The Second Patent Bargain

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ABSTRACT: The title of this Article—The Second Patent Bargain—references a maxim that many students are taught in introductory intellectual property and patent law classes. Issuance of a patent constitutes a "bargain with the public": In exchange for time-limited exclusive rights in an invention, an inventor agrees to disclose the invention and teach the public how to make and use it.

This Article argues that the patent term extension process—which extends, often by many years, the term of many patents on pharmaceuticals, medical devices, and other Food and Drug Administration ("FDA")-regulated products nearing the ends of their standard patent terms—should be analyzed as a second bargain with the public. Because new drugs, medical devices, and other FDA-regulated products cannot be marketed without approval by the FDA, patent term extension is designed to "restore" some of the patent term "lost" during the approval process. Under the current system, patent owners receive highly valuable extensions of up to five additional years. These extensions serve to protect the patent owner's exclusivity, high prices, and profits—sometimes billions of dollars in profits. The public bears the costs of extended exclusivity and delayed competition but currently receives no useful new information from the patent owner. Thus, from the public's perspective, the current "second patent bargain" comes up short.

This Article argues for a fulsome second patent bargain, a more balanced quid pro quo. Patent term extension provides the public with a golden opportunity to demand and obtain richer, more complete information about

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how to use, learn from, and otherwise benefit from the patented invention. More precisely, patent term extensions should be conditioned on public disclosure of late-stage technical data on the safety and effectiveness of the patented invention—small portions of the trove of information that patent owners already provide to the FDA in secret. Public disclosure of this information will improve health care, accelerate science, and help hold both industry and the FDA accountable, without significantly disturbing the existing incentive structure for innovative research and development ("R&D")-based companies.

INTRODUCTION

The title of this Article references an axiom invoked in every patent law class: Each patent grant constitutes a "bargain with the public." For decades, the U.S. Supreme Court has invoked this axiom to justify the U.S. patent system.[1] In 2023, it wrote, "[r]ight there in the text [of the U.S. Constitution], one finds the outline of what this Court has called the patent 'bargain.' In exchange for bringing 'new designs and technologies into the public domain through disclosure,' so they may benefit all, an inventor receives a limited term of 'protection from competitive exploitation.'"[2]

In theory, the patent bargain works like this: The public grants an inventor time-limited exclusive rights in their invention. While the patent remains in force, the inventor can block competitors from making, using, importing, and selling the patented invention, or demand compensatory payment for their infringement. In exchange, the public gets its end of the bargain: The inventor must disclose to the public a wealth of information. The inventor explains what their invention is, how it works, how to make and use it,[3] provides drawings "where necessary for the understanding of the subject matter sought to be patented,"[4] "set[s] forth the best mode contemplated by the inventor or joint inventor of carrying out the invention"[5]

1. *See, e.g.*, Universal Oil Prods. Co. v. Globe Oil & Refin. Co., 322 U.S. 471, 484 (1944) ("[T]he quid pro quo [for the patent grant] is disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of the monopoly has expired; and the same precision of disclosure is likewise essential to warn the industry concerned of the precise scope of the monopoly asserted."); Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484 (1974) (describing "disclosure" as "the *quid pro quo* of the right to exclude" (emphasis added) (citing *Universal Oil Prods. Co.*, 322 U.S. at 484)); *see also* Blanchard v. Sprague, 3 F. Cas. 648, 650 (C.C.D. Mass. 1839) (No. 1,518) (early case observing that patents should "secur[e] to the whole community great advantages from the free communication of secrets, and processes, and machinery"); Shubha Ghosh, *Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor After* Eldred, 19 BERKELEY TECH. L.J. 1315, 1319–21 (2004) (summarizing the Supreme Court's repeated invocation of the bargain). Oren Bracha has traced the roots of the theory of the patent bargain or "patent deal"—exclusive rights exchanged for useful disclosure—back to 1770s England. OREN BRACHA, OWNING IDEAS: THE INTELLECTUAL ORIGINS OF AMERICAN INTELLECTUAL PROPERTY, 1790–1909, at 252–53, 297–98 (2016).

2. Amgen Inc. v. Sanofi, 143 S. Ct. 1243, 1251 (2023) (quoting Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150, 151 (1989)).

3. 35 U.S.C. § 112(a) (2018).

4. *Id.* § 113.

5. *Id.* § 112(a). Although the best mode requirement remains part of the Patent Act, it was weakened by amendments made in the 2011 Leahy–Smith America Invents Act ("AIA"). 35 U.S.C. § 282(b)(3)(A); *see also, e.g.*, Peter Lee, *New and Heightened Public–Private Quid Pro Quos: Leveraging Public Support to Enhance Private Technical Disclosure*, *in* INTELLECTUAL PROPERTY, COVID-19 AND THE NEXT PANDEMIC 39, 49 (Haochen Sun & Madhavi Sunder eds., 2024) ("[I]n 2011, Congress reformed the best mode requirement in a manner that renders it essentially toothless.").

at the time of filing, and marks the precise metes and bounds of their claim to exclusive rights.[6]

Thus, right at the heart of the patent system is the production and regulation of information. Patent law is "information law" not only insofar as it confers to patent owners' property-like rights in knowledge;[7] patent law also promises the public information about patented inventions. Patent law is not just information law but *transparency* law.

In fact, patent-law-as-transparency-law goes further. The public bargains for even more information. Existing patent law requires or at least encourages public disclosure of not just information on the patented invention's properties but also some information on the patent's inventors and owners. Patent inventors must disclose their names[8] and residences.[9] Patent owners are encouraged (but not required) to record ownership of their patents on a public website administered by the U.S. Patent & Trademark Office ("USPTO").[10] Drug companies are encouraged to disclose the specific patents that cover their products in the Food and Drug Administration's ("FDA") "Orange Book" and "Purple Book."[11] The Patent Act also offers financial incentives to patent owners who mark, for public awareness, any commercial products they sell that embody the patent.[12]

This Article argues that when patent owners extend the expiration dates of their patents through a process known as "patent term extension," they effectively strike a new, *second* bargain with the public. This Article argues that in this second bargain, the public can and should demand some new information disclosure. As I explain more fully below,[13] the FDA and USPTO currently grant patent term extensions without requiring any meaningful new disclosure by patent owners. That is odd. Why violate the

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6. 35 U.S.C. § 112(b); *see also* Gill v. Wells, 89 U.S. 1, 25 (1873) (identifying, as one of patent disclosure's three "great ends . . . . [t]hat the government may know what they have granted and what will become public property when the term of the monopoly expires"); *Universal Oil Prods. Co.*, 322 U.S. at 484 (similar).

7. *See* 35 U.S.C. § 154(a).

8. 37 C.F.R. § 1.41(a) (2024).

9. *Id.* §§ 1.63(b)(2), 1.76.

10. *See* 35 U.S.C. § 261 ("The Patent and Trademark Office shall maintain a register of interests in patents and applications for patents and shall record any document related thereto upon request . . . ."); 37 C.F.R. § 3.11 (stating USPTO rules for recording assignments, licenses of government-owned patents, and joint research agreements). Failure to record an assignment with the USPTO renders the assignment void against subsequent purchasers. 35 U.S.C. § 261.

11. *Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book*, U.S. FOOD & DRUG ADMIN. (Dec. 12, 2025), https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book [https://perma.cc/NYP3-RPJG]; *Purple Book Database of Licensed Biological Products*, U.S. FOOD & DRUG ADMIN. (Dec. 18, 2025), https://purplebooksearch.fda.gov [https://perma.cc/4U9W-2HHK].

12. 35 U.S.C. § 287(a); *see* John R. Thomas, *Noticing Patents*, 24 COLUM. SCI. & TECH. L. REV. 299, 310–14 (2023).

13. *See infra* Section II.B.

axiom that *every* grant of patent term should be bargained with the public and yield useful new disclosure? This Article argues that requiring disclosure of undisclosed technical properties of patented inventions as a condition of patent term extensions is urgently useful, conceptually consistent with patent law's other disclosure requirements, entirely practical, and entirely legal.[14]

What is patent term extension?[15] It is a somewhat obscure[16] but enormously important process under which certain regulated companies extend the terms—i.e., the expiration dates—of key patents. The relevant provision of the Patent Act allows patent owners to extend the lives of already-issued patents beyond the standard term (twenty years) by up to five extra years (for a total term of up to twenty-five years).[17] Extension is designed to compensate patent owners for the time they spend obtaining regulatory approval; extensions "restore" a portion of patent term "lost" in regulatory review.[18] The statute and elaborate USPTO rules[19] provide formulae to calculate the precise duration of extension a given patent should receive, based on time spent on research and development ("R&D") and regulatory review.[20] The statute limits patent term extensions to fourteen years of patent term beyond the regulatory approval date of the patented product.[21]

Not all patents are eligible for term extension; by statute, only patents covering certain products regulated by the U.S. Department of Agriculture

14. *See infra* Section II.A.

15. Section II.B, *infra*, explains the mechanics of patent term extension in detail.

16. Leading patent law casebooks either omit mention of patent term extension or mention it only briefly. *See, e.g.*, SARAH BURSTEIN, SARAH R. WASSERMAN RAJEC & ANDRES SAWICKI, PATENT LAW: AN OPEN-ACCESS CASEBOOK (2022) (omitting mention of patent term extension); JONATHAN S. MASUR & LISA LARRIMORE OUELLETTE, PATENT LAW: CASES, PROBLEMS, AND MATERIALS (4th ed. 2025) (describing patent term extension in only a few sentences among more than five hundred pages); JOHN M. GOLDEN, F. SCOTT KIEFF, PAULINE NEWMAN & HENRY E. SMITH, PRINCIPLES OF PATENT LAW: CASES AND MATERIALS 854–57 (8th ed. 2024) (describing patent term extension for 4 pages among 1219 total pages).

17. 35 U.S.C. § 156. Patent term *extension* is distinct from patent term *adjustment*, which is awarded for USPTO delay. *See id.* § 154; Mark A. Lemley & Jason Reinecke, *Our More-than-Twenty-Year Patent Term*, 39 BERKELEY TECH. L.J. 681, 685–90 (2024). For excellent overviews of how patent term extension works and the products and regulated industries it applies to, see generally Erika Lietzan & Kristina M.L. Acri née Lybecker, *Distorted Drug Patents*, 95 WASH. L. REV. 1317 (2020) (discussing patent extension for drug patents); and WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RSCH. SERV., RS21129, PHARMACEUTICAL PATENT TERM EXTENSIONS: A BRIEF EXPLANATION (2002) (same). *See also infra* Section II.B.

18. See the formal title of the Hatch–Waxman Act, the "Drug Price Competition and Patent Term Restoration Act of 1984." Pub. L. No. 98-417, 98 Stat. 1585 (1984). The statute and literature often use the phrases "patent term extension" and "patent term restoration" interchangeably. I prefer the term "extension," as "extension" is the term that appears in 35 U.S.C. § 156, the most relevant section of statute, and for the additional reasons explained *infra* Section II.B.1.

19. *E.g.*, 37 C.F.R. § 1.775 (2024); *see infra* Section II.B.

20. *See infra* Section II.B.

21. 35 U.S.C. § 156(c)(3).

("USDA") and the FDA can be extended.[22] In practice, the USPTO seems never to have extended a patent on a USDA-regulated invention,[23] meaning that the FDA is de facto the only regulator where patent term extension matters.

