.C. § 355-1(i)(1)(C)).

85. See, e.g., U.S. Patent No. 6,315,720 (issued Nov. 13, 2001); Paradise, *supra* note 78, at 69–71.

86. Citizen Petition on behalf of Celgene Corp., No. FDA-2007-P-0113, at 17 (Sept. 20, 2007).

87. See generally Ameet Sarpatwari et al., *Using a Drug-Safety Tool to Prevent Competition*, 370 NEW ENG. J. MED. 1476 (2014) (criticizing Celgene’s strategy of patenting its REMS program); Alison Kodjak, *How a Drugmaker Gamed the System to Keep Generic Competition Away*, NPR (May 17, 2018, 5:00 AM), <https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away> [<https://perma.cc/LX42-7CZA>] (highlighting complaints surrounding Celgene’s ability to prevent generic competition from entering the market).

88. See Michael A. Carrier & Brenna Sooy, *Five Solutions to the REMS Patent Problem*, 97 B.U.L. REV. 1661, 1670–71 (2017); Paradise, *supra* note 78, at 69–72; Sarpatwari et al., *supra* note 87, at 1478.

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

Congress held a hearing to discuss the anticompetitive use of REMS.<sup>90</sup> Congress ultimately remedied the sample-sharing problem in 2019,<sup>91</sup> 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.<sup>92</sup> To do so, those systems must comply with a shared set of specifications, often called “technical standards.”<sup>93</sup> For example, a Wi-Fi-capable laptop must issue coded commands about authentication, data transmissions, and signal strength—commands that are defined in and thus copied from the detailed Wi-Fi technical standard.<sup>94</sup> Standards facilitate competition by avoiding fragmentation of the market: a world of incompatible phone dock connectors, for example, locks consumers into the Android or iOS ecosystem.<sup>95</sup> But interoperability commands and other specifications could be protected by IP rights, potentially giving the IP holder powerful control to suppress competition among those using the standard.<sup>96</sup>

Technical interoperability standards thus give rise to a difficult tension between IP rights and competition.<sup>97</sup> Even when a standard is not legally

90. See *Antitrust Concerns and the FDA Approval Process: Hearing Before the Subcomm. on Regul. Reform, Com. and Antitrust L. of the H. Comm. on the Judiciary*, 115th Cong. (July 27, 2017).

91. See CREATES Act, in *Further Consolidated Appropriations Act, 2020*, Pub. L. No. 116-94, § 610, 133 STAT. 2534, 3130 (2019).

92. See generally JOHN PALFREY & URS GASSER, *INTEROP: THE PROMISE AND PERILS OF HIGHLY INTERCONNECTED SYSTEMS* 1–18 (2012) (discussing the theory of interoperability); 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.

93. See Duan, *supra* note 92, at 258–61.

94. 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> [<https://perma.cc/8JLK-CX2Y>]; 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).

95. See, e.g., Jon Porter, *EU Proposes Mandatory USB-C on All Devices, Including iPhones with the Aim of Reducing E-Waste*, THE VERGE (Sept. 23, 2021, 7:26 AM), <https://www.theverge.com/2021/9/23/22626723/eu-commission-universal-charger-usb-c-micro-lightning-connector-smartphones> [<https://perma.cc/222P-QZVM>]; *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1207–08 (Fed. Cir. 2014); *Microsoft Corp. v. Motorola, Inc.*, 795 F.3d 1024, 1030 (9th Cir. 2015).

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

97. See, e.g., Mark A. Lemley, *Intellectual Property Rights and Standard-Setting Organizations*, 90 CALIF. L. REV. 1889, 1901–03 (2002); A. Douglas Melamed & Carl Shapiro,



mandatory but widely used, this tension has been central to major disputes.<sup>98</sup> In the decade-long feud between Oracle and Google,<sup>99</sup> 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.<sup>100</sup> 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.<sup>101</sup>

Patents on standards are no less contentious. 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.<sup>102</sup> But what satisfies the FRAND obligation<sup>103</sup> 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<sup>104</sup> and literature.<sup>105</sup> The Department of Justice (DOJ)

Collection: Unlocking Trust Enforcement, *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).

98. See generally JONATHAN BAND, INTERFACES ON TRIAL 3.0: GOOGLE V. ORACLE AMERICA AND BEYOND 5–13 (2021), <http://dx.doi.org/10.2139/ssrn.2876853> [<https://perma.cc/VF7V-5A9Q>] (describing history of interoperability litigation).

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

100. See generally 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/> [<https://perma.cc/SZ3Q-MP6Z>] (discussing amicus briefs filed in *Google*).

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

102. 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).

103. 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); see generally U.S. DEP'T OF JUST. & FED. TRADE COMM'N, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION (2007), <http://www.usdoj.gov/atr/public/hearings/ip/222655.pdf> [<https://perma.cc/2NF6-2C5J>] (discussing anticompetition concerns).

104. 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).

105. See generally, e.g., J. Gregory Sidak, *The Meaning of FRAND, Part II: Injunctions*, 11 J. COMPETITION L. & ECON. 201 (2015) (analyzing how a FRAND commitment affects enforcement of patent rights); Anne Layne-Farrar et al., *Pricing Patents for Licensing in Standard-Setting Organizations: Making Sense of FRAND Commitments*, 74 ANTITRUST L.J. 671 (2007) (evaluating the meaning of FRAND licensing); Herbert Hovenkamp, *FRAND and Antitrust*, 105 CORNELL L. REV. 1683 (2020), [https://scholarship.law.upenn.edu/faculty\\_](https://scholarship.law.upenn.edu/faculty_)

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.<sup>106</sup>

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 dealt many times with IP and interoperability standards.<sup>107</sup> 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.<sup>108</sup> In that 1996 rulemaking, and another one in 2008, the agency acknowledged the potentially problematic role of patents on the mandatory ATSC standard

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scholarship/2093 [https://perma.cc/XG2N-FYLB] (discussing when violations of FRAND commitments amount to antitrust violations); 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) (tracing the “historical development of antitrust patent licensing orders and consider[ing] how they inform current debates regarding FRAND commitments in the standard-setting context”).

106. See U.S. DEP’T OF JUST. & U.S. PAT. & TRADEMARK OFF., 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> [https://perma.cc/H5QN-PSQT] (“A patent owner’s voluntary F/RAND commitments may also affect the appropriate choice of remedy . . . .”); U.S. PAT. & TRADEMARK OFF. ET AL., 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> [https://perma.cc/TL79-NXNJ] (withdrawing 2013 statement and finding that special approach to FRAND patents would “result[] in harm to innovation and dynamic competition”); U.S. PAT. & TRADEMARK OFF. ET AL., DRAFT POLICY STATEMENT ON LICENSING NEGOTIATIONS AND 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> [https://perma.cc/3T7D-ELR7] (“[S]eeking 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. PAT. & TRADEMARK OFF. ET AL., 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> [https://perma.cc/VR49-494E].

107. 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).

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

but declined to take action because ATSC had already required FRAND licensing.<sup>109</sup>

But are ATSC patent holders living up to their FRAND commitments? ATSC royalties are reportedly several times higher in the United States than in other nations.<sup>110</sup> Especially following allegations of a cozy relationship between a key ATSC patent holder and the former FCC chair,<sup>111</sup> the agency's inaction on patents has come under fire from commentators and members of Congress.<sup>112</sup> Nevertheless, as recently as 2020, the FCC has maintained its no-action policy, despite two commissioners' dissents.<sup>113</sup>

### 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

109. *See id.* at 17794 (“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 FCC Rcd. 16731, 16760 (Nov. 3, 2008) (“In cases where stations choose to use a patented technology, we expect that such use will be offered on RAND terms.”).

110. *See* Zack Christenson, Opinion, *Abuse from Patent Pools*, FORBES (May 14, 2014, 4:48 PM), <https://www.forbes.com/sites/realspin/2014/05/14/abuse-from-patent-pools/> [<https://perma.cc/J7PH-6TSV>]; 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> [<https://perma.cc/623T-DEQK>].

111. *See* Cecilia Kang, *F.C.C. Watchdog Looks into Changes That Benefited Sinclair*, N.Y. TIMES (Feb. 15, 2018), <https://www.nytimes.com/2018/02/15/technology/fcc-sinclair-ajit-pai.html> [<https://perma.cc/FVF8-EPLU>].

112. *See* Letter from Frank Pallone, Jr., House of Reps., et al., to Ajit V. Pai, Chairman, Fed. Comm’n’s Comm’n 5–6 (Aug. 14, 2017) (on file with the Federal Communications Commission) <https://docs.fcc.gov/public/attachments/DOC-346883A2.pdf> [<https://perma.cc/4NV7-G9DA>]; Letter from Mike Pompeo, House of Reps., to Tom Wheeler, Chairman, Fed. Comm’n’s Comm’n (Oct. 27, 2014) (on file with the Federal Communications Commission) <https://docs.fcc.gov/public/attachments/DOC-330841A2.pdf> [<https://perma.cc/K9H8-AX32>]; 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/> [<https://perma.cc/A2QP-M7A6>].

113. *See* Second Report and Order on Reconsideration, 35 F.C.C. Rcd. 6793, 6823–24 (2020) (affirming Authorizing Permissive Use of the “Next Generation” Broadcast Television Standard, 83 Fed. Reg. 4498, 5016 (Feb. 2, 2018) (“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 in part) (“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 in part) (“[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.”).

(Hatch–Waxman).<sup>114</sup> Since the generic must be equivalent to an already approved drug (called the “listed drug”<sup>115</sup>), Hatch–Waxman requires any labeling or marketing materials for the generic to be “the same as the labeling approved for the listed drug.”<sup>116</sup> 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.<sup>117</sup> Accordingly, both Congress and the FDA have contemplated only minor, trivial exceptions to the expectation that generic and listed drug labels be the same.<sup>118</sup>

But what happens if the listed drug’s labeling text is copyrighted?<sup>119</sup> In the case *SmithKline Beecham Consumer Healthcare, LP v. Watson Pharmaceuticals, Inc.*,<sup>120</sup> the manufacturer of Nicorette gum asserted copyright protection on its labels and user guides against generic entrants required to use those labels and guides in the FDA approval process.<sup>121</sup> If successful, the copyright claim would have blocked generic competition on Nicorette even after the patents on the gum had expired.<sup>122</sup> Balancing

114. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, § 101, 98 Stat. 1585 (amending the Federal Food, Drug, and Cosmetic Act (FFDCA), Pub. L. 75-717, 52 Stat. 1040 (1938)) (codified as amended at 21 U.S.C. § 355(j)).

115. See Federal Food, Drug & Cosmetics Act (FFDCA) § 505, 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).

116. See FFDCA § 505(j)(2)(A)(v) (codified as amended at 21 U.S.C. § 355).

117. See Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17950, 17961 (Apr. 28, 1992) (“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> [<https://perma.cc/VQH3-8HWA>] (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)).

118. See 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. § 314.94(a)(8)(iv) (listing permissible labeling changes); Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872, 28884 (July 10, 1989) (“The [FDA] will not accept ANDA’s for products with significant changes in labeling . . .”).

119. On copyrightability of product labels, see generally Zvi S. Rosen, *Reimagining Bleistein: Copyright for Advertisements in Historical Perspective*, 59 J. COPYRIGHT SOC’Y USA 347 (2012).

120. 211 F.3d 21 (2d Cir. 2000).

121. See *id.* at 23–24.

122. See *id.*

the competing injustices of frustrating generic competition on an off-patent drug and ignoring the “more than one million dollars” spent on developing Nicorette labeling forced the district court and the FDA into tense negotiations, and led the U.S. Court of Appeals for the Second Circuit to alter the scope of copyright law in light of Hatch–Waxman.<sup>123</sup>

*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.”<sup>124</sup> In two cases, courts held that this same-labeling requirement does not conflict with copyright law because the statutory command “does not require a me-too applicant to ensure that its product label is identical to a registered label.”<sup>125</sup> The courts essentially put the ball in the EPA’s court to decide how to interpret “identical or substantially similar in . . . labeling” without treading on copyright law’s prohibition on substantial similarity.<sup>126</sup>

Lest these cases suggest the problem is limited to copyright law, consider the recent *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA* decision.<sup>127</sup> There, a divided Federal Circuit panel held that a generic drug maker’s FDA-approved label could induce infringement of a patented method of using a drug based on fragments of text in the label’s section on dosing and administration.<sup>128</sup> 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-

123. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 63 F. Supp. 2d 467, 469 (S.D.N.Y. 1999), *opinion amended by* 211 F.3d 21 (2d Cir. 2000); *see SmithKline*, 211 F.3d at 23–24; *infra* Section II.B.

124. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), § 3(c)(3)(B)(i)(I) (codified as amended at 7 U.S.C. § 136a).

125. *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) (finding no support for the proposition that the EPA forced applicants to use the same wording as previously registered labels).

126. *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”).

127. 7 F.4th 1320 (Fed. Cir. 2021) (per curiam) (petition for certiorari filed July 11, 2022).

128. *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).

labeling requirement.<sup>129</sup> 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.<sup>130</sup> Modifications to dosage and administration would seem to strike at the heart of safety,<sup>131</sup> leaving generics in the dark about how to comply with both Hatch–Waxman and patents. “The only clear thing now,” wrote dissenting Judge Sharon Prost, “is that no generic can know until hit with the bill whether it’s staying within the confines of the law.”<sup>132</sup>

IP cases involving mandatory labels 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.”<sup>133</sup> The government itself has vigorously opposed copyright assertion in mandatory labels, saying of the pesticide cases that “copyright liability on me-too manufacturers would thwart [the statutory] expedited-review

129. See *id.* at 1329; 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. 29, 2021) (Nos. 2018-1976, -2023).

130. See Federal Food, Drug, and Cosmetics Act (FFDCA) § 505(j)(2)(A)(viii), 21 U.S.C. § 355(j)(2)(A)(viii) (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 & RSCH., FDA, ANDA SUBMISSIONS—REFUSE-TO-RECEIVE STANDARDS: GUIDANCE FOR INDUSTRY 13 (2d rev. Dec. 2016), <https://www.fda.gov/media/86660/download> [<https://perma.cc/5QPZ-2MNT>] (“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.”).

131. See THEOPHRAST VON HOHENHEIM [PARACELTUS], SIEBEN DEFENSIONES [SEVEN DEFENSES] 25 (Karl Sudhoff ed., Verlag von Johann Ambrosius Barth 1915) (1538), <https://catalog.hathitrust.org/Record/100160006> [<https://perma.cc/RXK7-MJDD>] (“[A]llein die Dosis macht, daß ein Ding kein Gift ist.” [“The dose alone makes a thing not a poison.”]).

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

133. 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/> [<https://perma.cc/V6HQ-L2JV>]; see David Wallace, *Blow for Industry as GSK–Teva ‘Skinny Label’ Decision Upheld*, PINK SHEET (Aug. 6, 2021), <https://pink.pharmaintelligence.informa.com/PS144765/Blow-For-Industry-As-GSK-Teva-Skinny-Label-Decision-Upheld> [<https://perma.cc/25P7-W4A7>]; Ian Lopez, *Teva ‘Skinny Label’ Ruling Comes Amid Lawmaker Drug Cost Fight*, BLOOMBERG L. (Aug. 6, 2021, 3:24 PM), <https://news.bloomberg.com/health-law-and-business/teva-skinny-label-ruling-comes-amid-lawmaker-drug-cost-fight> [<https://perma.cc/ZZL3-NTEY>] (citing experts’ belief that the decision will lead to manufacturers being more careful which will paradoxically lead to more induced infringement); 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, 9:35 AM), <https://www.fiercepharma.com/pharma/court-reaffirms-235m-judgement-for-gsk-against-generic-manufacturer-teva-skinny-label-case> [<https://perma.cc/X2NG-5NSQ>] (acknowledging the Federal Circuit’s recognition of the confusion created by the ruling).

scheme for generic pesticides.”<sup>134</sup> That controversy is unsurprising. The cases discussed above exemplify 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.<sup>135</sup> But as the administrative state developed during the twentieth century, legislatures and agencies increasingly relied on external experts as law drafters. 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; states and 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.”<sup>136</sup> The latter technique is ubiquitous today: the National Institute of Standards and Technology reports over 24,000 standards incorporated by reference in federal regulations,<sup>137</sup> and the National Technology Transfer and Advancement Act of 1995<sup>138</sup> requires agencies to use privately developed standards in regulations by default.<sup>139</sup> Does copyright protect these legally mandated model codes and standards? The standards developers vigorously argue that it does, but the implication is that the

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134. 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. 2019) (No. 2018-1614); *see also* Brief for the United States as Amicus Curiae at 8, *SmithKline Beecham Consumer Healthcare, LP v. Watson Pharms., 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> [<https://perma.cc/2QQ6-N5RQ>] (arguing that copyright law is not a “basis for preventing the operation of the same-labeling requirement in the Hatch–Waxman Amendments”).

135. *See* *Wheaton v. Peters*, 33 U.S. (8 Pet.) 591, 668 (1834); *Banks v. Manchester*, 128 U.S. 244, 253 (1888); *Callaghan v. Myers*, 128 U.S. 617, 662 (1888).

136. *See generally* Peter L. Strauss, *Private Standards Organizations and Public Law*, 22 WM. & MARY BILL RTS. J. 497, 524–25 (2013) (noting congressional delegation of rulemaking power to OSHA, the Consumer Product Safety Commission, and NIST).

137. *Standards Incorporated by Reference (SIBR) Database*, NAT’L INST. STANDARDS & TECH., <https://sibr.nist.gov/> [<https://perma.cc/9XCW-PYXP>].

138. *See* Pub. L. No. 104-113, 110 Stat. 775 (1996).

139. *See id.* § 12(d)(1), 110 Stat. at 783; Emily S. Bremer, *Incorporation by Reference in an Open-Government Age*, 36 HARV. J.L. & PUB. POL’Y 131, 134–35 (2013).

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.<sup>140</sup> In 2011, the Administrative Conference of the United States expressed concerns that copyrights in incorporated legal texts were “particularly problematic” and recommended that agencies make greater efforts to require public access.<sup>141</sup> In 2012, Congress required that incorporated-by-reference pipeline safety standards be “made available to the public, free of charge,”<sup>142</sup> apparently in response to one congressional office being asked to pay \$1,000 for a copy of a mandatory standard.<sup>143</sup> 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.<sup>144</sup> The petition attracted at least 162 comments, many in support of increasing access to incorporated standards.<sup>145</sup> Yet the OFR refused to impose the requirement, in part claiming that the agency lacked the resources and authority to overcome copyright interests.<sup>146</sup>

Several courts have considered whether copyright law can preclude access to mandatory legal texts. *Building Officials & Code Administrators v. Code Technology, Inc.*<sup>147</sup> 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.<sup>148</sup> By contrast, *Practice Management Information Corp. v. American Medical Ass’n*<sup>149</sup> 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.<sup>150</sup> In *Veeck v. Southern Building Code Congress International*,

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140. See, e.g., Strauss, *supra* note 136, at 507; Lawrence A. Cunningham, *Private Standards in Public Law: Copyright, Lawmaking and the Case of Accounting*, 104 MICH. L. REV. 291, 294 (2005).

141. See Adoption of Recommendations, 77 Fed. Reg. 2257, 2257–58 (Jan. 17, 2012).

142. 49 U.S.C. § 60102(p).

143. See Bremer, *supra* note 139, at 175.

144. See Letter from Peter L. Strauss et al. to Off. of the Fed. Reg. 1, 4 (Feb. 10, 2012), <https://downloads.regulations.gov/NARA-12-0002-0002/content.pdf> [<https://perma.cc/A5G7-KYTY>], reprinted in Incorporation by Reference, 77 Fed. Reg. 11,414, 11,414–11,416 (Feb. 27, 2012); Strauss, *supra* note 136, at 530.

145. See Strauss, *supra* note 136, at 531–33.

146. See Incorporation by Reference, 79 Fed. Reg. 66,267, 66,268, 66,273 (Nov. 7, 2014).

147. 628 F.2d 730 (1st Cir. 1980).

148. *Id.* at 736.

149. 121 F.3d 516 (9th Cir. 1997), amended by, 133 F.3d 1140 (1998).

150. *Id.* at 518–19, 521. 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.



*Inc.*,<sup>151</sup> the U.S. Court of Appeals for the Fifth Circuit held incorporated model building codes to be uncopyrightable “facts” once they had been adopted as law.<sup>152</sup> The court was 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,”<sup>153</sup> 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.”<sup>154</sup>

Most recently, the organization Public.Resource.Org engaged in collecting and distributing federally incorporated private standards with the expectation that *Veck* protected such activity.<sup>155</sup> Public.Resource.Org nevertheless triggered high-profile copyright infringement lawsuits in 2013 and 2014.<sup>156</sup> The case, *American Society for Testing & Materials v. Public.Resource.Org, Inc. (ASTM)*, attracted dozens of amici curiae<sup>157</sup> and a strident concurring opinion comparing the use of copyright to the evils of the Roman emperor Caligula.<sup>158</sup> Yet the question remains unresolved: the U.S. Court of Appeals for the District of Columbia remanded *ASTM* to the district court for further factfinding,<sup>159</sup> which, as of this writing, is still ongoing.<sup>160</sup> 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 arguments in an adjudicatory proceeding.<sup>161</sup> If the work is both copyright protected and

151. 293 F.3d 791 (5th Cir. 2002).

152. *Id.* at 801.

153. *Id.* at 799.

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

155. 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 (2014), <https://www.govinfo.gov/app/details/CHRG-113hhr86344/CHRG-113hhr86344> [<https://perma.cc/YV5Y-6NE8>] (statement of Carl Malamud, President, Public.Resource.Org).

156. See *Am. Soc’y for Testing & Materials v. Public.Resource.Org, Inc. (ASTM)*, 896 F.3d 437, 441, 444 (D.C. Cir. 2018).

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

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

159. See *id.* at 458.

160. See *Am. Soc’y for Testing & Materials v. Public.Resource.Org, Inc.*, No. 1:13-cv-01215-TSC-DAR, 2022 WL 971735, at \*1 (D.D.C. Mar. 31, 2022), *appeal filed*, No. 22-7063 (D.C. Cir. June 3, 2022). 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 *id.*

161. See generally David Kluff, “*The Weakest Infringement Claims of All Time*”??? Patent Prosecution and the Physics of Fair Use, TRADEMARK & COPYRIGHT L. BLOG (Apr. 30, 2012),

necessary to secure or vindicate legal rights in the proceeding, then using the work is mandatory infringement. In *Jartech, Inc. v. Clancy*,<sup>162</sup> for example, city council members surreptitiously photographed a showing of a pornographic film to shut down the theater per the city's nuisance abatement ordinance.<sup>163</sup> The film producers (who also owned the theater) sued the city council for copyright infringement because of the photographs.<sup>164</sup> Because the photographs were made "not for subsequent use and enjoyment, but for evidence to be used in the nuisance abatement proceedings," the U.S. Court of Appeals for the Ninth Circuit held the city council's actions to be fair use and thus noninfringing.<sup>165</sup> Courts have similarly found no infringement based on copying works to prepare expert testimony,<sup>166</sup> to investigate defenses during litigation,<sup>167</sup> or to prove a parent's unsuitability for child custody.<sup>168</sup> A leading copyright treatise finds it "inconceivable" that reproduction of a work in the course of a judicial proceeding would constitute copyright infringement,<sup>169</sup> and one might wonder why there is not a simple doctrinal path for quickly dismissing cases like these.