Yet the FDA regulates socially and economically crucial industries that benefit from patent term extension: prescription drugs, vaccines, medical devices (including diagnostics), food additives, and more. Since patent term extension was created in 1984 as part of the landmark Drug Price Competition & Patent Term Restoration Act—better known as the Hatch–Waxman Act—the USPTO has granted about one thousand extensions.[24]

The pharmaceutical industry benefits from patent term extension most of all. A recent study found that "nearly every new drug applicant eligible for patent term restoration pursues this benefit."[25] Most FDA-approved drugs obtain a patent term extension.[26] That's no surprise; extension of a single patent on a blockbuster drug can protect billions of dollars in profits.[27] Extended-term patents on FDA-approved drugs and devices "are extremely important"[28] and are "some of the most valuable patents in the world."[29] Gilead's patent term extension on the HIV drug elvitegravir/cobicistat/em

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22. *See id.* § 156(f).

23. Frank J. West & B. Allison Hoppert, *Extending the Life of a Patent in the United States*, MANAGING INTELL. PROP., Nov. 1996, at 25, 27 ("[N]o applications for patent term extension have yet been received [as of 1996] for patents that required the regulatory approval of the USDA . . . ."); *Applications for Patent Term Extension and Patent Terms Extended Under 35 U.S.C. 156*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156 [https://perma.cc/CF6V-VP8F] (showing no patent term extension applications on products regulated by USDA).

24. Lemley & Reinecke, *supra* note 17, at 708 (calculating that 949 patents had received patent term extensions as of 2023); *Applications for Patent Term Extension and Patent Terms Extended Under 35 U.S.C. 156*, *supra* note 23 (last updated December 2025, listing 1077 extensions granted).

25. Erika Lietzan, Kristina M.L. Acri & Evan Weidner, *The Case of the Missing Device Patents, or: Why Device Patents Matter*, 33 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 409, 412 (2023).

26. *Id.* at 440 (calculating that "the overwhelming majority of eligible drug approvals—likely at least 75 percent—*do* result in a patent term restoration request"); *see also* Charles Clift, *The Value of Patent Term Extensions to the Pharmaceutical Industry in the USA*, 5 J. GENERIC MEDS. 201, 205–06 (2008) (calculating that twenty-six of the top forty best-selling drugs in the United States in 2006 received a patent term extension); Victor L. Van de Wiele, Aaron S. Kesselheim, Sarosh Nagar & S. Sean Tu, *The Prevalence of Drug Patent Term Extensions in the United States, 2000–2018*, 41 NATURE BIOTECHNOLOGY 903, 904 (2023) ("Between 2000 and 2018, 698 new drugs were approved and included in our cohort, of which 319 (45%) received PTE for an associated patent . . . ."). Although Van de Wiele found only 45% of new drugs approved between 2000 and 2018 received patent term extensions, their study may have undercounted extensions slightly because drugs approved in 2017 or 2018 may not have had their extensions granted as of the time of their study, given an average patent term extension application pendency of about three years. *See infra* note 211.

27. *See generally* Dianna Goldenson, *A Day Late and a Few Million Dollars Short*, 27 NATURE BIOTECHNOLOGY 538, 538–41 (2009). *See also* Clift, *supra* note 26, at 205–06.

28. Lemley & Reinecke, *supra* note 17, at 685.

29. S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 WASH. U. L. REV. 1673, 1673, 1678 (2022).

tricitabine/tenofovir alafenamide (Genvoya) is a vivid example: The extension extended patent protection on the drug and related HIV drugs from 2022 to 2025, shielding these products from generic competition and netting Gilead an estimated $10 billion in extra profits.[30]

Patent term extension succeeds at delivering benefits to patent-holding regulated industries, but it fails to bring new information to the public. I show below[31] that under current USPTO and FDA rules and practice, patent term extensions yield essentially no new disclosure from patent owners. The USPTO imposes a nominal "duty of disclosure" on patent term extension applicants,[32] but it is vague, toothless, and has apparently never been enforced.[33]

By implementing patent term extension in this way, the USPTO and FDA have missed an opportunity to disseminate extraordinarily useful technical information to the public. The first patent bargain—initial patent disclosure in exchange for initial patent grant—is almost always struck before a patented

30. Christopher Rowland, *Gilead Delayed Safer HIV Drug to Extend Monopoly Profits, Advocates Allege*, WASH. POST (Dec. 5, 2019), https://www.washingtonpost.com/business/economy/gilead-delayed-safer-hiv-drug-to-extend-monopoly-profits-advocates-allege/2019/12/05/71d4d6ae-1538-11ea-8406-df3c54b3253e_story.html (on file with the *Iowa Law Review*) (describing a specific extension of a patent on HIV drugs as "potentially worth billions of dollars"); *see also* S. Sean Tu & Timothy Bonis, *Drug Versioning and Legal Accountability for Preventable Product Harms*, 333 JAMA 1487, 1487 (2025). In 2019, my client PrEP4All, clinic students, and I unsuccessfully petitioned the USPTO to scrutinize and deny this specific extension. We petitioned the USPTO to deny the extension on the narrow, unusual ground that Gilead had withheld material information from the USPTO in its application. *See generally* Third Party Petition Relating to the Applications for Pat. Term Extension in U.S. Pat. Nos. 7,390,791 & 7,803,788 at 2, PrEP5All Collaboration, U.S. Patent Nos. 7,390,791 & 7,803,788 (Dec. 4, 2019), https://www.dropbox.com/scl/fi/8dob91h7h90e0aa22jx88/PrEP4All-petition-re-PTE-December-4-2019-FINAL-with-active-URLs-reduced-file-size.pdf?rlkey=rq711lp3mwn7ts50buetf5geb&dl=0 [https://perma.cc/9MLU-DPQ2]. The USPTO denied the petition in February 2020. *See In re* Third Party Petition Relating to the Applications for Pat. Term Extension in U.S. Pat. Nos. 7,390,791 & 7,803,788, 2020 WL 3468297, at *1 (Dec. Comm'r Pat. Feb. 14, 2020).

31. *See infra* Section II.B.

32. 37 C.F.R. 1.765(a) (2024) ("All such individuals who are aware, or become aware, of material information adverse to a determination of entitlement to the extension sought, which has not been previously made of record in the patent term extension proceeding must bring such information to the attention of the Office or the Secretary, as appropriate, in accordance with paragraph (b) of this section, as soon as it is practical to do so after the individual becomes aware of the information. Information is material where there is a substantial likelihood that the Office or the Secretary would consider it important in determinations to be made in the patent term extension proceeding.").

33. *See* Erika Lietzan, *Patent Term Restoration – Denied!*, OBJECTIVE INTENT (Jan. 7, 2019), https://objectiveintent.blog/2019/01/07/patent-term-restoration-denied [https://perma.cc/3EBE-XHBP] [hereinafter Lietzan, *Patent Term Restoration – Denied!*] (showing that no patent term extension application has ever been denied for noncompliance with the duty of disclosure); *cf. In re* Third Party Petition Relating to the Applications for Patent Term Extension in U.S. Patent Nos. 7,390,791 & 7,803,788, *supra* note 30 (USPTO decision denying a petition by HIV/AIDS advocacy group PrEP4All that encouraged USPTO to scrutinize a patent term extension applicant's compliance with USPTO's own duty of disclosure); *see infra* Section II.B.4.

invention's properties are fully tested and fully known.[34] To strike a second patent bargain—new disclosure by patent owners in exchange for patent term *extension*—would be particularly valuable to the public because it would occur late in the lifecycle of an invention, after both patent issuance and regulatory approval. The second patent bargain could unlock rich, detailed information on the properties of the patented invention gathered by the patent owner and its affiliates in the years since the patent was filed. The second patent bargain would be doubly valuable because the technical information disclosed to the public could come directly from these volumes of certified, verified, and organized technical information that companies submit to and create with FDA experts to obtain FDA approval but do not typically disclose to the world.[35] (The same meticulous FDA approval process incurs the delay that creates eligibility for patent term extension in the first place.) Technical information contained in patents is often hard to use. It may be incomplete, incorrect, or even fraudulent.[36] By contrast, technical information in FDA files is relatively reliable, complete, and useful[37]—a boon to consumers and researchers and a fair trade for the lucrative patent term extension.

As to pharmaceutical and medical device products specifically, the second patent bargain provides an opportunity to obtain a larger fraction of the reams of important safety and effectiveness data that manufacturers collect on their products and submit to the FDA but do not always share with the public.[38] Unlocking the FDA's files of data would be valuable to scientific

34. *See, e.g.*, *In re* Brana, 51 F.3d 1560, 1568 (Fed. Cir. 1995) ("FDA approval . . . is not a prerequisite for finding a compound useful within the meaning of the patent laws. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful [and ripe for patenting] is well before it is ready to be administered to humans." (citations omitted)); CFMT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 1338 (Fed. Cir. 2003) (holding that the legal standard for obtaining a patent "does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect"); *see also* Jeanne C. Fromer, *Dynamic Patent Disclosure*, 69 VAND. L. REV. 1715, 1719–21 (2016) [hereinafter Fromer, *Dynamic Patent Disclosure*]; Maya M. Durvasula & Lisa Larrimore Ouellette, *Beyond the Pharmaceutical Patent Arms Race*, 43 YALE J. REGUL. (forthcoming 2026) (manuscript at 26) ("[P]harmaceutical patent applications are typically filed long before anyone knows whether the drug is actually effective or safe, much less whether it provides any health benefits beyond the existing standard of care.").

35. *See infra* Section III.A.

36. *See* Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 560–62 (2009) [hereinafter Fromer, *Patent Disclosure*]; Janet Freilich, *Prophetic Patents*, 53 U.C. DAVIS L. REV. 663, 700–04 (2019) [hereinafter Freilich, *Prophetic Patents*]; Janet Freilich, *The Replicability Crisis in Patent Law*, 95 IND. L.J. 431, 445–48, 473 (2020) [hereinafter Freilich, *The Replicability Crisis in Patent Law*]. *See generally infra* Part I (discussing informational deficiencies in modern patents and an emerging shift toward post-filing disclosure).

37. *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMMS. & TECH. L. REV. 345, 370–71 (2007); Amy Kapczynski, *Dangerous Times: The FDA's Role in Information Production, Past and Future*, 102 MINN. L. REV. 2357, 2373–74 (2018).

38. *See* 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

researchers, consumer watchdogs, medical associations, and everyday doctors and patients.[39]

This is an urgent moment for the sharing of safety and effectiveness data, as there is an ongoing crisis of data secrecy in the pharmaceutical and medical device industries. To quote a 2016 Doctors Without Borders report, "it is estimated that around half of all the clinical trials that have ever been carried out have never reported results" and that "[w]hen clinical trial data are kept secret and the reporting of results are biased, informed decisions about providing the best possible treatment are impossible to make."[40] Amy Kapczynski and I wrote in 2021 that there is "an emerging consensus that independent researchers need better access to clinical trial data to keep both the industry and regulators honest and accountable."[41] That remains true today, as ClinicalTrials.gov—the largest publicly accessible database of safety and effectiveness data on drugs, vaccines, and devices—provides only high-level (albeit highly useful) summary data and continues to lack data from thousands of important trials.[42]

We have in the United States not only a crisis of drug *spending* but a crisis of drug *value*. We don't know which drugs work best for patients, and

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CALIF. L. REV. 493, 503, 514–15 (2021) (describing the large volume of information submitted to FDA and the comparatively small fraction of that information disclosed to the public). But note that companies do sometimes submit fraudulent data to the FDA. *See, e.g.*, *DOJ Previews Enforcement Policies Aimed at Clinical Trial Fraud*, COOLEY (Dec. 20, 2021), https://www.cooley.com/news/insight/2021/2021-12-20-doj-enforcement-policies-clinical-trial-fraud [https://perma.cc/T4QL-ES58] (recounting a DOJ investigation into a research firm that allegedly "invented" entire clinical trials, including data and medical records, for submission to the FDA).