Copyright-protected texts also are sometimes required for regulatory compliance. *Gulfstream Aerospace Corp. v. Camp Systems International, Inc.*<sup>170</sup> held that copyright law could not preclude an aircraft maintenance business from making copies of the airplane manufacturer's manuals to perform government-mandated repairs.<sup>171</sup> The court feared that enforcing copyright in the manuals would let the manufacturer "gain a judicially enforced monopoly" in the repair market.<sup>172</sup> 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

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<https://www.trademarkandcopyrightlawblog.com/2012/04/the-weakest-infringement-claims-of-all-time-patent-prosecution-and-the-physics-of-fair-use/> [<https://perma.cc/3JLL-XJYF>] (recognizing that patent prosecutors generally must include copyrighted material as evidence in their filings with the United States Patent and Trademark Office).

162. 666 F.2d 403 (9th Cir. 1982).

163. *See id.* at 405.

164. *See id.*

165. *Id.* at 407–08.

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

167. *See* Healthcare Advocs., Inc. v. Harding, Earley, Follmer & Frailey, 497 F. Supp. 2d 627, 637 (E.D. Pa. 2007).

168. *See* Bond v. Blum, 317 F.3d 385, 395 (4th Cir. 2003), *abrogated on other grounds by* Kirtsaeng v. John Wiley & Sons, Inc., 579 U.S. 197, 200 (2016).

169. *See* 4 MELVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 13.05[D][2] (Matthew Bender, rev. ed. 2022) [hereinafter NIMMER].

170. *See* 428 F. Supp. 2d 1369 (S.D. Ga. 2006).

171. *See id.* at 1371, 1376, 1381.

172. *Id.* at 1380.

foreign patent laws required them to do; patent attorneys breathed a sigh of relief when the courts found no infringement.<sup>173</sup>

Sometimes the mandate is not so obvious. In the case *Georgia v. Public.Resource.Org, Inc.*,<sup>174</sup> the Supreme Court considered whether state-authored annotations to the official code of laws were subject to copyright protection, such that reproducing the entire official code was prohibited.<sup>175</sup> The courts sharply divided on this question: a 5–4 Supreme Court majority and the U.S. Court of Appeals for the Eleventh Circuit found that no copyright protection inhered,<sup>176</sup> while the district court and dissenting Justices disagreed.<sup>177</sup>

Mandatory infringement offers one framework for understanding *Public.Resource.Org*. The dissents primarily focused on the fact that the nonbinding official annotations “do not even purport to embody the will of the people because they are not law.”<sup>178</sup> Chief Justice John Roberts, for the majority, replied that the dissents’ understanding of the annotations “undersells their practical significance.”<sup>179</sup> 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 Antonin Scalia, a skeptic of legislative history, conceded that “[s]ince most judges use legislative history, . . . you must use legislative history as well.”<sup>180</sup> Thus, Chief Justice Roberts observed 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

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173. See, e.g., *Am. Inst. of Physics v. Schwegman, Lundberg & Woessner, P.A.*, No. 0:12-cv-528, 2013 WL 4666330, at \*10, \*19 (D. Minn. Aug. 30, 2013) (“[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.”); David Kluff, *Copyright Claims Based on Submission of Prior Art to Patent Office Finally Dismissed: Were They the “Weakest Infringement Claims of All Time”?*, TRADEMARK & COPYRIGHT L. BLOG (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/> [<https://perma.cc/USB4-7HGL>].

174. 140 S. Ct. 1498 (2020).

175. See *id.* at 1503–04.

176. See *id.* at 1504–06.

177. See *id.* at 1505 (describing the district court’s opinion); *id.* at 1517 (Thomas, J., dissenting).

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

179. *Id.* at 1512.

180. ANTONIN SCALIA & BRYAN A. GARNER, *MAKING YOUR CASE: THE ART OF PERSUADING JUDGES* 49 (2008).

unconstitutional.<sup>181</sup> Justice Clarence Thomas’s rejoinder that one could glean the same information from the case reports did not answer Chief Justice Roberts’s point under this interpretation.<sup>182</sup> The case law alone cannot make citizens “assured” that the legislature has accepted the unconstitutionality of its laws.<sup>183</sup> Citizens need access to nonbinding legislative works, so that they can make legislative intent arguments and thus effectively participate in the legal process.

While most of the examples of mandatory infringement have affected limited populations of regulated entities—asthma patients, oil refineries, information technology developers, and 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 necessary 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,<sup>184</sup> billions of dollars of raised gas prices,<sup>185</sup> and inflated prices for out-of-date building codes and standards.<sup>186</sup> 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<sup>187</sup> and Celgene’s database patent of questionable inventiveness having similar anticompetitive effects.<sup>188</sup> 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.<sup>189</sup>

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181. *Public.Resource.Org, Inc.*, 140 S. Ct. at 1512, 1513.

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

183. *See id.* at 1512.

184. *See supra* Section I.A.

185. *See Unocal I*, 138 F.T.C. 1, 111–12 (2004); *supra* Section I.B.

186. *See* Strauss, *supra* note 136, at 509–10; *cf.* Emily S. Bremer, *On the Cost of Private Standards in Public Law*, 63 U. 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). Professor Bremer’s study is discussed *infra* text accompanying notes 440–44.

187. *See* SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc., 211 F.3d 21, 24 (2d Cir. 2000); *supra* text accompanying notes 116–19.

188. *See supra* note 88 and accompanying text.

189. *See supra* Section I.G.

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, such as the American Medical Association (AMA), will lobby intensely and exploit political connections to secure regulatory mandates on their holdings.<sup>190</sup> Indeed, IP holders have engaged in extreme—even criminal—behavior to secure mandates on their holdings.<sup>191</sup>

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.<sup>192</sup> The dueling judicial opinions on legal text copyrights and drug-label patent infringement reveal similar uncertainty.<sup>193</sup> Nor does the commentary reach consensus. In environmental law, for example, some scholars have described the possibility of a mandate to use patented technology as a “doomsday scenario,” while others envision it as a “catalyst for innovation.”<sup>194</sup>

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190. See *supra* note 150 (discussing *Prac. Mgmt. Info. Corp. v. Am. Med. Ass’n*, 121 F.3d 516, 521 (9th Cir. 1997)); see also *supra* notes 110–13 and accompanying text (discussing the close relationship of an IP holder and a regulatory agency).

191. See *supra* text accompanying notes 50–53 (discussing criminal fraud in product hopping).

192. Compare *SmithKline*, 211 F.3d at 29 (rejecting a manufacturer’s claim of copyright infringement for generic drug labeling where the copying was required), with *Syngenta Crop Prot., L.L.C. v. Willowood, L.L.C.*, 944 F.3d 1344, 1357 (Fed. Cir. 2019) (finding validity for copyright infringement where the infringer could create an “independently created label”).

193. Compare *Am. Soc’y for Testing & Materials v. Public.Resource.Org, Inc.*, No. 1:13-cv-1215-TSC, 2017 WL 473822 at \*24–25 (D.D.C. Feb. 2, 2017) (barring distribution and use of copyrighted standards), *vacated in part, rev’d in part*, 896 F.3d 437 (D.C. Cir. 2018), and *GlaxoSmithKline L.L.C. v. Teva Pharm. USA*, 7 F.4th 1320, 1327 (Fed. Cir. 2021) (per curiam) (finding that the partial copying of a drug label was an infringing use), *petition for cert. filed*, No. 22-37 (U.S. July 11, 2022), with *ASTM*, 896 F.3d at 458 (reversing the district court’s finding of infringement), and *GlaxoSmithKline*, 7 F.4th at 1342–43 (Prost, J., dissenting) (disagreeing with the majority’s decision to affirm liability for an infringing use).

194. Compare Gollin, *supra* note 16, at 219 n.128 (discussing that a mandate will preclude the use of technology due to excessive costs), and Adam Gunderson, Comment, *Protecting the Environment by Addressing Market Failure in Intellectual Property Law: Why Compulsory Licensing of Green Technologies Might Make Sense in the United States: A Balancing Approach*, 2014 BYU L. REV. 671, 672 (expressing concern about “[p]atent suppression” of desirable environmental technologies), with Ofer Tur-Sinai, *Patents and Climate Change: A Skeptic’s View*, 48 ENV’T. L. 211, 258 (2018) (describing an increase in innovation by implementing a mandate), Derzko, *supra* note 20, at 21 (arguing that a mandate to use patented technology can make it “advantageous to develop a new environmental technology”), 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”), and Paul Gormley, Comment, *Compulsory Patent Licenses and Environmental Protection*, 7 TUL. ENV’T. L.J. 131, 143–45 (1993) (describing IP holders’ incentives to withhold access to environmental

What gives the case studies of mandatory infringement these common themes of public harm, private attractiveness, and decisional uncertainty? It may be tempting to simply 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.<sup>195</sup> A more general explanation of these themes beyond particular cases or actors is 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 this Article now turns.

## II. A THEORY OF HARM

The harmfulness, attractiveness, and undecidability observed in mandatory infringement are best explained as consequences of the mechanics of the regulation–IP overlap. While there is nothing inherently incompatible between regulation and IP rights,<sup>196</sup> and indeed IP law itself is in a sense a regulatory system,<sup>197</sup> 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, rent-seeking behavior, and government offloading of IP acquisition costs to regulated entities.

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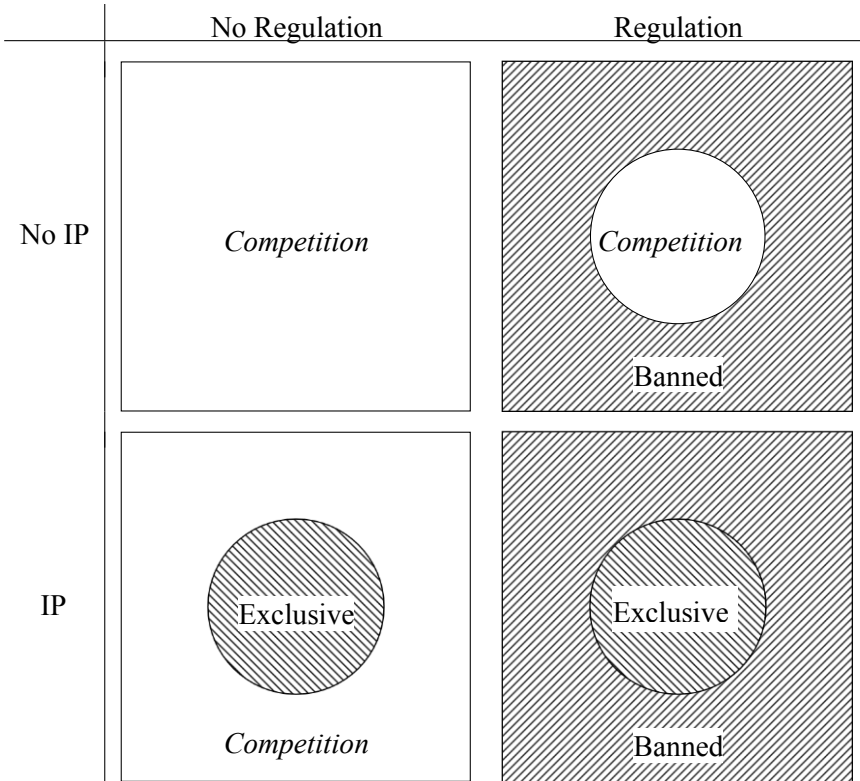
technologies). Curiously, these positions do not correlate with the authors' views on patents generally: those finding mandatory infringement potentially desirable are skeptical of patents to varying degrees, and the critics are generally favorable to patents. *See, e.g.*, Tur-Sinai, *supra*, at 214–15; 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.