39. *See* Morten & Kapczynski, *supra* note 38, at 502–15 (describing the many socially valuable uses of safety and effectiveness data).

40. MÉDECINS SANS FRONTIÈRES [DOCTORS WITHOUT BORDERS], LIVES ON THE EDGE: TIME TO ALIGN MEDICAL RESEARCH AND DEVELOPMENT WITH PEOPLE'S HEALTH NEEDS 19 (2016), https://msfaccess.org/sites/default/files/R%26D_report_LivesOnTheEdge_Updated29Sept_ENG_2016.pdf [https://perma.cc/ZV9Z-E84D] (footnote omitted).

41. Morten & Kapczynski, *supra* note 38, at 497.

42. *Who's Sharing Their Clinical Trial Results?*, FDAAA TRIALS TRACKER (Dec. 23, 2025), https://fdaaa.trialstracker.net [https://perma.cc/6NKZ-Y2YH]; *see also* Reshma Ramachandran, Christopher J. Morten & Joseph S. Ross, *Strengthening the FDA's Enforcement of ClinicalTrials.gov Reporting Requirements*, 326 JAMA 2131, 2131 (2021) ("Recent estimates suggest that approximately 60% of trials fail to report results on time and more than 30% . . . have not yet reported results."); OFF. OF INSPECTOR GEN., U.S. DEP'T HEALTH & HUM. SERVS., THE NATIONAL INSTITUTES OF HEALTH DID NOT ENSURE THAT ALL CLINICAL TRIAL RESULTS WERE REPORTED IN ACCORDANCE WITH FEDERAL REQUIREMENTS 4–7 (2022), https://oig.hhs.gov/documents/audit/8302/A-06-21-07000-Complete%20Report.pdf [https://perma.cc/UE37-JWVB] (reporting that NIH had failed to disclose results of its own trials to ClinicalTrials.gov). The Department of Health and Human Services' Office of Inspector General announced in January 2024 that it is investigating the FDA's failure to enforce the federal statute that requires submission of trial results to ClinicalTrials.gov and expects to issue a report on the subject in 2026. *See Food and Drug Administration's Oversight of the Submission of Applicable Clinical Trial Results to ClinicalTrials.gov*, OFF. INSPECTOR GEN., U.S. DEP'T HEALTH & HUM. SERVS. (Jan. 2, 2024), https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000825.asp [https://perma.cc/6UKZ-P67S].

a growing number of FDA-approved drugs seem to provide no benefits at all.[43] Data secrecy contributes to the drug affordability crisis in the United States; we cannot collectively shift toward negotiating fairer prices for drugs that reflect their value without ready access to information on that value.[44]

Important information on the safety, effectiveness, and value of drugs, vaccines, and medical devices remains secret today despite intensive and successful data transparency efforts that took off in the 1990s and 2000s.[45] The second Trump Administration and new Secretary of Health & Human Services ("HHS") Robert F. Kennedy, Jr., have promised "radical transparency" at the FDA and other public health agencies,[46] but layoffs have decimated the FDA's public communications staff,[47] and the FDA has not begun any significant new data-sharing initiatives.[48]

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43. *See, e.g.*, Neel U. Sukhatme & M. Gregg Bloche, *Health Care Costs and the Arc of Innovation*, 104 MINN. L. REV. 955, 982–83 (2019) (highlighting how current FDA protocols can fast-track medications that offer patients marginal, if any, health improvements); Matthew Herder, *Pharmaceutical Drugs of Uncertain Value, Lifecycle Regulation at the US Food and Drug Administration, and Institutional Incumbency*, 97 MILBANK Q. 820, 838–39 (2019) (observing that the FDA rarely uses its PMR authority to compel evidence of clinical effectiveness outside of accelerated approvals); Thomas J Hwang, Joseph S Ross, Kerstin N Vokinger & Aaron S Kesselheim, *Association Between FDA and EMA Expedited Approval Programs and Therapeutic Value of New Medicines: Retrospective Cohort Study*, BMJ 3 (2020), https://www.bmj.com/content/bmj/371/bmj.m3434.full.pdf [https://perma.cc/JCK7-MJAR] ("Overall, 31% (84/267) of FDA drug approvals and 31% (83/267) of EMA drug approvals were rated as having high therapeutic value . . . ."); Christopher Morten, *What's Value in Health Care? Powerful Companies Make It Hard to Know*, LAW & POL. ECON. PROJECT (July 22, 2025), https://lpeproject.org/blog/whats-value-in-health-care-powerful-companies-make-it-hard-to-know [https://perma.cc/LE24-97VK] (pointing to drugs like Sarepta's Duchenne muscular dystrophy treatments, which maintained FDA approval and high price tags despite post-market trials failing to confirm any measurable therapeutic benefit).

44. For analysis of value-based pricing of drugs, vaccines, and medical services more broadly, see generally Anna Kaltenboeck et al., *Grounding Value-Based Drug Pricing in Population Health*, 107 CLINICAL PHARMACOLOGY & THERAPEUTICS 1290, 1290–91 (2020); PETER J. NEUMANN, JOSHUA T. COHEN & DANIEL A. OLLENDORF, THE RIGHT PRICE: A VALUE-BASED PRESCRIPTION FOR DRUG COSTS 16–17 (2021); Thomas Waldrop, Value-Based Pricing of Prescription Drugs Benefits Patients and Promotes Innovation, CTR. FOR AM. PROGRESS (Sept. 2021), https://www.americanprogress.org/wp-content/uploads/sites/2/2021/09/ValueDrugPricing-report-1.pdf [https://perma.cc/5N6K-YH2N]; and Daniel J. Hemel & Lisa Larrimore Ouellette, *Valuing Medical Innovation*, 75 STAN. L. REV. 517, 535–36 (2023).

45. Morten & Kapczynski, *supra* note 38, at 525–26; Ramachandran et al., *supra* note 42, at 2132; Christopher J. Morten, Gabriel Nicholas & Salomé Viljoen, *Researcher Access to Social Media Data: Lessons from Clinical Trial Data Sharing*, 39 BERKELEY TECH. L.J. 109, 117, 178–81 (2024) [hereinafter Morten et al., *Researcher Access to Social Media Data*].

46. *Radical Transparency*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/radical-transparency/index.html [https://perma.cc/T8YX-YC7Z].

47. Elaine Chen, Lizzy Lawrence & Isabella Cueto, *After RFK Jr.'s 'Radical Transparency' Pledge, HHS Shutters Much of Its Communications, FOIA Operations*, STAT NEWS (Apr. 1, 2025), https://www.statnews.com/2025/04/01/hhs-rfk-job-cuts-communications-foia-operations (on file with the *Iowa Law Review*).

48. To its credit, the FDA has recently begun publishing Complete Response Letters ("CRLs") from recent approvals and rejections of drug applications. *See* Press Release, U.S. Food & Drug Admin., FDA Announces Real-Time Release of Complete Response Letters, Posts Previously

Data secrecy is a problem for patients, for scientists, for public health, for public budgets, and for those who wish to hold the FDA accountable. Here are three concrete, urgent examples:

(1) Lecanemab (Leqembi), a breakthrough Alzheimer's drug, may have a lethal side effect—brain swelling and bleeding.[49] The drug is used by thousands of Americans and is expected to generate over $2 billion in sales per year by 2030.[50] Concerns over dozens of patient deaths that may have been caused by the drug have led academic researchers at Stanford, Johns Hopkins, and University College London to seek unpublished data on the drug's safety, but the FDA and the drug's manufacturer, Eisai, have so far declined to share it.[51] One researcher wrote in 2023 that "the maker of lecanemab has refused to share any clinical trial data with other researchers" and called the manufacturer's actions "a betrayal of the hopes of patients and risks causing them enduring harm."[52]

(2) GLP-1 agonists, including semaglutide (Ozempic), are diabetes and weight-loss drugs that have recently become among the most profitable products on earth. They promise health benefits that may transform the lives of billions of people, but their popularity and high costs have prompted rationing. In 2024, for example, the North Carolina State Health Plan revoked coverage of Ozempic for weight loss.[53] Unpublished data held by Ozempic's

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Unpublished Batch of 89 (Sept. 4, 2025), https://www.fda.gov/news-events/press-announcements/fda-announces-real-time-release-complete-response-letters-posts-previously-unpublished-batch-89 [https://perma.cc/7THN-45SM]. CRLs offer valuable summaries of safety and effectiveness data and the FDA's analysis of that data. *See id.* However, CRLs themselves contain only summaries of the data and thus only a portion of what researchers seek. *See* Gregory H. Levine, Beth P. Weinman, Lauren Sager & Ava Kamb, *FDA Makes Good on Promise to Publish CRLs for Unapproved Drugs and Biologics*, ROPES & GRAY (Sept. 11, 2025), https://www.ropesgray.com/en/insights/alerts/2025/09/fda-makes-good-on-promise-to-publish-crls-for-unapproved-drugs-and-biologics [https://perma.cc/J69E-2ACL].

49. Robert Langreth & Gerry Smith, *The US Approved an Alzheimer's Drug. Seven Patients Subsequently Died*, BLOOMBERG (Mar. 31, 2025, 1:47 PM), https://www.bloomberg.com/news/features/2025-03-31/deaths-linked-to-alzheimer-s-drug-leqembi-spur-concerns-over-who-gets-it (on file with the *Iowa Law Review*); Corrie Pelc, *Drug that Slows Alzheimer's Is Safe and Effective, Real-World Data Shows*, MEDICALNEWSTODAY (May 16, 2025), https://www.medicalnewstoday.com/articles/lecanemab-drug-slows-alzheimers-safe-effective-side-effects-real-world-data [https://perma.cc/5RWLZV5N].

50. Oliver Barnes, *Alzheimer's Drug Leqembi Falls Short of Blockbuster Status in Faltering US Rollout*, FIN. TIMES (Apr. 22, 2024), https://www.ft.com/content/1e02c10c-f7c4-48e9-a6a4-774531b56350 (on file with the *Iowa Law Review*).

51. Madhav Thambisetty, *Manufacturers Need to Be More Open About a Dangerous Alzheimer's Drug Side Effect*, STAT NEWS (Nov. 28, 2023), https://www.statnews.com/2023/11/28/lecanemab-leqembi-aducanumab-donanemab-side-effects-aria-brain (on file with the *Iowa Law Review*); Melody Petersen, *Alzheimer's Drug's Potentially Fatal Side Effect, ARIA, Obscured by 'Soothing Acronym,' Doctors Say*, L.A. TIMES (June 17, 2024, 3:00 AM), https://www.latimes.com/science/story/2024-06-17/alzheimers-drug-has-potentially-fatal-side-effects [https://perma.cc/FA87-CSA5].

52. Thambisetty, *supra* note 51.

53. *See* Simone Foxman & Madison Muller, *North Carolina Drops Coverage of Costly Weight-Loss Drugs*, BLOOMBERG L. (Jan. 27, 2024, 3:36 PM), https://www.bloomberglaw.com/bloomberglawnews/insurance/X9BDOAKO000000 (on file with the *Iowa Law Review*); *see also* Letter from Dale

manufacturer, Novo Nordisk, and the FDA promises to shed further light on the drug's long-term properties and thereby inform an active debate over its costs and benefits to individual patients and society as a whole.[54]

(3) Eteplirsen (Exondys 51) is a treatment for a rare and devastating form of muscular dystrophy. The drug costs hundreds of thousands of dollars per year but has never shown any measurable therapeutic benefit in even a single successful clinical trial.[55] The drug may have been approved by the FDA in 2016 under pressure from the company; the senior FDA official who ultimately made the approval decision remarked at the time that the drug's manufacturer, Sarepta, was likely to go bankrupt without the approval.[56] The approval prompted the resignation and retirement of two senior FDA scientists.[57] A science journalist, NYU Professor Charles Seife, spent years pursuing Freedom of Information Act ("FOIA") requests for the safety and effectiveness data underlying eteplirsen's approval, seeking to scrutinize the FDA's analysis.[58] Seife took his FOIA requests all the way to the Second Circuit but ultimately only obtained an incomplete portion of the safety and effectiveness data he sought.[59] Since then, the FDA has continued to approve other muscular dystrophy drugs made by Sarepta despite negligible proof of effectiveness, prompting one former FDA scientist to decry a "mockery of scientific reasoning and approval standards" that have served patients well over decades.[60] An independent investigation by the Office of Inspector General at HHS concluded in 2025 that the FDA's approval of eteplirsen

Folwell, Chair, Bd. of Trs., N.C. State Health Plan, to Xavier Becerra, Sec'y, U.S. Dep't of Health & Hum. Servs. (July 29, 2024), https://www.shpnc.gov/documents/folwell-request-usdhhs-glp1/download?attachment [https://perma.cc/D9AN-CD43].

54. Dylan Scott, *Can Ozempic Be a Breakthrough Drug and Overpriced at the Same Time?*, VOX (Apr. 3, 2024, 8:00 AM), https://www.vox.com/future-perfect/2024/4/3/24119220/ozempic-wegovy-weight-loss-medicare-coverage-price [https://perma.cc/9FBN-UA3K].

55. Mark Terry, *Going Its Own Way, European Regulators Reject Sarepta's Exondys 51 for DMD*, BIOSPACE (Sept. 21, 2018), https://www.biospace.com/going-its-own-way-european-regulators-reject-sarepta-s-exondys-51-for-dmd-fd1a [https://perma.cc/P9K3-NV7G]; Rachel E. Sachs, W. Nicholson Price II & Patricia J. Zettler, *Rethinking Innovation at FDA*, 104 B.U. L. REV. 513, 521 (2024).

56. *See* Sachs et al., *supra* note 55, at 519–20.

57. Charles Seife, *FDA Documents Reveal Depths of Internal Rancor Over Drug's Approval Process*, UNDARK (Aug. 2, 2017), https://undark.org/2017/08/02/fda-eteplirsen-janet-woodcock [https://perma.cc/9SEB-5EEE].

58. Charles Seife, *Is the FDA Withholding Data About a Controversial Drug to Protect Its Manufacturer?*, SCI. AM. (Nov. 29, 2017), https://www.scientificamerican.com/article/is-the-fda-withholding-data-about-a-controversial-drug-to-protect-its-manufacturer [https://perma.cc/2ASU-RGPV].

59. Seife v. U.S. Food & Drug Admin., 43 F.4th 231, 242–44 (2d Cir. 2022). Clinic students and I represented Seife in this effort, alongside co-counsel.

60. Brittany Trang, *'Sarepta's Like a Curse on Me': FDA Commissioner Dismisses Controversy over Elevidys*, STAT NEWS (Sept. 11, 2024), https://www.statnews.com/2024/09/11/sarepta-elevidys-fda-decision-califf-clinical-trials-fail (on file with the *Iowa Law Review*).

"deviated from FDA's recommended practices" and "raised concerns" about agency integrity.[61]

A second patent bargain tethered to patent term extension could unlock this secret data on Leqembi, Ozempic, and Exondys 51. The manufacturers of all three drugs applied to the USPTO for patent term extension.[62] The USPTO has already granted extensions of patents on Ozempic and Exondys 51, of about three and three-and-a-half years, respectively.[63]

Public access to safety and effectiveness data on medical products yields real benefits. Public access to safety and effectiveness data made available by the FDA, other regulators, and manufacturers—sometimes proactively and sometimes in response to FOIA requests and public pressure—has helped quell (some) misinformation and resolve (some) debates over the safety of COVID-19 vaccines;[64] exposed mistakes made by the FDA and other regulators in approving opioids, sparking regulatory reform;[65] reshaped doctors' use of influenza medicines;[66] (belatedly) improved the safety of cancer chemotherapy regimens;[67] and more. One consumer advocacy group, Public Citizen,

61. OFF. OF INSPECTOR GEN., DEP'T HEALTH & HUM. SERVS., OEI-01-21-00400, HOW FDA USED ITS ACCELERATED APPROVAL PATHWAY RAISED CONCERNS IN 3 OF 24 DRUGS REVIEWED 9 (2025), https://oig.hhs.gov/documents/evaluation/10160/OEI-01-21-00400.pdf [https://perma.cc/9LRE-U7X3].

62. *Applications for Patent Term Extension and Patent Terms Extended Under 35 U.S.C. 156*, *supra* note 23 (from the U.S. Patent and Trademark Office site, click on the links to download spreadsheets of patent term extension applications and grants; alternatively, download the spreadsheets of applications at https://perma.cc/3F4C-4R2J (noting application for extension by Leqembi) and granted extensions at https://perma.cc/H7FU-GVDJ (noting extensions for Ozempic and Exondys 51)).

63. *Id.*

64. *See, e.g.*, Steven Kwasi Korang et al., *Vaccines to Prevent COVID-19: A Living Systematic Review with Trial Sequential Analysis and Network Meta-Analysis of Randomized Clinical Trials*, PLOS ONE 2 (Jan. 21, 2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC8782520/pdf/pone.0260733.pdf [https://perma.cc/EU5G-Z2KL]; Hilda Bastian, *The FDA Really Did Have to Take This Long*, ATLANTIC (Aug. 23, 2021), https://www.theatlantic.com/science/archive/2021/08/fda-pfizer-vaccine-full-approval/619870 (on file with the *Iowa Law Review*) (observing that "early, publicly available data have now been thoroughly scrutinized").

65. Independent analysis of the clinical trial data that supported approval of Purdue Pharma's addictive oxycodone product, OxyContin, and other opioid painkillers by drug regulators worldwide has underscored the paucity of evidence on addiction that regulators initially demanded and has helped shape a present-day consensus that regulators must more carefully scrutinize new drugs for addictive potential. *See* James Heyward et al., *Key Evidence Supporting Prescription Opioids Approved By the U.S. Food and Drug Administration, 1997 to 2018*, 173 ANNALS INTERNAL MED. 956, 956 (2020); Jessie Pappin, Itai Bavli & Matthew Herder, *On What Basis Did Health Canada Approve OxyContin in 1996? A Retrospective Analysis of Regulatory Data*, 19 CLINICAL TRIALS 584, 585 (2022); Sam Hornblower, *How the FDA Helped Ignite, and Then Worsened, the Opioid Crisis*, BLOOMBERG (Apr. 25, 2025, 5:00 AM), https://www.bloomberg.com/news/features/2025-04-25/the-fda-s-untold-role-in-igniting-the-opioid-crisis (on file with the *Iowa Law Review*).

66. *Tamiflu Campaign*, BMJ, https://www.bmj.com/tamiflu [https://perma.cc/4PTH-XJKL].

67. Gardiner Harris, *The Johnson & Johnson Cancer Drug Scandal that Encapsulates Corruption in Health Care*, STAT NEWS (Apr. 3, 2025), https://www.statnews.com/2025/04/03/eryth

claims to have used publicly available safety data to help convince the FDA to remove twenty-three dangerous drugs from the U.S. market between 1971 and 2019.[68] Another nonprofit, the Institute for Clinical and Economic Review ("ICER"), conducts comparative and cost-effectiveness analyses of drugs, devices, and other medical products that guide coverage, pricing, and reimbursement decisions by public and private payers alike.[69] But ICER has complained that lack of access to certain safety and effectiveness data limits its work.[70]

The proposed second patent bargain could fuel noncommercial research on safety and effectiveness data without significant harm to the legitimate financial interests of the companies that make these products.[71] New social value can be created while leaving private value intact.

Finally, this sort of second patent bargain—public disclosure of late-stage safety and effectiveness data on pharmaceuticals and vaccines as a quid for the quo for patent term extension—is already part of federal statute. Such a bargain was expressly contemplated by Congress when it enacted the Hatch–Waxman Act—though not clearly worded or ultimately implemented by the FDA and USPTO. Still, a provision of the Act mandating public disclosure of safety and effectiveness data on pharmaceuticals remains good law, lying neglected in the plain text of the statute.[72] Reforming patent law to require new disclosure as a condition of patent term extension would make good on a promise the Hatch–Waxman Act made forty years ago.

This Article proceeds in four parts. Part I situates the Article's argument in the broader context of patent theory and doctrine. Although patent law's disclosure requirement has its skeptics, the dominant (and correct) view

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ropoietin-epo-scandal-cancer-drug-johnson-and-johnson-no-more-tears-excerpt (on file with the *Iowa Law Review*).

68. Brief for Pub. Citizen as Amici Curiae Supporting Respondent, Food Mktg. Inst. v. Argus Leader Media, 139 S. Ct. 2356 (2019) (No. 18-481), 2018 WL 7890208, at *18.

69. Cohen, *Leveraging Clinical- and Cost-Effectiveness Data to Inform Drug Pricing and Reimbursement*, LYFEGEN, https://www.lyfegen.com/post/leveraging-clinical-and-cost-effectiveness-data-to-inform-drug-pricing-and-reimbursement [https://perma.cc/W7U8-CWYF]; Kristin Mickle, *The Growing Influence of the Institute of Clinical and Economic Review on Payer Decisions in the US*, EVIDERA 2–5 (2019), https://www.evidera.com/resource/pdf-the-growing-influence-of-the-institute-of-clinical-and-economic-review-on-payer-decisions-in-the-us/?dl=1 [https://perma.cc/T9R9-VAA4].

70. *See, e.g.*, Naoko A Ronquest, Kyle Paret, Ian Gopal Gould, Christine L Barnett & Deirdre M Mladsi, *The Evolution of ICER's Review Process for New Medical Interventions and a Critical Review of Economic Evaluations (2018-2019): How Stakeholders Can Collaborate with ICER to Improve the Quality of Evidence in ICER's Reports*, 27 J. MANAGED CARE & SPECIALTY PHARM. 1601, 1610 (2021) ("ICER accounted for many of the manufacturer-provided new clinical data currently unavailable in the public domain. However, because the data provision to ICER is voluntary, it is unknown whether the participating manufacturers chose data favorable to their products."). For an exemplary ICER publication complaining of lack of access to data on Alzheimer's drugs, see generally GRACE LIN ET AL., INST. FOR CLINICAL & ECON. REV., LECANEMAB FOR EARLY ALZHEIMER'S DISEASE (2023).