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

196. 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).

197. *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 (2007) (proposing treatment of patent law akin to other regulatory regimes).

**Figure 1**



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

### 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 competition across the entire space, such that consumers may enjoy diverse choices among products or services that meet their needs.<sup>198</sup> The space is not infinite; rather, it is bounded by a market definition of “commodities reasonably interchangeable by consumers for the same purposes.”<sup>199</sup>

IP rights demarcate a region of the competitive space and give the IP holder temporary exclusivity there (Figure 1, bottom left).<sup>200</sup> Patents contain textual claims that specify their boundaries and exclude others from acting within those boundaries.<sup>201</sup> Copyright protection does not define a boundary explicitly but excludes exact copies as well as derivative works that are often demarcated by a test of substantial similarity.<sup>202</sup> IP rights thus exclude competitors from perfect or close substitutes to the protected work or technology, but they 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.<sup>203</sup> “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

198. 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).

199. *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: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION* ¶ 533e (5th ed. 2022 Cum. Supp.) (defining the limit of the market as commodities not reasonably interchangeable by consumer for the same purpose).

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

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

202. *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, 746–48 (2009) (explaining the test for substantial similarity).

203. *See, e.g.*, Edmund W. Kitch, *Elementary and Persistent Errors in the Economic Analysis of Intellectual Property*, 53 *VAND. L. REV.* 1727, 1730, 1734 (2000); Lemley, *supra* note 200, at 996 n.26; Yoo, *supra* note 198, at 219; 2 AREEDA & HOVENKAMP, *supra* note 199, ¶ 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).



substitutes for such product, process, or work to prevent the exercise of market power.”<sup>204</sup> Similarly, Congress amended the patent laws in 1988 to reject a presumption of market power in patent cases<sup>205</sup> because the presumption “prevents courts from considering whether there are substitute products for a patented product.”<sup>206</sup> These views led the Supreme Court in *Illinois Tool Works Inc. v. Independent Ink, Inc.*<sup>207</sup> 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.”<sup>208</sup> Imperfect-substitute competition effectively acts as a safety valve, ensuring that IP rights do not presumptively create market power.

Regulation also carves a region within this competitive space, but it excludes conduct *outside* (Figure 1, top right).<sup>209</sup> Hatch–Waxman forces all generic drugs to share common labeling,<sup>210</sup> for example, and the FCC’s adoption of the ATSC standard precludes television manufacturers from choosing competing broadcast protocols.<sup>211</sup> Activities permitted under a regulation will generally be similar in some respects, placing them close together in the competitive space.<sup>212</sup>

Despite constraining the competitive space, the expectation is that regulatory mandates still leave open a safety valve for competition and

204. U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY 4 (2017) (citing *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 45–46 (2006)), <https://www.justice.gov/atr/IPguidelines/download> [<https://perma.cc/AS4L-SSKW>].

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

206. S. REP. NO. 100-492, at 12 (1988).

207. 547 U.S. 28 (2006).

208. *Id.* at 45; see also *FTC 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”).

209. See 2 AREEDA & HOVENKAMP, *supra* note 199, ¶ 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 199.

210. See *supra* text accompanying notes 115–16.

211. See *supra* text accompanying notes 107–09.

212. A 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 vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419, 428–29 (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”).

do not inherently produce monopolies.<sup>213</sup> The FDA repeatedly accounted for concerns about generic competition in implementing the albuterol ban,<sup>214</sup> and the FCC specifically concluded that mandating a digital television standard “will encourage technological innovation and competition.”<sup>215</sup> Agencies are likely attuned to the competitive consequences of their actions because of a long line of economic criticism that firms can capture agencies to exclude competition, which has led to close scrutiny and oversight.<sup>216</sup> And where administrative agencies know that their actions 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.<sup>217</sup> Social-regulation agencies such as the FDA and the EPA do not have these economic regulation tools,<sup>218</sup> 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.

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213. See 2 AREEDA & HOVENKAMP, *supra* note 199, at ¶ 572b (“In general, the ongoing cost of regulatory compliance is not an entry barrier when equally applicable to old and new firms.”).

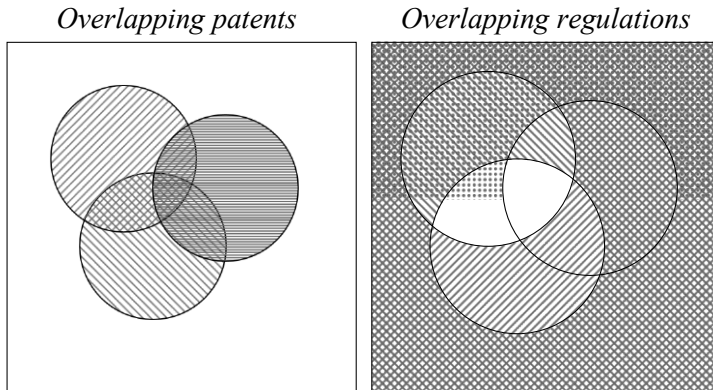
214. See *infra* note 265.

215. ATSC 1996, *supra* note 108, at 17789.

216. See, e.g., 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 affected by entry and therefore has an incentive to induce the agency to prevent new firms from entering the industry.”); BREYER, *supra* note 196, 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).

217. See VISCUSI ET AL., *supra* note 216, at 358–61.

218. See *Antitrust Concerns and the FDA Approval Process*, *supra* note 90, at 8 (testimony of Scott Gottlieb, Commissioner, FDA) (“FDA doesn’t oversee any aspect of drug pricing as part of our regulatory mandate . . . .”); see generally VISCUSI ET AL., *supra* note 216, at 5–8 (explaining the difference between economic and social regulation).

**Figure 2**

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

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).<sup>219</sup> Two regulations could overlap to exclude an entire market—one requires what the other prohibits—but chances are that an agency or court would be alerted to the conflict and fix it.<sup>220</sup> 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).<sup>221</sup> It is the

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

220. 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 . . .”).

221. For example, *Pom Wonderful L.L.C. 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 (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

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 or ATSC-compliant televisions, for example. 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. Professor Melville B. Nimmer and Professor David Nimmer’s copyright treatise characterized 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.”<sup>222</sup> They optimistically predicted that “there is scant reason to be hospitable to the claim” of IP infringement<sup>223</sup>—whether their assessment is correct is the subject of Part 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.<sup>224</sup> 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.<sup>225</sup> 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

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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 118.

222. NIMMER, *supra* note 169, § 1.19[A][2].

223. *Id.*

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

225. *See, e.g.*, Prac. 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).

district court held an unusual conference with the FDA (which was not a party to the litigation) to persuade the agency to “revisit” its decision and accommodate copyright concerns.<sup>226</sup> The FDA refused, saying that it “had never been directed by Congress to consider potential copyright rights in approving generic drug labeling.”<sup>227</sup> By contrast, the court thought that the FDA “surely ha[d] 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.<sup>228</sup> Simply put, the agency expected the court to solve the problem by bending IP law, while the court expected the agency to solve it by bending regulations.

The regulator and the court confronting each other directly was unusual to *SmithKline* and observing the FDA passing the buck perhaps forced the district court to not pass it back: the court reversed its prior grant of a preliminary injunction, which the Second Circuit affirmed.<sup>229</sup> 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<sup>230</sup> (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.”<sup>231</sup> An agency’s failure to deal with mandated IP infringement would seem to fit this test, and yet the only APA challenge one might find to the agencies’ 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.<sup>232</sup> 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–

226. See *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharm., Inc.*, 2000 Copyright L. Dec. (CCH) ¶ 28,036, at 32,149, 32,152 (S.D.N.Y. 1999).

227. *Id.* at 32,152 (quoting FDA letter to court) (internal alterations omitted).

228. *Id.* at 32,154, 32,154 n.3.

229. See 211 F.3d 21, 23 (2d Cir. 2000).

230. Pub. L. No. 79-404, 60 Stat. 237 (1946) (codified as amended at 5 U.S.C. § 500).

231. *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) (discussing the scope of judicial review of arbitrary or capricious agency action); *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971) (noting need for agency to “consider[] the relevant factors”), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99, 105 (1977); *Nat’l Audubon Soc’y v. Hoffman*, 132 F.3d 7, 17–18 (2d Cir. 1997) (evaluating an action of the Forest Service under the arbitrary or capricious standard).

232. *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 107–13 (discussing controversies that arise when the government mandates interoperability standards).

benefit findings that could have served as the basis for judicial review.<sup>233</sup> 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.<sup>234</sup>

### 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-à-vis the competition: "the greater the usefulness the greater the reward."<sup>235</sup> 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.<sup>236</sup> Knowing this, an innovator would ordinarily not invest in marginal improvements that do not provide consumers with value.

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233. See *supra* note 109 (discussing regulatory standards concerning patented technology). 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) (noting however 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, 313, 314 n.8 (3d Cir. 2007) (noting applicability of patent reasonable-royalty test to construction of FRAND obligation).

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

235. 2 JOHN STUART MILL, *PRINCIPLES OF POLITICAL ECONOMY WITH SOME OF THEIR APPLICATIONS TO SOCIAL PHILOSOPHY* 498 (1848), <https://catalog.hathitrust.org/Record/001308505> [<https://perma.cc/5C7F-QZQQ>] (justifying preference for patents over government rewards); see, e.g., Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 *YALE L.J.* 544, 548 (2019) (discussing preference for IP over "government-set rewards"); Carrier & Shadowen, *supra* note 35, at 181–82 & nn.69–71 (discussing how patents may fare in a competitive market); 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, which are "not systematically inadequate").

236. See *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 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)); see also Dennis W. Carlton et al., *Does the FTC's Theory of Product Hopping Promote Competition?*, 12 *J. COMPETITION L. & ECON.* 495, 504 (2016) (discussing the behavior of potential buyers in the market of new generic products); 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, 211 (2019) (noting that "a generic company could . . . market its own products" while observing complications).

But making the 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.<sup>237</sup> In the context of de facto mandatory interoperability standards, this well-known value-increase phenomenon is often called “hold-up.”<sup>238</sup> 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.<sup>239</sup> Market forces give private, standard-setting organizations incentives to select technologies and IP to standardize based on costs and quality, while the government lacks such incentives.<sup>240</sup> And in many cases, the regulatory scheme associated with mandatory infringement also requires 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.<sup>241</sup>

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.<sup>242</sup> Thus, Reckitt Benckiser lobbied heavily for states to mandate use of its buprenorphine sublingual film, despite that product being potentially worse than the tablet

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237. See, e.g., *Apple, Inc. v. Motorola, Inc.*, 869 F. Supp. 2d 901, 913 (N.D. Ill. 2012) (distinguishing the “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.”), *rev’d in part on other grounds*, 757 F.3d 1286 (Fed. Cir. 2014); Joseph Farrell et al., *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 97, at 548 (discussing the three functions of “[s]tandard-setting organizations (SSOs)”).