71. *See infra* Section III.A and Part IV. For past analysis of the minimal private losses associated with sharing safety and effectiveness data on drugs and vaccines held by the FDA, see Morten & Kapczynski, *supra* note 38, at 549–55.

72. 21 U.S.C. § 355(*l*)(1)(E); *see infra* Section II.A.

among courts and scholars is that disclosure of information on patented inventions is essential to a well-functioning patent system, economy, and society. Information disseminated by the patent system benefits not just competitors and future inventors but other constituencies, consistent with the Constitution's broad command to "promote the Progress of Science and useful Arts."[73] Scholars have argued for expansion of patent law's mandatory disclosures, contending that the patent system can and should require disclosure of not just early-stage technical data collected before patent filing but also late-stage information on the commercialized products actually used by people. This Article combines these theories in a new way: It argues that patent law should be reformed to induce disclosure of late-stage, post-filing information useful to researchers, watchdogs, doctors, patients, and other noncommercial consumers of information.

Part II presents the problem of today's broken second patent bargain. Section II.A looks back at 1984's Hatch–Waxman Act and shows that the Act's framers contemplated—and perhaps promised—public disclosure of late-stage data on the properties of pharmaceuticals and medical devices as a kind of quid pro quo for patent term extension on these products. Section II.B details how patent term extension works today: USPTO and FDA work together to extend patent terms without requiring any meaningful new disclosure from the beneficiaries. Section II.B also defends my view that patent term extensions are best viewed, conceptually and doctrinally, as new grants of patent exclusivity rather than somehow part of the original patent grant.

Part III describes an effective second patent bargain. Section III.A implements a new quid pro quo, including details of submission, verification, and publication of useful information. Section III.B traces two paths by which the new quid pro quo could become law of the land: one through rule reform at the FDA and USPTO, which could reactivate neglected provisions of the Hatch–Waxman Act,[74] and one through Congress, which could simply amend the Patent Act anew.

Part IV responds to a serious potential counterargument based in contemporary constitutional doctrine—that mandatory disclosure of secret data on patented inventions could work a taking under the Takings Clause. Part IV explains that there is no taking.

I. THE SECOND PATENT BARGAIN IN THEORY

The American patent system is built on the theory of the patent bargain. Since our patent system's inception, it has conditioned patents on mandatory public disclosure of detailed information about the patented invention.[75] The Supreme Court announced in 1989 that "the ultimate goal of the patent

73. U.S. CONST. art. I, § 8, cl. 8 (Intellectual Property Clause).

74. 21 U.S.C. § 355(*l*)(1); 35 U.S.C. § 156(d)(4), (e)(1).

75. Amgen Inc. v. Sanofi, 143 S. Ct. 1243, 1251 (2023).

system is to bring new designs and technologies into the public domain through disclosure."[76] The Court reiterated in 2023, in *Amgen v. Sanofi*,[77] that the patent bargain is rooted in the specific text of the Constitution's Progress Clause, which authorizes Congress to create patents not for the specific benefit of inventors but for the sake of social *progress*: "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[78] The Court wrote,

> Reflecting the *quid-pro-quo* premise of patent law, the [original Patent Act of 1790] required the applicant to deposit with the Secretary of State a "specification . . . so particular . . . as . . . to enable a workman or other person skilled in the art or manufacture . . . to make, construct, or use the same." The statute made clear that this disclosure would ensure "the public may have the full benefit [of the invention or discovery], after the expiration of the patent term."[79]

Today's Patent Act is very similar.[80] It requires (among other disclosure requirements) that:

> The [patent] specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.[81]

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76. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989).

77. *Amgen Inc.*, 143 S. Ct. at 1251 (describing the theory of the patent bargain and U.S. patent laws disclosure requirements as existing "[r]ight there in the text" of the Intellectual Property Clause); *see also* Graham v. John Deere Co., 383 U.S. 1, 6 (1966) ("[T]hings which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the Progress of . . . useful Arts.'" (alteration in original)).

78. U.S. CONST. art. I, § 8, cl. 8.

79. *Amgen Inc.*, 143 S. Ct. at 1251 (citations omitted).

80. *Bonito Boats, Inc.*, 489 U.S. at 148 ("Today's patent statute is remarkably similar to the law as known to Jefferson in 1793."). The Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") has effectively globalized patent law's disclosure requirement. Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 29(1), Jan. 1, 1995 ("Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application."). The premise that every patent grant is conditioned on the quid pro quo of disclosure is now nearly universal.

81. 35 U.S.C. § 112(a).

In light of this requirement, the *Amgen* Court held invalid certain broad patent claims Amgen had obtained, covering not just its cholesterol-lowering antibody drug evolocumab (Repatha) but also a "vast number" of related drug candidates, because Amgen's patent disclosed too little infor-mation on how to identify and manufacture this vast number.[82] Amgen's patent claims were invalid because Amgen's patent "forced [the public] to engage in 'painstaking experimentation' to see what works"; it failed to explain sufficiently what works and what doesn't.[83]

Who uses the information disclosed in patents, and how? For starters, scientists and engineers in industry, academia, and government laboratories read patents for technical information that may not be published in the scientific literature or elsewhere—diagrams, step-by-step recipes, details of an invention's design and implementation, procedures for measuring an invention's properties, and more.[84] As Jeanne Fromer has put it, "patent disclosure indirectly stimulates future innovation by revealing the invention's design so that others can use it fruitfully when the patent term expires and design around, improve upon, or be inspired by the invention, even during the patent term."[85] Competitor companies, patent examiners, and courts read patents and their claims to understand the "metes and bounds" of the exclusive rights conferred by the patent—what is covered by the patent and what is not.[86] Patents also provide important and otherwise inaccessible

82. *Amgen Inc.*, 143 S. Ct. at 1256–58.

83. *Id.* at 1256.

84. *See* Lisa Larrimore Ouellette, *Do Patents Disclose Useful Information?*, 25 HARV. J.L. & TECH. 545, 560–62, 566–71 (2012) [hereinafter Ouellette, *Do Patents Disclose Useful Information?*] (describing useful technical information currently provided by patents); Lisa Larrimore Ouellette, *Who Reads Patents?*, 35 NATURE BIOTECH. 421, 422 (2017) [hereinafter Ouellette, *Who Reads Patents?*]; *see also* Alan Devlin, *The Misunderstood Function of Disclosure in Patent Law*, 23 HARV. J.L. & TECH. 401, 410–11 (2010) (describing the role of disclosure in the patent system); Clarisa Long, *Patents and Cumulative Innovation*, 2 WASH. U. J.L. & POL'Y 229, 229–30 (2000) (discussing how the patent system may balance incentives during research).

85. Fromer, *Patent Disclosure*, *supra* note 36, at 541; *see also* Gill v. Wells, 89 U.S. 1, 25–26 (1874) (describing, as two of the three "great ends" of patent law's disclosure requirement, "[t]hat licensed persons desiring to practice the invention may know, *during the term*, how to make, construct, and use the invention" and "[t]hat other inventors may know what part of the field of invention is unoccupied" (emphasis added)).

86. *See* Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1141, 1197 (2008) (explaining this function of patent law's disclosure requirement and urging patent law to require patent inventors to provide better definitions of terms used in the patent); Fromer, *supra* note 36, at 565–69 (describing the "legal layer" of patents and the legal audience that uses the information presented in patents); Timothy R. Holbrook, *Patents, Presumptions, and Public Notice*, 86 IND. L.J. 779, 823 (2011). Jason Rantanen has shown that this definitional or boundary-drawing function of patent law's disclosure requirement works in tandem with patent disclosure's information-dissemination function; the more detailed and thorough the technical disclosure, the clearer the definition of the claims. Jason Rantanen, *Patent Law's Disclosure Requirement*, 45 LOY. U. CHI. L.J. 369, 378 (2013).

information to patent-holding companies' investors and to repeat customers of the companies' products.[87]

In recent years, some scholars have argued that information disseminated by the patent system should serve not just these sophisticated constituencies but everyday end consumers, too, by informing us about the products we choose among and consume.[88]

Colleen Chien, for example, has observed that the Patent Act imposes on the USPTO a longstanding—albeit little-analyzed—obligation to "disseminat[e] to the public information with respect to patents and trademarks."[89] Even the *Amgen* Court implied that the public's interests are not coextensive with inventors'; the public is supposed to benefit from patent disclosure in other, additional ways:

> Amgen warns that an affirmance risks "destroy[ing] incentives for breakthrough inventions." But striking the proper balance between incentivizing inventors and ensuring the public receives the full benefit of their innovations is a policy judgment that belongs to Congress. Since 1790, Congress has included an enablement

87. *See* Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 644 (2002); Timothy R. Holbrook, *The Expressive Impact of Patents*, 84 WASH. U. L. REV. 573, 591 (2006); J. Jonas Anderson, *Nontechnical Disclosure*, 69 VAND. L. REV. 1573, 1582 (2016).

88. *See* Colleen V. Chien, *Contextualizing Patent Disclosure*, 69 VAND. L. REV. 1849, 1866 (2016); W. Nicholson Price II, *Regulating Secrecy*, 91 WASH. L. REV. 1769, 1806 (2016) (describing diffuse but important benefits flowing from regulators' oversight, researchers' oversight, and broad public oversight of patent-intensive regulated industries); Anderson, *supra* note 87, at 1591 (observing that the information in a patent "may encourage a consumer to purchase [the patented product], even though that information is not technical in nature"). *But see* Thomas, *supra* note 12, at 333–34 (arguing consumers care little about whether products are patented); Christopher A. Cotropia, *Patents as Signals of Quality in Crowdfunding*, 2021 U. ILL. L. REV. 193, 224 (empirical study showing that typical consumers ignore patents). Of course, the dominant, orthodox account of the patent system and the "patent bargain" is that patent law's disclosure requirement already benefits consumers *indirectly*, not least by catalyzing follow-on invention and promoting low-cost competition (and so increasing social welfare). But I see a distinction between the *indirect* benefits contemplated by the orthodox patent bargain and *direct* informational benefits to consumers. To imagine regular people reaping informational benefits directly from the patent system has parallels with established theories in copyright and trade secrecy of the rights of consumers, workers, and others who are not primarily creators or "innovators," especially "readers' rights" and "rights to know." On "reader's rights" in copyright law, see, for example, Jessica Litman, *The Public Domain*, 39 EMORY L.J. 965, 974 (1990); Jessica Litman, *Readers' Copyright*, 58 J. COPYRIGHT SOC'Y U.S.A. 325, 330 (2011); and Rebecca Tushnet, Note, *Legal Fictions: Copyright, Fan Fiction, and a New Common Law*, 17 LOY. L.A. ENT. L.J. 651, 654 (1997). On "rights to know" in trade secrecy law, see, for example, ORLY LOBEL, TALENT WANTS TO BE FREE 98–120 (2013).

89. Chien, *supra* note 88, at 1875 (citing 35 U.S.C. § 2(a)(2) (2012)). Chien has further noted U.S. patent law continues to incentivize patent owners to disseminate knowledge broadly to the American public (not just experts) through the wide sale of products that embody their patents. *Id.* at 1855, 1867.