238. See sources cited *supra* note 237 (discussing patents); *Google L.L.C. 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 94, at 25 (describing hold-up).

239. See generally SHAPIRO & VARIAN, *supra* note 237, at 261–96 (describing “standards wars”).

240. See *infra* Section II.D (discussing cost-offloading).

241. See *Antitrust Concerns and the FDA Approval Process*, *supra* note 90, 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 . . .”).

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

formulation.<sup>243</sup> 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 Professor Bernard Chao explained in the context of de facto compatibility standards, detaching IP value from technical merit can encourage "horizontal innovation[s]" that offer no consumer benefit, such as incompatible razor blade cartridge connectors or different-shaped computer connectors.<sup>244</sup>

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 development costs were "between \$250 and \$400 million per firm."<sup>245</sup> Yet experts estimated that the environmental benefit was small, and by one expert's estimate, any environmental damage from not enforcing the CFC ban would be repaired in "roughly another week."<sup>246</sup> And consider SmithKline Beecham's "more than one million dollars" spent on developing mandatory Nicorette labeling.<sup>247</sup> 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."<sup>248</sup> 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. Professor 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

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243. See *supra* Section I.A.

244. Bernard Chao, *Horizontal Innovation and Interface Patents*, 2016 WIS. L. REV. 287, 295–307.

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

246. Swenson, *supra* note 46, at 1867; see also Albuterol IV, *supra* note 245, at 33614 ("We believe that the direct benefits of this proposed regulation are small relative to the overall benefits of the Montreal Protocol.") (citing data from the United Nations).

247. See SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharm., Inc., 211 F.3d 21, 23 (2d Cir. 2000); *supra* text accompanying notes 121–23.

248. Cunningham, *supra* note 140, at 311, 311 n.98.



by the FDA.<sup>249</sup> But why did AHPA not push the FDA to update its regulations? It would seem that an updated, “must-have edition”<sup>250</sup> 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 regulatory compliance largely drives demand for *Herbs of Commerce*, 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 rulemaking process inefficiencies,<sup>251</sup> may in part also be an effect of mandatory infringement distorting incentives to commercialize innovation.

The incentive distortions resulting from rent-seeking are surprisingly pernicious. For example, commentators commonly argue 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.<sup>252</sup> 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 nominal changes, forcing students to buy new, higher priced copies rather than cheaper used ones.<sup>253</sup> 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

249. See Strauss, *supra* note 136, at 509–10.

250. See *id.* at 510 (quoting AHPA’s online bookstore).

251. See, e.g., Adoption of Recommendations, 77 Fed. Reg. 2257, 2258 (Jan. 17, 2012); Bremer, *supra* note 139, at 183–84.

252. See Brief of Amici Curiae American Society for Testing and Materials et al. at 24, Georgia v. Public.Resource.Org, Inc., 140 S. Ct. 1498 (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 to Tyler Ochoa (Feb. 19, 2001, 19:51 EST), <https://www3.wcl.american.edu/cni/0102/27972.html> [<https://perma.cc/RU5E-ZXZY>] (“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?”).

253. See KAITLYN VITEZ, THE STUDENT PUBLIC INTEREST RESEARCH GROUPS, OPEN 101: AN ACTION PLAN FOR AFFORDABLE TEXTBOOKS 1, 7 (2018), <https://studentpirgs.org/assets/uploads/archive/sites/student/files/reports/Open%20101%20-%20An%20Action%20Plan%20for%20Affordable%20Textbooks.pdf> [<https://perma.cc/35DS-4E4B>].

the quality of the works, and IP protection enables the author or inventor to recapture at least a portion of that value from those users.<sup>254</sup> IP law thus enables a Coasean allocation of property rights that enables bargaining between creators and users of works.<sup>255</sup>

Yet where regulation mandates the use of IP, there are two more players in the value equation: the public and the government, both of which take a share of the IP's value. Consider, for example, the Unocal gasoline patents.<sup>256</sup> 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—competing refineries bear the entire cost in the form of infringement liability.

The public's share could be justified as redistributive policy,<sup>257</sup> though sometimes puzzlingly. Why should albuterol-using patients bear the cost of a cleaner environment, intermediated by pharmaceutical industry profits?<sup>258</sup> But the government's unpaid share is the troubling one. It is odd enough 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.<sup>259</sup> In *Practice Management*, for example, a health care regulator made massive concessions to the AMA, agreeing to use its copyrighted medical coding system to the exclusion of all others, advertise the AMA's

254. 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*, 16 *INNOVATION POL'Y & ECON.* 53, 54 (Nat'l Bureau of Econ. Research ed., 2016); cf. Ted Sichelman, *Commercializing Patents*, 62 *STAN. L. REV.* 341, 358–61 (2010) (discussing and critiquing this “reward” theory of IP).

255. See Robert P. Merges, Comment, *Of Property Rules, Coase, and Intellectual Property*, 94 *COLUM. L. REV.* 2655, 2657 (1994).

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

257. See Theodore J. Lowi, *Four Systems of Policy, Politics, and Choice*, 32 *PUB. ADMIN. REV.* 298, 300 tbl.1 (1972).

258. See *infra* notes 277–80 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.

259. 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).

copyright, and “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.<sup>260</sup> 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.<sup>261</sup> 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

This Part considers contemporary approaches to mandatory infringement cases, including efforts by Congress to look to the future to aid in drafting the most robust regulations to avoid mandatory infringement cases. Additionally, this Part considers courts’ attempts to deal with mandatory infringement cases by using competition law and IP law. However, as this Part will demonstrate, 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. Ultimately, in Part IV, this Article will propose a solution that contains aspects of all three approaches but addresses the problems of buck-passing, rent-seeking, and cost-offloading directly.

#### 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, or mandating fair IP licensing. Some agencies, such as the EPA, have statutory authorization to compulsorily license patent rights,<sup>262</sup> and ancillary authority as a general matter might enable any agency to regulate patents affecting its domain.<sup>263</sup>

Yet the nature of mandatory infringement leads agencies to fail to address it, even when aware of the relevant IP rights and their statutory

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260. *Prac. Mgmt. Info. Corp. v. Am. Med. Ass’n*, 877 F. Supp. 1386, 1388–89 (C.D. Cal. 1994) (internal quotation omitted), *rev’d*, 121 F.3d 516 (9th Cir. 1997).

261. 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).

262. See Clean Air Act (CAA) § 308, 42 U.S.C. § 7608; 40 C.F.R. § 95.3 (2022).

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

authority. This is illustrated well in the albuterol inhaler regulation, so that situation is used as a case study here.<sup>264</sup>

*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 competition<sup>265</sup> but nevertheless asserted that it was “bound by existing patent and exclusivity laws with regard to the approval of generic versions of innovator products.”<sup>266</sup> Generic availability was controlled not by the FDA but “by U.S. patent laws” and other external forces.<sup>267</sup> The agency characterized its sole duty as implementing clean air laws that “mandate the phaseout of non-essential uses of CFCs” regardless of how “the phaseout . . . may affect the availability of generic products.”<sup>268</sup> Because of that duty, the FDA refused even to conduct a cost–benefit study despite calls to do so.<sup>269</sup>

Importantly, the FDA could not argue that it lacked authority to avoid mandating a patented technology because the agency could have delayed its regulation until a generic HFA inhaler was available.<sup>270</sup> The agency’s appeals to its statutory duties and its lack of patent capacity are thus better

264. The OFR’s rulemaking on incorporation by reference is a second useful case study on these three phenomena, so the Article discusses it in the footnotes.

265. *See, e.g.*, Albuterol II, *supra* note 44, at 47724 (committing to “consider the cost of alternative products” in view of public comments); *Metered Dose Inhaler Phaseout*, *supra* note 45, at 49 (statement of Dr. John Jenkins, Dir., Div. of Pulmonary Drug Prods., Ctr. for Drug Evaluation and Rsch.) (“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 17187–89 (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 245, at 33616; Albuterol V, *supra* note 3, at 17174–75.

266. *Metered Dose Inhaler Phaseout*, *supra* note 45, at 49.

267. Albuterol II, *supra* note 44, at 47733; *accord* Use of Ozone-Depleting Substances, 67 Fed. Reg. 48370, 48380 (Food & Drug Admin. July 24, 2002) (to be codified at 21 C.F.R. pt. 2) [hereinafter Albuterol III] (“When generic products become available is dictated by manufacturers’ decisions whether to produce a generic product, by U.S. patent laws, by the exclusivity provision of the act, by the approvability of any particular generic drug application, and by the manufacturers’ eligibility to receive ODS under the Montreal Protocol and the Clean Air Act.”); *see also* Albuterol V, *supra* note 3, at 17178 (“[W]e do not have the institutional expertise to evaluate patents . . .”).

268. Albuterol II, *supra* note 44, at 47736; *see* Albuterol V, *supra* note 3, at 17176.

269. Albuterol II, *supra* note 44, at 47733.

270. *Cf.* Albuterol III, *supra* note 267, at 48374 (requiring two approved CFC-free products as a prerequisite to banning CFC-containing inhalers).

understood as directing critics of the ban to the patent laws, not regulatory power.<sup>271</sup>

*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 were “between \$250 and \$400 million per firm.”<sup>272</sup> Because of those investments, the agency found that monopoly pricing on albuterol inhalers “not only reward[s] the developers of the HFA technology, but also would serve as a signal to potential developers of other environmentally benign technologies.”<sup>273</sup>

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 may have been repaired in “roughly another week.”<sup>274</sup> 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.<sup>275</sup> The FDA’s assumption about traditional patent incentives in a distorted mandatory-infringement market led the agency to credit 3M with far more innovative merit than it deserved.<sup>276</sup>

*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

271. See also Letter from Janet Woodcock, Director, Ctr. for Drug Evaluation & Rsch., Food & Drug Admin., to William Franzblau, Vice President, Legal Affairs, Prometheus Labs., Inc. (Oct. 7, 2013), [https://downloads.regulations.gov/FDA-2013-P-0572-0003/attachment\\_1.pdf](https://downloads.regulations.gov/FDA-2013-P-0572-0003/attachment_1.pdf) [<https://perma.cc/9UL5-X825>] (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). 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 referenced documents.” See *Incorporation by Reference*, 79 Fed. Reg. 66267, 66273 (Nov. 7, 2014).

272. Albuterol IV, *supra* note 245, at 33615.

273. *Id.* at 33614.

274. Swenson, *supra* note 46, at 1867; see also Albuterol IV, *supra* note 245, at 33614 (“We believe that the direct benefits of this proposed regulation are small relative to the overall benefits of the Montreal Protocol.”).

275. See Albuterol IV, *supra* note 245, at 33615.

276. Compare this to another case where, 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 *Incorporation by Reference*, 79 Fed. Reg. at 66272–73.

patients paying over \$40 more according to a 2015 study.<sup>277</sup> That cost bump outpriced an estimated five percent of adults and three percent of children with insurance—to say nothing of uninsured patients.<sup>278</sup> And despite the FDA’s predictions that competition would return as early as 2010,<sup>279</sup> 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.<sup>280</sup>

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.”<sup>281</sup> It thus solely focused on uninsured patients.<sup>282</sup> 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 a minuscule effect.<sup>283</sup>

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

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

278. See *id.* at 1176.

279. See Albuterol IV, *supra* note 245, at 33609–10 (expecting generic entry on HFA-134a inhalers between 2010 and 2015); see also Albuterol V, *supra* note 3, at 17183 n.12 (pushing estimates out until 2017 due to new patents).