> mandate as one feature among many designed to achieve the balance it wishes.[90]

Of course, the information produced by the patent system is imperfect. Scholars lament that patents are written mostly by lawyers and are sometimes intentionally obfuscatory, making them hard for scientists and other technical readers to understand—let alone everyday people.[91] Scholars have also observed that the USPTO and courts enforce patent law's disclosure requirements inconsistently, meaning patents are riddled with incomplete, incorrect, even fraudulent data.[92] Yet most scholars have, like the Supreme Court, continued to endorse the value of patent law's disclosure requirement, urging reforms that would improve the quality and quantity of technical information.[93]

To this end, there is growing scholarly consensus that patent law should do more to structure and incentivize disclosure of information generated *after* patent filing—post-filing information.[94] Post-filing information is, by

90. Amgen Inc. v. Sanofi, 143 S. Ct. 1243, 1257 (2023) (alteration in original).

91. *See* Fromer, *Patent Disclosure*, *supra* note 36, at 563–85; Ouellette, *Do Patents Disclose Useful Information?*, *supra* note 84, at 557.

92. *See* Fromer, *Patent Disclosure*, *supra* note 36, at 539; Freilich, *Prophetic Patents*, *supra* note 36, at 663; Freilich, *The Replicability Crisis in Patent Law*, *supra* note 36, at 441–42; Lisa Larrimore Ouellette, Victoria Fang & Nicholas T. Ouellette, *How Will AI Affect Patent Disclosures?*, 43 NATURE BIOTECH. 26, 26–28 (2025); Janet Freilich & Arti K. Rai, *What Patents on AI-derived Drugs Reveal*, 388 SCIENCE 924, 924–26 (2025).

93. *See, e.g.*, Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 628–35 (2010) (arguing that U.S. patent law should better fulfill patents' "teaching" function by requiring clearer disclosures and working examples to improve technological knowledge dissemination and innovation); Sean B. Seymore, *Patenting the Unexplained*, 96 WASH. U. L. REV. 707, 715–20 (2019) (arguing that patent laws' minimal disclosure requirements yields uninformed patents); Freilich, *Prophetic Patents*, *supra* note 36, at 687–701 (empirically analyzing the prevalence and impact of "prophetic examples" in patents and arguing they often hinder innovation); *Patent Disclosure*, *supra* note 36, at 569–94 (suggesting various reforms to the disclosure requirement to make patents' technical information more useful to technical readers); Ouellette, *Do Patents Disclose Useful Information?*, *supra* note 84, at 590–601 (suggesting a different set of reforms toward the same end); *see also id.* at 540–47 (summarizing academic debate over the disclosure value of the patent system). *But see* Devlin, *supra* note 84, at 410–11; Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 105, 111, 119 (arguing patent law's disclosure requirements are irrelevant for self-disclosing inventions).

94. The patent system encourages inventors and their employers to file patents early in the life of an invention, before its properties are fully tested and known. *See, e.g.*, Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 69–70 (2009) ("The United States patent system is intentionally structured to encourage patent filing early in an invention's development."); Mark A. Lemley, *Ready for Patenting*, 96 B.U. L. REV. 1171, 1172 (2016) ("In an important class of cases—those in which the inventor has an idea but does not yet know if it will work—the patent system encourages the inventor to patent first and figure it out later, if at all."); Lisa Larrimore Ouellette, Pierson*, Peer Review, and Patent Law*, 69 VAND. L. REV. 1825, 1832 (2016) ("[I]n practice, patents often are awarded too early."); Fromer, *Dynamic Patent Disclosure*, *supra* note 34, at 1715 ("[T]he current state of patent disclosure—which many think is poor and does not achieve its objective of stimulating innovation—is impoverished in part because it occurs so

definition, nonexistent at the time a patent gets filed. Yet post-filing information on patented inventions is enormously valuable to scientists and engineers, the business community, and the broader public. It describes not just early prototypes and hypothetical embodiments but actual commercial products in wide use, and it can link these commercial products with early research data disclosed in patents, presenting a more complete picture.[95] As Fromer has put it, "much of the innovation process, from refinement to prototyping to market research to mass production," typically occurs after patent filing.[96] The patent system already requires or encourages disclosure of small amounts of post-filing information; for example, provisions of the Patent Act encourage patent owners to mark commercialized products that embody their patents[97] and record changes in patents' ownership.[98] Patent law could do more. Chien has recommended reform to require public disclosure of inventors' follow-on scientific publications, patent non-assertion pledges, and other public commitments.[99] Fromer[100] and John Thomas[101] have advocated reform of the Patent Act to require patent owners to disseminate information linking commercial products they and their licensees make to the patents that describe and cover these products. Nicholson Price, Arti Rai, Janet Freilich, and Peter Lee have proposed requiring patent owners to disclose much more detailed post-filing technical information, such as data on the manufacture, safety, utility, and reliability of the patented invention.[102]

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early in the process of innovation, at the time a patent is filed."). Post-filing information is also sometimes called "post-filing evidence," "ex post data," and other names. *See* Timothy R. Holbrook, *Patent Disclosures and Time*, 69 VAND. L. REV. 1459, 1502 (2016); Dmitry Karshtedt, *Nonobviousness: Before and After*, 106 IOWA L. REV. 1609, 1671 (2021); Freilich, *The Replicability Crisis in Patent Law*, *supra* note 36, at 481.

95. Fromer, *Dynamic Patent Disclosure*, *supra* note 34, at 1722–23.

96. *Id.* at 1715–16.

97. 35 U.S.C. § 287(a); *see also* Thomas, *supra* note 12, at 307–23.

98. *See supra* note 10; *see also* Thomas, *supra* note 12, at 333; Colleen Chien, *The Who Owns What Problem in Patent Law* 1–4 (Santa Clara Univ. Sch. L. Legal Stud. Rsch. Papers Series, Working Paper No. 03-12, 2012), https://digitalcommons.law.scu.edu/cgi/viewcontent.cgi?article=1191&context=facpubs [https://perma.cc/3T33-RZGT]; Chien, *supra* note 88, at 1867 ("The law has long encouraged *ongoing* dissemination of the invention outside of the four corners of the patent . . . ." (emphasis added)).

99. Chien, *supra* note 88, at 1880–86.

100. Fromer, *Patent Disclosure*, *supra* note 36, at 591–94.

101. Thomas, *supra* note 12, at 339–42.

102. W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1050–53 (2016) (considering amendment of the Patent Act to mandate disclosure of late-stage, post-filing information on biologic drug manufacturing); Freilich, *The Replicability Crisis in Patent Law*, *supra* note 36, at 481 (suggesting law reform to require disclosure of post-filing information); Lee, *supra* note 4, at 40–62 (proposing that ongoing disclosure requirements be added to the patent system, with focus on resuscitating patent law's currently moribund "best mode" requirement and suggestion to compel disclosure of data submitted to FDA and other regulators); Osmat Azzam Jefferson, W. Nicholson Price II, S. Sean Tu, Saurabh Vishnubhakat & Arti K. Rai, *The Puzzle of Biologics Manufacturing Platform Patents*, 43 NATURE BIOTECH. 295, 295–99 (2025) (urging enhanced notice requirements

To mandate disclosure of post-filing information makes theoretical sense.[103] The public must wait until patent expiration to *practice* a patent freely, but the public can and should *learn* from and about the patented invention throughout the period the patent holds force.[104] Per Becky Eisenberg, "[b]y providing an exclusionary right that survives public disclosure, the patent system protects innovators from free riders without the need for secrecy."[105]

This Article builds on this foundation. In my view, the patent system cannot fulfill the Progress Clause's mandate "to promote the Progress of Science and useful Arts" unless and until it mandates and structures disclosure of useful post-filing technical information on patented inventions—information useful not just to other inventors and the business community but also end consumers, noncommercial researchers, and the broad public.[106] Not all inventions have equal value. "Innovative" inventions may be patentable and patented—new, nonobvious, enabled, and (modestly) useful—but no better or even worse than existing products.[107] The patent system will work best when it not only incentivizes new inventions but also disseminates information on the *value* of those inventions. I intend to expand on this general theory in future work.[108]

This Article begins by plucking some low-hanging fruit. Envision how this general premise could play out with a subset of patents that cover drugs, medical devices, and other products regulated by the FDA that are crucial to human health and flourishing. The FDA holds *enormous* troves of post-filing information on the value of these products—on their safety and effectiveness especially.[109] And yet the FDA, as a rule, keeps most of this post-filing information secret, meaning that patients, payers, researchers, and the broad public struggle to determine which medical inventions are genuine breakthroughs and which are worthless (or worse), even years after

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for biologic drug manufacturing patents); *cf.* Price II, *supra* note 88, at 1802 (proposing mandated and ongoing "regulatory disclosure" through sector-specific regulators of patent-intensive industries, rather than through the patent system per se).

103. *See, e.g.*, Fromer, *Patent Disclosure*, *supra* note 36, at 595–97; Robert G. Bone, *A New Look at Trade Secret Law: Doctrine in Search of Justification*, 86 CALIF. L. REV. 241, 266–67 (1998); WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 326–31 (2003) (on the economic benefits of patenting and wide dissemination of technical knowledge rather than protection via secrecy and trade secrecy law).

104. Bone, *supra* note 103, at 266; Fromer, *Patent Disclosure*, *supra* note 36, at 541.

105. Rebecca S. Eisenberg, *Data Secrecy in the Age of Regulatory Exclusivity*, *in* THE LAW AND THEORY OF TRADE SECRECY 467, 487 (Rochelle C. Dreyfuss & Katherine. J. Strandburg eds., 2011).

106. U.S. CONST. art. I, § 8, cl. 8.

107. *See, e.g.*, Robin Feldman, *Understanding 'Evergreening': Making Minor Modifications of Existing Medications to Extend Protections*, 41 HEALTH AFFS. 801, 803 (2022) ("Although some minor modifications may be of value to some patients, studies suggest that others have little or no value in terms of therapeutic benefit or patient compliance.").

108. *See infra* Conclusion for some incipient thoughts.

109. Morten & Kapczynski, *supra* note 38, at 503.

they make their way to market.[110] The manufacturers of these products routinely obtain multiyear extensions on the terms of the patents on these products without disclosing any new technical information, in violation of the bedrock theory of the patent bargain. This Article proposes that extension of the patents on these products could and should act as a "trigger" for disclosure of some of the valuable post-filing information held by the FDA.

This Article is the first to propose using patent term extension in this way. Patent term extension has seen two significant "waves" of scholarship, neither of which addresses the disclosure obligations (if any) that should "attach to extensions. The first wave occurred in the 1980s, around the time patent term extension was first debated and then enacted, as part of 1984's Hatch–Waxman Act. The first wave focused at a rather high level on whether patent term extensions are wise public policy or instead a "giveaway" to the pharmaceutical and medical device industries—a heated debate in the literature fueled not just by law professors but by prominent brand- and generic-side lawyers and by then-Representative Al Gore.[111]

The second wave of scholarship on patent term extension began in the 2010s.[112] Scholars reopened debate over whether the current rules strike an

110. *See supra* Introduction; *see also* Morten & Kapczynski, *supra* note 38, at 502–29 (explaining the social value of disclosure of clinical trial data, the existing sources of this data, and the limitations of these sources).

111. *See, e.g.*, Peter Huber, *The Old-New Division in Risk Regulation*, 69 VA. L. REV. 1025, 1036 & n.45 (1983); Albert Gore, Jr., *Patent Term Extension: An Expensive and Unnecessary Giveaway*, 1 HEALTH AFFS. 25, 25–26 (1982) (arguing against the wisdom of PTE); Alfred B. Engelberg, *Patent Term Extension: An Overreaching Solution to a Nonexistent Problem*, 1 HEALTH AFFS. 34, 34–35 (1982) (generic-side lawyer arguing against the need for PTE); Peter Barton Hutt, *The Importance of Patent Term Restoration to Pharmaceutical Innovation*, 1 HEALTH AFFS. 6, 19–21 (1982) (brand-side lawyer arguing for PTE); Alan D. Lourie, *Patent Term Restoration*, 66 J. PAT. OFF. SOC'Y 526, 549–50 (1984) [hereinafter Lourie, *Patent Term Restoration*] (same); Alan D. Lourie, *Patent Term Restoration: History, Summary, and Appraisal*, 40 FOOD DRUG COSM. L.J. 351, 361–62 (1985) [hereinafter Lourie, *History, Summary, and Appraisal*] (same).

112. *See generally* Jaime F. Cárdenas-Navia, *Thirty Years of Flawed Incentives: An Empirical and Economic Analysis of Hatch-Waxman Patent-Term Restoration*, 29 BERKELEY TECH. L.J. 1301 (2014) (analyzing the impact of PTE in the Hatch–Waxman Act and advocating for reforms); Lietzan et al., *supra* note 25 (comparing the use of patent extensions by drug companies and medical device companies); Lietzan & Acri, *supra* note 17 (finding that drugs with longer clinical testing programs have shorter effective patent lives and PTE is often not effective at giving drugs a fourteen-year effective patent life); Erika Lietzan, *The History and Political Economy of the Hatch-Waxman Amendments*, 49 SETON HALL L. REV. 53 (2018) (discussing the history of the Hatch–Waxman Act and arguing that it left patent-owning companies in a worse position than producers of generics); Reed F. Beall, Jonathan J. Darrow & Aaron S. Kesselheim, *Patent Term Restoration for Top-Selling Drugs in the United States*, 24 DRUG DISCOVERY TODAY 20 (2019) (analyzing how frequently drugs receive patent extensions and the impact of extensions on generic entry); Robin Feldman, *Patent Term Extensions and the Last Man Standing*, 42 YALE L. & POL'Y REV. 1 (2023) (finding that drug companies often extend their patents for longer than the Hatch–Waxman Act intended); John R. Thomas, *Revisiting Patent Linkage*, 35 TEX. INTELL. PROP. L.J. 291 (2025) (criticizing the Hatch–Waxman Act's patent-linkage provisions). For a 1990s paper in the same vein, see generally Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA: J.L. & TECH. 389 (1999).

appropriate balance between the interests of patent-holding "innovator" companies and the interests of their low-cost "copycat" competitors. Most of this scholarship has focused on patent term extensions on drugs (which constitute more than ninety percent of all extensions),[113] though Erika Lietzan has studied extensions on medical device patents[114] and food additives.[115] The second wave of scholarship revisits many of the first wave's important questions of incentives, pricing, and access: Does patent term extension provide long enough extensions on enough patents on enough products to permit innovative companies to recoup their R&D costs and return the profits their investors expect? Does the system unduly delay the launch of low-cost generic and biosimilar products? Does patent term extension distort R&D by incentivizing certain kinds of medical research over other, perhaps more socially beneficial kinds?[116] Should patent term extension be abolished altogether—as Brazil recently did,[117] and some international scholars have proposed?[118] Should patent owners be able to "double count" FDA and USPTO delays that occur on the same days when benefitting from both patent term extension and patent term adjustment?[119]

Those are vital questions, but they are not the subject of this Article. This Article instead begins from the assumption that patent term extensions are here to stay, argues they do not currently comport with the theory of the patent bargain, and proposes attaching new disclosure requirements to them. Although no prior scholarship has addressed this subject, it turns out that disclosure of late-stage, post-filing information on the safety and effectiveness of FDA-regulated drugs *was* on the minds of some members of

113. *See infra* Section II.B (describing the present-day state of patent term extension).

114. Lietzan et al., *supra* note 25.

115. Erika Lietzan, *Food Additive Approvals—and Patents*, OBJECTIVE INTENT (Jan. 7, 2018), https://objectiveintent.blog/2018/01/07/food-additive-approvals-and-patents [https://perma.cc/89N9-PYNM].

116. Lietzan & Acri, *supra* note 17, at 1353–57 (suggesting the structure of the PTE system encourages work on products with short clinical trials and discourages work on other kinds of products with long trials (e.g., Alzheimer's disease)); LISA LARRIMORE OUELLETTE & HEIDI WILLIAMS, REFORMING THE PATENT SYSTEM 13–16 (2020), https://www.hamiltonproject.org/wp-content/uploads/2023/01/Ouellette_Williams_LO_6.16_FINAL.pdf [https://perma.cc/PN6E-TWHY] (urging reform of PTE to better compensate the developers of drugs with longer clinical development).

117. Eduardo Mercadante, *Brazilian Supreme Court Abolishes Patent Term Extension*, LONDON SCH. ECON. & POL. SCI. (May 14, 2021), https://blogs.lse.ac.uk/internationaldevelopment/2021/05/14/brazilian-supreme-court-abolishes-patent-term-extension [https://perma.cc/3DHC-TAEF].

118. Yuanqiong Hu, Dimitri Eynikel, Pascale Boulet & Gaelle Krikorian, *Supplementary Protection Certificates and Their Impact on Access to Medicines in Europe: Case Studies of Sofosbuvir, Trastuzumab and Imatinib*, J. PHARM. POL'Y & PRAC. 1, 9 (2020), https://link.springer.com/content/pdf/10.1186/s40545-019-0198-6.pdf [https://perma.cc/4PNT-G5X2].

119. *See* John R. Thomas, *Towards FDA–USPTO Cooperation*, 66 ARIZ. L. REV. 1021, 1041–43 (2024).

Congress when they debated and enacted patent term extension and the broader Hatch–Waxman Act. Section II.A traces that history.

II. THE HATCH–WAXMAN ACT'S BROKEN PROMISE AND THE PRESENT-DAY PROCESS OF PATENT TERM EXTENSION

This Part visits the past before returning to the present. Section II.A begins with a brief summary of the history of the Hatch–Waxman Act, focusing on an overlooked section of the Act—section 104—that promised transparency of safety and effectiveness data after product approval but has not been implemented by the FDA. Section II.B then turns to the present-day process of patent term extension, providing readers with an understanding of its relevant features. Section II.B closes by observing how the elaborate process devised and implemented by the FDA and USPTO does not produce meaningful new public disclosure, even though the Act delegated to USPTO authority to impose disclosure requirements on applicants for patent term extension.

A. *THE HATCH–WAXMAN ACT PROMISED A SECOND PATENT BARGAIN: PATENT TERMS EXTENDED AND SECRET DATA DISCLOSED*

> Safety and effectiveness data and information which has been submitted in an application [to the FDA] for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown [if any one of six conditions is met] . . . .[120]

These words are federal law today, part of the U.S. Code, codified at 21 U.S.C. § 355(*l*). They have been federal law for forty years, enacted in 1984 as section 104 of the Hatch–Waxman Act.[121]

On their face, these words seem to promise public disclosure of "safety and effectiveness data and information which has been submitted" to the FDA when any one of six events defined by statute occurs, "unless extraordinary circumstances are shown."[122] One triggering event is approval of a competitor generic version of the drug.[123] As Eisenberg has written, this provision of the Hatch–Waxman Act seems to give the FDA "the authority (and arguably a statutory mandate) to make more non-summary safety and

120. 21 U.S.C. § 355(*l*).

121. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 104, 98 Stat. 1585, 1597.

122. 21 U.S.C. § 355(*l*)(1). Under § 355(*l*)(1)(E), disclosure is triggered not just by generic approval but also "upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted"—i.e., the earliest date a generic *could* legally be approved by the FDA, even if no generic application was actually submitted. *Id.*

123. *Id.*

effectiveness data available [to the public] right now."[124] Nevertheless, the FDA has not done so.

How did these words become federal law, and why? Answering those questions requires reviewing the origins of the Hatch–Waxman Act and the FDA's interpretation of the Act. This review offers two important insights. First, it underscores *why* public access to safety and effectiveness data matters. Second, it illuminates the latent, if less than crystal clear, authority of the FDA and USPTO to demand new disclosure in exchange for patent term extensions. Clarifying, strengthening, and exercising that authority are the focus of Part III.

The Hatch–Waxman Act is widely viewed as a grand legislative compromise.[125] In the standard account, this grand compromise was brokered between two powerful, antagonistic corporate lobbies—brand-name drug companies and generic drug companies.[126] As Lietzan has documented, many accounts go further, presenting the Hatch–Waxman Act as "*privately* negotiated between the two industries," with little input or influence by other stakeholders in pharmaceuticals, health, consumer regulation, and patent law.[127]

The most famous provisions of the Hatch–Waxman Act do indeed suggest a bargain hammered out, tit for tat, between these two drug lobbies. On one side of the deal, innovative brand-name drug and device companies received the Act's most lucrative benefit: patent term extensions (section 201 of the Act). Brand-name companies also received FDA-granted "regulatory exclusivities," which further shield brand-name products from generic competition by preventing the FDA from approving generic versions for periods of years after the brand-name product is first approved, even in the absence of patent protection (section 103 of the Act).[128] On the other side,

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124. Eisenberg, *supra* note 105, at 473.

125. Lietzan collects numerous examples of this conventional wisdom in the literature and case law in her magisterial history of the Hatch–Waxman Act. Lietzan, *supra* note 112, at 53, 56–57; *see also, e.g.*, Feldman, *supra* note 112, at 2 (describing the Hatch–Waxman Act as a "a grand legislative compromise"); Lourie, *History, Summary, and Appraisal*, *supra* note 111, at 354 (describing the Hatch–Waxman Act as a "compromise package" negotiated by the "research-based [pharmaceutical] industry" and "generic companies"); 130 CONG. REC. 24977 (1984) (floor statement of Sen. Orrin Hatch, describing the Act as a "great compromise").

126. *See, e.g.*, Lourie, *History, Summary, and Appraisal*, *supra* note 111, at 354; Rebecca S. Eisenberg & Daniel A. Crane, *Patent Punting: How FDA and Antitrust Courts Undermine the Hatch-Waxman Act to Avoid Dealing with Patents*, 21 MICH. TELECOMMS. & TECH. L. REV. 197, 244 (2015) ("The Hatch-Waxman Act is a complex compromise between the interests of innovators and generics . . . ."); Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 727 (2005) (describing the Hatch–Waxman Act as "a complex legislative compromise between the interests of research pharmaceutical firms and generic competitors"); *see* Lietzan, *supra* note 112, at 56–57 nn.19 & 20.

127. Lietzan, *supra* note 112, at 56–57 (emphasis added).

128. FDA-administered regulatory exclusivities are themselves thornily complex. For overviews, see generally EISENBERG, *supra* note 105; Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMMS. & TECH. L. REV. 419 (2012); and Erika Lietzan, *The Myths of Data Exclusivity*, 20 LEWIS & CLARK L. REV. 91 (2016).

generic companies received, among other things, a simpler, "abbreviated" FDA approval process that relies on "reference" data previously submitted by a brand-name company, making market entry cheaper, faster, and more predictable (section 101 of the Act).[129] Generic companies also received a statutory "safe harbor" provision that exempts them from patent infringement liability for R&D activity undertaken to obtain the FDA's approval (section 202 of the Act). A few weeks prior to the Act's passage, Senator Hatch himself painted the Act as a "groundbreaking compromise in the public interest" in which the two lobbies had found middle ground:

> The research-based drug industry obtains an extension of patents for new drug discoveries to compensate them for the time spent off-market in Food and Drug Administration review. The generic drug industry gets the ability to bring generic copies of off-patent drugs to market as soon as the patent expires, without the needless reduplication of studies and tests already in FDA's files.
>
> The public receives the best of both worlds—cheaper drugs today and better drugs tomorrow.[130]

Note that in Hatch's telling, the public's interest is coextensive with the pharma companies'. Members of the public benefit by consuming cheap generic drugs today and consuming improved brand-name drugs tomorrow.