280. See Rebecca Voelker, *Generic Albuterol Inhaler Approved*, 323 J. AM. MED. ASS’N 1887, 1887 (2020); see also Albuterol V, *supra* note 3, at 17191; Albuterol IV, *supra* note 245, at 33615 (estimating \$850 million a year in revenues for HFA-134a inhaler manufacturers due to generic ban).

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

282. See, e.g., Albuterol IV, *supra* note 245, 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).

283. See 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 (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*, 65 Fed. Reg. 24268, 24276 (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.

respond to them and craft regulations that mitigate undesirable market power.

### 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 are the federal antitrust laws, FTC authority, and related unfair competition laws.<sup>284</sup> The patent and copyright misuse doctrines similarly prohibit anticompetitive use of IP rights.<sup>285</sup> These competition laws seem relevant to mandatory infringement as a species of what leading commentators have called “[p]redation by abuse of governmental procedures,”<sup>286</sup> “regulatory gaming,”<sup>287</sup> or “cheap exclusion.”<sup>288</sup> And these laws have successfully resolved mandatory infringement cases.<sup>289</sup> In *Practice Management*, for example, the Ninth Circuit found copyright misuse where a federal agency's arrangement with the AMA to mandate a copyrighted medical coding system “gave the AMA a substantial and unfair advantage over its competitors,” and the court 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.”<sup>290</sup>

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.<sup>291</sup>

*IP as an antitrust exception.* Traditionally, IP has been treated as “an exception to the general rule against monopolies” under the competition laws.<sup>292</sup> 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.

284. See generally 2 AREEDA & HOVENKAMP, *supra* note 199, ¶¶ 300–02 (explaining the enforcement power of the FTC and its remedial doctrines).

285. 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).

286. ROBERT H. BORK, *THE ANTITRUST PARADOX: A POLICY AT WAR WITH ITSELF* 347 (1978).

287. Dogan & Lemley, *supra* note 41, at 687.

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

289. See e.g., *Unocal II*, 140 F.T.C. 123, 175 (2005); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 684–85 (E.D. Pa. 2014).

290. *Prac. Mgmt. Info. Corp. v. Am. Med. Ass'n*, 121 F.3d 516, 521 (9th Cir. 1997) (internal quotations omitted).

291. See generally *supra* Part II (analyzing the challenges of mandatory infringement).

292. *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 sources cited *supra* note 203.

First, the exception depends on imperfect substitute competition,<sup>293</sup> but regulation closes off that avenue of competition in mandatory infringement cases.<sup>294</sup> Second, courts justify the exception on the grounds that antitrust enforcement against IP rights might diminish incentives to innovate.<sup>295</sup> The rent-seeking distortion of mandatory infringement lessens this concern.<sup>296</sup>

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.<sup>297</sup> Courts and commentators have been skeptical of the doctrine as inconsistent with firms' general right of refusal to deal with rivals,<sup>298</sup> but have nevertheless suggested that antitrust law could require a monopolist to share, in some conditions, facilities that competitors cannot practically or reasonably duplicate.<sup>299</sup> 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.<sup>300</sup> 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 several cases, the Supreme Court has held that “a regulatory structure designed to deter and remedy anticompetitive harm” can make it “less plausible that the antitrust laws

293. See *supra* text accompanying notes 203–208.

294. See *supra* Section II.A; cf. 2 AREEDA & HOVENKAMP, *supra* note 199, ¶ 518e.1. (“[O]n some occasions a single patent or copyright *does* confer market power.”).

295. 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 omitted).

296. See *supra* Section II.C.

297. See *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 599, 605 (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)); 2 AREEDA & HOVENKAMP, *supra* note 199, ¶ 771a.

298. See, e.g., *Verizon Commc’ns Inc. v. L. Offs. of Curtis V. Trinko, LLP*, 540 U.S. 398, 407–08, 411 (2004).

299. *MCI Commc’ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1132–33 (7th Cir. 1983); 2 AREEDA & HOVENKAMP, *supra* note 199, ¶ 773a.

300. 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) (discussing the “essential facilities” doctrine where competitors of a monopoly are allowed access to the monopoly’s facilities when they are not easily duplicated); Joshua D. Sarnoff, *The Patent System and Climate Change*, 16 VA. J.L. & TECH. 301, 333 (2011) (discussing times when regulators forced patent-holders to license technologies).



contemplate . . . additional scrutiny” in the regulated space.<sup>301</sup> Since mandatory infringement, by definition, involves a regulatory structure, these principles could superficially weigh against antitrust enforcement, as some courts have held.<sup>302</sup>

Again, mandatory infringement cases should 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.”<sup>303</sup> The buck-passing and cost-offloading problems, however, suggest that agencies may not be diligent about managing competition.<sup>304</sup> As Professor 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.<sup>305</sup>

*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.<sup>306</sup> To the extent that an IP holder lobbies a regulator to mandate use of its intellectual property, this doctrine precludes treatment of that lobbying as grounds for a competition law violation.<sup>307</sup>

*Noerr–Pennington* was central to the Unocal gasoline regulation situation.<sup>308</sup> In its complaint of unfair competition, the FTC alleged that Unocal had misrepresented to California regulators that its proposed gasoline standards were “non-proprietary,” despite knowing it had

301. *Trinko*, 540 U.S. at 412; see *Credit Suisse Sec. (USA) LLC v. Billing*, 551 U.S. 264, 275–76 (2007) (finding that the “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)); see also *United States v. Nat’l Ass’n of Sec. Dealers, Inc.*, 422 U.S. 694, 734 (1975) (discussing the need for antitrust laws to enforce regulatory schemes); see generally 2 AREEDA & HOVENKAMP, *supra* note 199, ¶ 243d (defining “spheres in which antitrust law is fully displaced”) (internal quotes omitted).

302. See *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 687 (E.D. Pa. 2014) (discussing that the FDA’s authority over REMS “actually diminishes the need for antitrust scrutiny”); Carrier, *supra* note 271, at 38 & n.262.

303. 2 AREEDA & HOVENKAMP, *supra* note 199, ¶ 243d.

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

305. See, e.g., Michael A. Carrier, *Of Trinko, Tea Leaves, and Intellectual Property*, 31 J. CORP. L. 357, 365–66 (2006); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 70 (2009).

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

307. See Dogan & Lemley, *supra* note 41, at 719–21.

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

pending patent applications on those standards.<sup>309</sup> Unocal rebutted on factual grounds—it claimed that “non-proprietary” merely meant not confidential<sup>310</sup>—but more importantly on a *Noerr–Pennington* assertion that its representations before regulators were First Amendment–protected government petitioning activities.<sup>311</sup> The administrative law judge agreed with Unocal, holding that even if the company’s representations were untrue, the Supreme Court’s “broad view of *Noerr–Pennington* immunity” shielded Unocal’s representations from FTC scrutiny.<sup>312</sup>

With over sixty-two pages of analysis, the FTC reversed the administrative law judge.<sup>313</sup> 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*.<sup>314</sup> Misrepresentations may be “condoned in the political arena” but “not immunized when used in the adjudicatory process”<sup>315</sup> or before the Patent Office.<sup>316</sup> Based on these and other cases and considerations, the FTC found that Unocal’s misrepresentations were not immunized under *Noerr–Pennington*.<sup>317</sup>

Although the FTC found *Noerr–Pennington* overcome, its decision reveals 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.<sup>318</sup> More importantly, overcoming *Noerr–Pennington* requires 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 violation of a competition law.<sup>319</sup> For IP holders that do not go beyond

309. See *Unocal I*, 138 F.T.C. at 6.

310. See Answer of Resp’t Union Oil Co. of California 1–2, *Unocal I*, 138 F.T.C. 1 (2004), <https://www.ftc.gov/sites/default/files/documents/cases/2003/03/030321unocalanswer.pdf> [<https://perma.cc/3LRZ-KZLM>].

311. See *id.* at 3.

312. *Unocal I*, 138 F.T.C. at 165, 180 (emphasis added).

313. See *id.* at 17–78.

314. *Id.* at 22.

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

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

317. *Id.* at 72.

318. See Dogan & Lemley, *supra* note 41, at 719 (discussing *Unocal*’s inconsistency with *Rambus Inc. v. FTC*, 522 F.3d 456, 464–65 (D.C. Cir. 2008)).

319. 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.

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

Doctrines of IP law can also overcome mandatory infringement. Limitations on IP rights are constitutionally required<sup>320</sup> and often designed to prevent IP rights from overly encroaching on competition.<sup>321</sup> 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 untrammelled. These failures stem from the distinctive features of mandatory infringement<sup>322</sup>: courts pass the buck to agencies, overvalue innovation incentives despite rent-seeking, or ignore the government’s offloading of costs.

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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.

320. *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, 221 (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).

321. *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).

322. *See supra* Part II.

## 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<sup>323</sup> or what technologies are sufficiently inventive to merit patents.<sup>324</sup> 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.<sup>325</sup> Second, ideas are not protectable, only specific expressions of those ideas are.<sup>326</sup> 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.<sup>327</sup> Similarly, the doctrine of *scènes à faire* precludes copyright in “expressions that are standard, stock, or common to a particular topic.”<sup>328</sup> Courts and leading commentators have considered the applicability of these doctrines to mandatory infringement cases.<sup>329</sup> Most notably, *Veeck* relied on merger to hold private building codes uncopyrightable.<sup>330</sup> *Veeck* presents one possible pathway for responding to mandatory infringement generally: the Fifth Circuit held that a legal mandate to use a copyrighted

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323. See *Feist*, 499 U.S. at 345–46.

324. See *Graham*, 383 U.S. at 17–18.

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

326. See 17 U.S.C. § 102(b).

327. See *Baker v. Selden*, 101 U.S. 99, 104 (1879); *Comput. Assocs. Int’l, Inc. v. Altai, Inc.*, 982 F.2d 693, 707–08 (2d Cir. 1992).

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

329. See, e.g., *Practice Mgmt. Info. Corp. v. Am. Med. Ass’n*, 121 F.3d 516, 520 n.8 (9th Cir. 1997) (“This court has not allowed the owners of copyrights in expressions mandated by industry standards to use their copyrights to stifle independent creative expression in the industry.”); *Am. Soc’y for Testing & Materials v. Public.Resource.Org, Inc.*, No. 13-cv-1215, 2017 WL 473822, at \*25 (D.D.C. Feb. 2, 2017), *vacated*, 896 F.3d 437 (D.C. Cir. 2018) (granting an injunction to protect not-for-profit organization that created public standards); 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, Brace Memorial Lecture, *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, *supra* note 139, at 170–71 (discussing the merger doctrine and considerations in applying *Veeck*); Cunningham, *supra* note 140, at 306–07 (discussing *County of Suffolk v. First Am. Real Estate Solutions*, 261 F.3d 179 (2d Cir. 2001)); 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”).

330. See *Veeck v. S. Bldg. Code Cong. Int’l, Inc.*, 293 F.3d 791, 800–02 (5th Cir. 2002).

work rendered the idea of legal compliance coextensive with the expression of the work, precluding copyright protection.<sup>331</sup>

The difficulty with applying protectability doctrines like merger to mandatory infringement is that it appears to strip the author of much value and diminish incentives to create further candidate works for public benefit.<sup>332</sup> 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.”<sup>333</sup> Other courts have refused to apply copyright protectability doctrines to mandatory infringement in part to “limit[] the economic consequences that might result.”<sup>334</sup>

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 Professor Lawrence A. Cunningham finds, if the author expects the code to be made mandatory.<sup>335</sup> The cost-offloading problem compounds this qualification.<sup>336</sup> 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 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,<sup>337</sup> novelty,<sup>338</sup> nonobviousness,<sup>339</sup> and sufficiency of written description.<sup>340</sup> One can find similarities, particularly between the

331. *See id.* at 802.

332. *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-Authorized Works Are Adopted or Enacted by Reference into Law*, 78 WASH. L. REV. 589, 613 (2003); Hughes, *supra* note 329, at 92 (“[C]reated fact works’ may need the incentive of copyright . . .”).

333. *Veeck*, 293 F.3d at 816–17 (Wiener, J., dissenting).

334. *ASTM*, 896 F.3d at 447; *see also* *Google LLC v. Oracle Am., Inc.*, 141 S. Ct. 1183, 1197 (2021) (opting to decide the 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.”).

335. *See* Cunningham, *supra* note 140, at 311 & n.98; *supra* Section II.C.

336. *See supra* Section II.D.

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

338. *See* 35 U.S.C. § 102.

339. *See id.* § 103.

340. *See id.* § 112.

prohibition on patenting abstract ideas<sup>341</sup> and copyright's idea-expression dichotomy.<sup>342</sup> But while copyright protectability doctrines can arguably account for post-creation events such as a legal mandate,<sup>343</sup> patent's protectability doctrines are explicitly measured from the time of patent filing.<sup>344</sup> 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<sup>345</sup> and likely were ineligible for patenting as well.<sup>346</sup> Many patents involved in product hopping, including those on buprenorphine, have been invalidated.<sup>347</sup> Unocal's mandatory patents on gasoline formulations were also forcefully (though unsuccessfully) challenged based on Unocal's hasty revisions to make its patents match California's emissions standards.<sup>348</sup> 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.<sup>349</sup>

## 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

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

342. See, e.g., Lateef Mtima, *The Idea Exclusions in Intellectual Property Law*, 28 TEX. INTELL. PROP. L.J. 343, 349 (2020).

343. See *Veeck v. S. Bldg. Code Cong. Int'l, Inc.*, 293 F.3d 791, 802 (5th Cir. 2002) (en banc) (incorporating 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 329, 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."), and Colendich, *supra* note 332, at 613–14.

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

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

346. See *Paradise*, *supra* note 78, at 75–76; *Carrier & Sooy*, *supra* note 88, at 1686.

347. See *Indivior UK Ltd. v. Dr. Reddy's Lab'ys S.A.*, 18 F.4th 1323, 1330 (Fed. Cir. 2021) (petition for en banc rehearing filed Jan. 26, 2022); *Indivior Inc. v. Dr. Reddy's Lab'ys, S.A.*, 930 F.3d 1325, 1330–31 (Fed. Cir. 2019); *BioDelivery Scis. Int'l, Inc. v. RB Pharm. Ltd.*, No. IPR2014-00325, 2015 WL 4045328, at \*16 (P.T.A.B. June 30, 2015), *aff'd mem.*, 667 F. App'x 997 (Fed. Cir. 2016).

348. See *Union Oil Co. of Cal. v. Atl. Richfield Co.*, 208 F.3d 989, 997–1001 (Fed. Cir. 2000); *cf. id.* at 1002 (Lourie, J., dissenting in part) (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.

349. See *supra* Section II.C.

quotations and parodies.<sup>350</sup> Patent law, by contrast, includes only a few irrelevant exceptions to infringement.<sup>351</sup> 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.<sup>352</sup>

Courts have often used fair use to deal with mandatory copyrights.<sup>353</sup> 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.<sup>354</sup> 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.<sup>355</sup> And fair use only excuses particular uses of copyrighted works rather than condoning all uses, as a finding of unprotectability would.<sup>356</sup> To courts concerned with the economic incentives fallout of resolving a mandatory infringement case against the

350. See 17 U.S.C. § 107. Another potentially relevant infringement-execute 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 COMPUT. & HIGH TECH. L.J. 275, 276–77 (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 21–25, *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharm., Inc.*, 211 F.3d 21 (2d Cir. 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> [<https://perma.cc/PV39-Z6HR>]. 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 (2014).

351. See 35 U.S.C. § 287(c)(1) (doctors' use of patented surgical methods); see also *Madey v. Duke Univ.*, 307 F.3d 1351, 1361–62 (Fed. Cir. 2002) (describing research exemption to patent infringement as "very narrow and strictly limited").

352. 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 hold-up issues); Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1205–09 (2000).

353. See, e.g., *Am. Soc'y for Testing & Materials v. Public.Resource.Org, Inc.*, 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) (per curiam).

354. 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 Lloyd Weinreb, who passed away recently, was my copyright law professor, and I remember him discussing this point about fairness in class.

355. 17 U.S.C. § 107(2).

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

IP holder, fair use's more limited effect may be attractive over resolution by protectability doctrines like merger.<sup>357</sup>

Yet fair use "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.<sup>358</sup> 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,<sup>359</sup> 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."<sup>360</sup> Under the first factor, which examines the "purpose and character of the use,"<sup>361</sup> courts frequently consider Judge Pierre Leval's "transformativeness" test, which asks whether a use is "productive" and employs the copyrighted work "in a different manner or for a different purpose from the original."<sup>362</sup> These inquiries can work well for traditional fair uses such as parodies and academic quotations.<sup>363</sup> But with respect to mandatory infringement, would-be competitors typically must make complete and exact copies for purposes identical to the copyright holders: 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.<sup>364</sup> Courts have weighed these factors against mandatory infringement being fair use.<sup>365</sup> 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

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357. See *supra* note 334 (citing cases).

358. *Georgia v. Public.Resource.Org, Inc.*, 140 S. Ct. 1498, 1513 (2020).

359. Of the five modern Supreme Court decisions on fair use, four dealt with literary works. See *Campbell*, 510 U.S. at 571–72; *Stewart v. Abend*, 495 U.S. 207, 211 (1990); *Harper & Row Publishers, Inc. v. Nation Enters.*, 471 U.S. 539, 541–42 (1985); *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 419–20 (1984). The fifth was *Google LLC v. Oracle Am., Inc.*, 141 S. Ct. 1183, 1190 (2021) (involving a copyright for a computer program).

360. 17 U.S.C. § 107(3).

361. *Id.* § 107(1).

362. 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).

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

364. See *supra* Section I.E.

365. See, e.g., *Am. Soc'y for Testing & Materials v. Public.Resource.Org, Inc.*, No. 13-cv-1215, 2017 WL 473822, at \*16 (D.D.C. Feb. 2, 2017) (characterizing republication of copyrighted mandatory standards as tantamount to "offer[ing] them for free in competition").



considered transformative.<sup>366</sup> 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.”<sup>367</sup>

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.”<sup>368</sup> And the fourth factor, sometimes called “undoubtedly the single most important element of fair use,”<sup>369</sup> considers “the effect of the use upon the potential market for or value of the copyrighted work.”<sup>370</sup> If the fair use doctrine is to overcome market power caused by mandatory infringement and restore competition, then these considerations would seem to work directly contrary to that objective.<sup>371</sup> Indeed, in *ASTM*, the U.S. Court of Appeals for the D.C. Circuit agreed that “there may be some adverse impact on the market for the copyrighted works” and remanded the case to the district court to find how much the copyright holders’ markets were worth and whether they could make money on derivative works.<sup>372</sup> If the district court found those markets to be highly valuable and the derivative works markets to be insufficient compensation,<sup>373</sup> then *ASTM* might suggest that fair use should tolerate mandatory infringement more when the monopoly profits are highest.

*Google LLC v. Oracle America, Inc.*<sup>374</sup> offers a better route for applying market considerations to mandatory infringement. Justice Stephen Breyer, writing for the Court, agreed that Google’s use of Oracle’s assumed-copyrighable Java commands harmed Oracle’s market

366. 896 F.3d 437, 449–50 (D.C. Cir. 2018).

367. *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).

368. 17 U.S.C. § 107(1).

369. *Harper & Row Publishers, Inc. v. Nation Enters.*, 471 U.S. 539, 566 (1985); *see* *Stewart v. Abend*, 495 U.S. 207, 238 (1990).

370. 17 U.S.C. § 107(4).

371. *See, e.g., Am. Soc’y for Testing & Materials v. Public.Resource.Org, Inc.*, No. 13-cv-1215, 2017 WL 473822, at \*18 (D.D.C. Feb. 2, 2017) (making “logical presumption” that duplication of copyrighted standards “negatively impacts the potential market”).

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

373. 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. Public.Resource.Org, Inc.*, No. 1:13-cv-01215, 2022 WL 971735, 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 Sixty-Six 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).

374. 141 S. Ct. 1183 (2021).

but observed that “a potential loss of revenue is not the whole story.”<sup>375</sup> In particular, he pointed to “the public benefits the copying will likely produce” as weighing strongly in favor of fair use.<sup>376</sup> 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.”<sup>377</sup>

Justice 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.<sup>378</sup> Its consideration of “public benefits of copying” could give courts further opportunity to consider the rent-seeking and cost-offloading effects of mandatory infringement.<sup>379</sup> 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.<sup>380</sup>

### 3. Remedial Limitations

The third category of IP law-based 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 to limit anticompetitive injury. The two main IP remedies are monetary compensation and injunctive relief.

*Monetary compensation.* Intuitively, damages-based approaches are well-suited for 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, previously described as “de facto mandatory infringement,”<sup>381</sup> suggests a workable pathway for dealing with de jure mandatory infringement. In *Ericsson, Inc. v. D-*

375. *Id.* at 1206.

376. *Id.* at 1206, 1208.

377. *See id.* at 1208.

378. *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).

379. *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.*

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

381. *See supra* Section I.D.

*Link Systems, Inc.*,<sup>382</sup> the Federal Circuit considered whether a patent holder's FRAND commitment, made in the course of developing the Wi-Fi standard, affected damages under 35 U.S.C. § 284.<sup>383</sup> Observing that a Wi-Fi 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."<sup>384</sup> As a result, the traditional damages factors required alteration in view of the FRAND commitment, with several of those factors being "irrelevant."<sup>385</sup>

*Ericsson* informs mandatory infringement in two ways. First, many agencies call for FRAND licensing of mandatory patents,<sup>386</sup> 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 hold-up and overvaluation problems,<sup>387</sup> 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.<sup>388</sup> 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<sup>389</sup> but could lead to unreasonable outcomes in mandatory infringement cases involving just a few patents.

382. See 773 F.3d 1201 (Fed. Cir. 2014).

383. See *id.* at 1226, 1229.

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

385. *Id.* at 1230–31.

386. See, e.g., *supra* text accompanying notes 107–13 (FCC expecting FRAND licensing of digital television patents); OFFICE OF MGMT. & BUDGET, OMB CIRCULAR A-119, FEDERAL PARTICIPATION IN THE DEVELOPMENT AND USE OF VOLUNTARY CONSENSUS STANDARDS AND IN CONFORMITY ASSESSMENT ACTIVITIES sec. 2(d) (Jan. 27, 2016), [https://www.whitehouse.gov/wp-content/uploads/2020/07/revised\\_circular\\_a-119\\_as\\_of\\_1\\_22.pdf](https://www.whitehouse.gov/wp-content/uploads/2020/07/revised_circular_a-119_as_of_1_22.pdf) [<https://perma.cc/8QKF-HLYQ>] ("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").

387. See *supra* Section II.C.

388. 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).

389. See Jorge L. Contreras, *Aggregated Royalties for Top-Down FRAND Determinations: Revisiting "Joint Negotiation"*, 62 ANTITRUST BULL. 690, 692–94 (2017).

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.<sup>390</sup> But this allocation ignores cost-offloading, as some of the intrinsic value of a patented technology goes to the government and the public.<sup>391</sup> This is the fundamental problem with all IP-based approaches to mandatory infringement, as they can only allocate value between 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.<sup>392</sup> 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.<sup>393</sup>

Ordinarily, courts have discretion over injunctive relief and can take mandatory infringement into account. In *eBay Inc. v. MercExchange, LLC*,<sup>394</sup> the Court directed lower courts hearing IP cases to consider a four-factor test for injunctive relief, in which the fourth factor asks whether “the public interest would not be disserved by a permanent injunction.”<sup>395</sup> Courts have applied this factor to public concerns such as doctors' access to medical treatments.<sup>396</sup> The strong public interest in competitive markets should weigh heavily on this factor.<sup>397</sup> 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.<sup>398</sup>

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

391. See *supra* Section II.D.

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

393. See Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1092 (1972); Mark A. Lemley & Phil J. Weiser, *Should Property or Liability Rules Govern Information?*, 85 TEX. L. REV. 783, 784 (2007).

394. 547 U.S. 388 (2006).

395. *Id.* at 391; see *Salinger v. Colting*, 607 F.3d 68, 77–78 (2d Cir. 2010) (applying *eBay* to copyright cases).

396. 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).

397. 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)).

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

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 creating an injunction against marketing that generic.<sup>399</sup> In cases involving patents and generic drugs,<sup>400</sup> 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.<sup>401</sup> A better solution 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,<sup>402</sup> 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 the value created or received.

The proposal below consists of two parts. The first is the creation of a trans-substantive 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.

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

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

401. See *supra* Part III.

402. See Approval and Promulgation of Air Quality Implementation Plans, 80 Fed. Reg. 21176, 21178 (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).

### A. *Default Royalty-Free Access*

By default, a regulated entity should have royalty-free access to use any IP rights to comply with a regulatory or legal mandate. In 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,<sup>403</sup> are common across IP law. The “historic kinship” between patent and copyright law has been questioned factually,<sup>404</sup> but in practice, the two IP schemes share rules on indirect infringement,<sup>405</sup> substantial noninfringing uses,<sup>406</sup> and laches,<sup>407</sup> 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.”<sup>408</sup> Both IP regimes also (inconsistently) disallow extraterritorial assertion of rights in the interest of international comity.<sup>409</sup>

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.<sup>410</sup> Such an exception would also be consistent with the overall IP objective of advancing progress and innovation,<sup>411</sup> insofar as the undue restraints on competition posed by mandatory infringement distort innovation incentives.<sup>412</sup> Unlike existing IP doctrines applied to mandatory infringement,<sup>413</sup> a trans-substantive approach avoids the interstices of individual IP regimes, which makes sense because the

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

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

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

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

407. See *SCA Hygiene Prods. 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)).

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

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

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

411. See U.S. CONST. art. I, § 8, cl. 8.

412. See *supra* Section II.C.

413. See *supra* Section III.C.

problem of mandatory infringement depends only on the general nature of IP protection.<sup>414</sup> 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.<sup>415</sup> 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.<sup>416</sup>

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 affect royalty-free access.<sup>417</sup> 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.<sup>418</sup> 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.<sup>419</sup> 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, compensation should 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.

*IP holder compensation.* The government IP use statute, § 1498, epitomizes the first component of government IP compensation, at least

414. *See supra* Section II.A.

415. 211 F.3d at 25, 29.

416. 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”).

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

418. *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.

419. *See supra* Section II.C.

in the federal context. Under that law, the government must pay “reasonable and entire compensation” for unauthorized use of patents or copyrights.<sup>420</sup> 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.<sup>421</sup> Others have treated § 1498 as tantamount to eminent domain.<sup>422</sup> 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,<sup>423</sup> infringement is a tort subject to sovereign immunity and not a taking,<sup>424</sup> and § 1498 provides the sole remedy for government IP use to the exclusion of the Fifth Amendment.<sup>425</sup> The distinction is important because lawmakers often characterize eminent domain as repugnantly extraordinary; § 1498, by contrast, is a well-trodden procedural law that the government invokes frequently.<sup>426</sup> As applied to mandatory infringement, § 1498 has many 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

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420. See 28 U.S.C. § 1498. See generally Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 298–307 (2016) (describing how § 1498 allows the government to use patents without patent holder permission).

421. 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, 518 (2002); Segal, *supra* note 61, at 88; Trotter Hardy, *The Copyrightability of New Works of Authorship: “XML Schemas” as an Example*, 38 HOUS. L. REV. 855, 877 (2001) (explaining that 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) (reasoning that a policy of open access to law supports “a *Kelo*-style eminent domain approach to proprietary legal information”).

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

423. *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).

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

425. 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).

426. See Morten & Duan, *supra* note 425, at 13–33 (providing historical examples of the government’s use of § 1498).



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.<sup>427</sup>

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.<sup>428</sup> Many will qualify,<sup>429</sup> but some will not.<sup>430</sup> To the extent necessary, regulators or legislators could invoke § 1498 explicitly to avoid questions of whether the authorization and consent test is satisfied.<sup>431</sup> Also, § 1498 does not apply to state government use, because in those cases traditional sovereign immunity applies.<sup>432</sup> Finally, despite § 1498’s straightforward applicability to mandatory infringement and the fact that critics 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.<sup>433</sup> The license could also be obtained through a government procurement process. Finally, the government could simply offer no

427. See *Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis*, 583 F.3d 1371, 1377–78 (Fed. Cir. 2009); *To the Secretary of the Air Force*, 38 Comp. Gen. 276, 279 (1958) (explaining that any government procurement invitation automatically authorizes patent use under § 1498).

428. 28 U.S.C. § 1498(a); see *Madey v. Duke Univ.*, 413 F. Supp. 2d 601, 607 (M.D.N.C. 2006) (stating that 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) (reasoning that § 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”).

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

430. 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.

431. Cf. *Brennan et al.*, *supra* note 420, at 346 (describing procedure for explicit invocation of § 1498).

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

433. See *Hemel & Ouellette*, *supra* note 235, at 565–66 (discussing Michael R. Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q.J. ECON. 1137 (1998)).

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.<sup>434</sup> One potential solution is to allow the government to defray that liability by imposing user fees on regulated entities that use mandatory IP rights.<sup>435</sup> 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 to resolve the cost-offloading problem. To the extent that the government extracts value from its adoption of another's IP, it can impose a fee on regulated entities 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.<sup>436</sup> A regulator's assessment of IP royalties against regulated entities is essentially a cost-benefit analysis, of the kind that courts frequently review under the arbitrary-and-capricious standard.<sup>437</sup> 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.<sup>438</sup>

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434. 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 402. Concerns about the deterrent effect of government compensation must be weighed against this existing deterrence phenomenon.

435. 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). Professor Tejas N. 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.

436. See 5 U.S.C. § 706(2)(A).

437. 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.”) (first citing *City of Portland v. EPA*, 507 F.3d 706, 713 (D.C. Cir. 2007); and then citing *Owner-Operator Indep. Drivers Ass'n v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 206 (D.C. Cir. 2007)).

438. 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

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.<sup>439</sup> 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, Professor Emily S. Bremer’s study of pipeline safety standards is instructive.<sup>440</sup> Following enactment of a statute requiring that mandatory pipeline safety standards be “made available to the public, free of charge, on an Internet Web site,”<sup>441</sup> 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).<sup>442</sup> Professor Bremer takes the lack of agreement with ASME as a failure of the free access statute.<sup>443</sup> 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

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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. *Id.* at 343–44. 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. *Id.* at 344. In other words, the *NCTA* framework potentially avoids the government cost-offloading problem.

439. *See, e.g., Veeck v. S. Bldg. Code Cong. Int’l, Inc.*, 293 F.3d 791, 805–06 (5th Cir. 2002); Cunningham, *supra* note 140, at 320 (“[C]opyright revenue is not a main reason or motivation for its production of materials.”).

440. *See* Bremer, *supra* note 186, at 281.

441. Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011, Pub. L. No. 112-90, § 24, 125 Stat. 1904, 1919 (2012) (codified as amended at 49 U.S.C. § 60102). *See* Bremer, *supra* note 186, at 297–98.

442. *See* Bremer, *supra* note 186, at 324–25. Of the three other pipeline standards developers, two were no longer actively developing standards and one already made them available for free. *See id.* at 325.

443. *See id.* at 327–28.

supplant ASME with free competitive standards.<sup>444</sup> 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.<sup>445</sup> 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.<sup>446</sup> 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.<sup>447</sup> By recognizing that traditional IP and competition theory do not generally apply well to mandatory infringement, courts and lawmakers can address these problems head-on, enabling competition alongside the public benefits of well-regulated markets.<sup>448</sup>

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.<sup>449</sup> “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,<sup>450</sup> or whether the IP right was defined before or after the mandating regulation.<sup>451</sup>

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444. *Id.* at 298 (describing subsequent amendments to § 60102). Professor 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.

445. *See supra* Part I.

446. *See supra* Part II.

447. *See supra* Part III.

448. *See supra* Part IV.

449. *See supra* text accompanying notes 257–258.

450. *See* Cunningham, *supra* note 140, at 298–99.

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

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,<sup>452</sup> drug product hopping, the REMS question, digital television, and litigation over mandatory copyrighted standards,<sup>453</sup> among others. Nor is environmental protection standing still. In 2015, the EPA issued a long-term plan for phasing out greenhouse gases.<sup>454</sup> Among the chemicals it has designated for phaseout: HFA-134a.<sup>455</sup>

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452. A petition for certiorari in the case was filed in July 2022. Steve Brachmann, *GSK Argues Unusual Facts of Case Behind Teva's SCOTUS Petition Limits CAFC's Skinny Label Holding*, IP WATCHDOG (Aug. 24, 2022, 12:15 PM), <https://www.ipwatchdog.com/2022/08/24/gsk-argues-unusual-facts-case-behind-tevas-scotus-petition-limits-cafcs-skinny-label-holding/id=151033/> [<https://perma.cc/C58G-W69D>].

453. See generally, *Am. Soc'y for Testing & Materials v. Public.Resource.Org, Inc.*, No. 13-cv-01215, 2022 WL 971735 (D.D.C. Mar. 31, 2022) (mem.) (arguing the merits of furthering access to documents incorporated into regulations).

454. See Protection of Stratospheric Ozone: Change of Listing Status for Certain Substitutes Under the Significant New Alternatives Policy Program, 80 Fed. Reg. 42,870, 42,871 (July 20, 2015), *recognized as invalid* by *Mexichem Fluor, Inc. v. EPA*, 866 F.3d 451, 453 (D.C. Cir. 2017).

455. See Protection of Stratospheric Ozone: Change of Listing of Substitutes Under the Significant New Alternatives Policy Program, 80 Fed. Reg. 42,870, 42,881–83 (July 20, 2015); Protection of Stratospheric Ozone: Listing of Substitutes Under the Significant New Alternatives Policy Program; Supplemental Proposal, 86 Fed. Reg. 55,549, 55,550 (Oct. 6, 2021).