But there were other members of Congress who shaped the Hatch–Waxman Act—and the Act contains more sections than the handful Hatch summarizes above. Hatch's remarks omit any reference to section 104, the portion of the Act that promised that "[s]afety and effectiveness data and information which has been submitted" to the FDA will be disclosed to the public.[131] Hatch's omission was likely intentional; section 104 was added to the Act not by Hatch but by the Act's other architect, Representative Henry Waxman.[132]

Waxman was close with consumer watchdog groups, labor unions, academic researchers, and other constituencies outside the pharmaceutical and medical device industries themselves.[133] (One indicator of this closeness:

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129. For an overview of the "Abbreviated New Drug Application" and related "Abbreviated Biologics License Application" approval processes, see generally Justina A. Molzon, *The Generic Drug Approval Process*, 5 J. PHARMACY & L. 275 (1996).

130. 130 CONG. REC. 23764 (1984).

131. 21 U.S.C. § 355(*l*).

132. *See* James T. O'Reilly, *Knowledge Is Power: Legislative Control of Drug Industry Trade Secrets*, 54 U. CIN. L. REV. 1, 15–17 (1985); Jane A. Fisher, *Disclosure of Safety and Effectiveness Data Under the Drug Price Competition and Patent Term Restoration Act*, 41 FOOD DRUG COSM. L.J. 268, 281–86 (1986).

133. *See, e.g.*, Nicole Duran, *America's Watchdog*, UCLA MAG. (Oct. 1, 2010), https://newsroom.ucla.edu/magazine/henry-waxman [https://perma.cc/DH9K-6VPD]; Michael Doyle, *Rep. Waxman–Legislative Craftsman, Savvy Politico–Won't Run Again*, SACRAMENTO BEE (Oct. 8, 2014, 11:35 AM), https://www.sacbee.com/news/nation-world/article2590005.html [https://perma.cc/FJ65-76YH].

Ralph Nader reportedly said that "Henry [Waxman] is the only argument against term limits" in Congress.[134]) In the years leading up to the Hatch–Waxman Act, consumer watchdogs and academic researchers had clamored for a law like section 104—a law guaranteeing public disclosure of safety and effectiveness data on drugs, medical devices, and other medical products. In 1978, a bill that would have mandated broad disclosure of safety and effectiveness data, the Drug Regulation Reform Act ("DRRA"), failed in Congress,[135] despite strong support from the Center for Law and Social Policy, the Environmental Defense Fund, and Public Citizen.[136] In 1979 and 1980, prominent articles in the *Duke Law Journal* and *Harvard Law Review* called for law reform to mandate public access to this data.[137]

A few years later, debate over the Hatch–Waxman Act created a new opening for proponents of public disclosure of safety and effectiveness data. Waxman and allied members of Congress invited consumer groups, labor unions, senior citizen organizations, and professors to testify in hearings on the Hatch–Waxman Act alongside industry executives and lawyers.[138] Among the organizations that provided testimony were Public Citizen, the Consumers Union, and the Natural Resources Defense Council.[139] Waxman himself was circumspect about what exactly he understood the goals and effect section 104 to be.[140] But he apparently worked with Public Citizen and other advocates of data transparency to develop section 104. In 1985, shortly after the Act's enactment, pharmaceutical industry lawyer James T.

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134. Tom Tugend, *Waxman Imparts Capitol Hill Wisdom*, JEWISH J. (Oct. 21, 2009), https://jewishjournal.com/community/73471 [https://perma.cc/N32L-H7LZ].

135. *See generally* William W. Vodra, *The Drug Regulation Reform Act of 1978: Putting Some Economic Issues into Different Contexts*, 1 MANAGERIAL & DECISION ECON. 184 (1980) (describing the DRRA's data disclosure provisions from the FDA's perspective).

136. *See Analysis of Drug Regulation Reform Act of 1978: Hearings on S. 2755 Before the Subcomm. on Health & Sci. Rsch. of the Comm. on Hum. Res.*, 95th Cong. 625–26 (1978) (statement of Marcia D. Greenberger, Head of Women's Rts., Ctr. for L. & Soc. Pol'y); *id.* at 645–46 (statement of Anita Johnson, Staff Att'y, Env't Def. Fund); *id.* at 668 (statement of Sidney Wolfe, Dir., Pub. Citizen's Health Rsch. Grp.).

137. Robert M. Halperin, Comment, *FDA Disclosure of Safety and Effectiveness Data: A Legal and Policy Analysis*, 1979 DUKE L.J. 286, 323–26; Thomas O. McGarity & Sidney A. Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837, 837–39 (1980).

138. *See, e.g.*, 130 CONG. REC. 24425 (1984) ("[T]he bill before us has been endorsed by an overwhelming majority of the brand name drug companies as well as the generic drug industry, consumer, senior citizen, and labor groups.").

139. *See Drug Price Competition and Patent Term Restoration Act of 1984: Hearing on S. 2748 Before the S. Comm. on Lab. & Hum. Res.*, 98th Cong. 228–32 (1984) [hereinafter *Hatch–Waxman Act Hearing*] (statement of Louise Greenfield, Staff Att'y, Pub. Citizen's Cong. Watch); *id.* at 322–23 (statement of Rhoda Karpatkin, Exec. Dir., Consumers Union); *id.* at 315–21 (statement of S. Jacob Scherr, Senior Staff Att'y, Nat. Res. Def. Council).

140. *See* Fisher, *supra* note 132, at 285–86 (summarizing the "Waxman view" of section 104 as requiring new disclosure of safety and efficacy data while simultaneously downplaying the significance of any deviation from existing FDA practice); O'Reilly, *supra* note 132, at 14–19 (same).

O'Reilly wrote that Waxman and allied "[a]dvocates of drug data disclosure acted quietly in attaching a full disclosure provision, buried amidst many unrelated and controversial provisions" to the Hatch–Waxman Act.[141] Although Waxman was circumspect, Waxman's allies at Public Citizen were not: At hearings on the Act, they renewed the argument that public access to safety and effectiveness data was essential. For example:

> Public Citizen strongly urges that all safety and effectiveness data be available to the public upon request. Restricting access to this data only thwarts attempts by the public to review and evaluate certain FDA decisions. There is no commercial value to this data after the patented drug is approved, because would-be competitors are restricted from marketing an identical product by patents and because the data is unnecessary to those who intend to manufacture a generic version after relevant patents expire.
>
> Public Citizen's Health Research Group has investigated drug safety and effectiveness data obtained after time-consuming lawsuits under the Freedom of Information Act. Such independent evaluations can reveal dangers neither disclosed by the drug manufacturers nor detected by FDA.[142]

Note how Public Citizen envisioned an additional role for the public beyond that of consumer: the public using not just drugs but *information about drugs*.[143] As such, Public Citizen envisioned the Hatch–Waxman Act not as a two-way legislative compromise but an even grander, multi-dimensional compromise brokering the interests of pharmaceutical and medical device companies, competitors, investors, researchers, end consumers, and the broad public. A new quid pro quo: The extended-term patents created by the Hatch–Waxman Act shield innovative products from generic competition for longer, providing larger incentives for research, but in exchange, the public gets access to rich research data that would otherwise remain hidden in FDA files. In short, this vision of the Hatch–Waxman compromise prefigured the broader vision of patent law I offered in Part I—the Act reconceiving this corner of patent law as *transparency* law.

As the Hatch–Waxman Act moved toward enactment, some other observers apparently shared Public Citizen's understanding of section 104 as promising a major new data transparency mandate. Indeed, certain

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141. O'Reilly, *supra* note 132, at 16; *see also id.* at 15 n.86 (crediting Public Citizen as "one of the initiators of the terms of the disclosure provisions of the 1984 [Hatch–Waxman] Act").

142. *Hatch–Waxman Act Hearing*, *supra* note 139, at 259–60 (statement of Louise S. Greenfield & Janet S. Hathaway, Staff Att'ys, Pub. Citizen's Cong. Watch, and William B. Schultz, Att'y, Pub. Citizen Litig. Grp.). Public Citizen urged Congress to amend the Hatch–Waxman Act to mandate disclosure of safety and effectiveness data immediately upon product approval, rather than wait until a generic version of the drug is approved or could hypothetically become approved. *Id.*

143. Or at least expert portions of the public, such as Public Citizen's own staff.

stakeholders opposed section 104 for this very reason. Some brand-name drug companies acknowledged that section 104 promised disclosure only after generic entry in the United States—i.e., after the patent monopoly was already expired or otherwise lost and competition assured—but nonetheless expressed concern that free-riding generic companies would exploit the data for regulatory approval outside the United States. For example, executives from Johnson & Johnson, American Home Products (now part of Pfizer), and Hoffman-La Roche submitted a joint statement warning that section 104 would:

> permit the public disclosure of all of the extensive and costly research data generated by research-based pharmaceutical companies, at least as soon as FDA approval of a generic version of the new drug could become effective, even though the data may be of significant value to foreign competitors or may retain proprietary value in the United States.[144]

Rep. Thomas Bliley, vociferously opposed to section 104, echoed the pharma executives' concern as the bill advanced out of committee.[145] Other members of Congress did too.[146] (Section III.A explains why their concern over international free riding is misplaced—inter alia, the FDA could prohibit resubmission of FDA-disclosed data to other drug regulators, as the drug regulators of Canada and the European Union do in their successful data-sharing programs.)

Despite this opposition, section 104 became federal law with enactment of the Hatch–Waxman Act. And yet the FDA today does not generally make "[s]afety and effectiveness data and information which has been submitted in [a new drug application] . . . available to the public" when the drug goes generic.[147] What happened?

As Eisenberg has written, "[t]he statutory exception for 'extraordinary circumstances', copied from the FDA's rules, has turned out to provide much broader protective cover against disclosure as a matter of administrative practice than the plain meaning of the word 'extraordinary' can support."[148] Rather than remove or amend section 104, Hatch and other supporters of

144. *Hatch–Waxman Act Hearing*, *supra* note 139, at 120 (letter of Verne Willaman, John R. Stafford & Irwin Lerner).

145. H.R. REP. NO. 98-857, at 73 (1984) (quoting the executives nearly verbatim: "The bill . . . provides for the public disclosure of all of the extensive and costly research data generated by research-oriented pharmaceutical companies, even though those safety and effectiveness data may be of significant value to foreign competitors or may retain proprietary value in the United States.").

146. *See, e.g.*, *Hatch–Waxman Act Hearing*, *supra* note 139, at 32 ("[Senator Hatch:] Concern has been expressed over the possibility that under S. 2748, FDA might be required to release safety and efficacy data for drugs which are subject to ANDA's, which data may be commercially valuable, and that it could be used by foreign competitors to support their applications for approval in foreign countries.").

147. 21 U.S.C. § 355(*l*).

148. Eisenberg, *supra* note 105, at 483 (footnote omitted).

secrecy organized to create copious legislative history insisting the "extraordinary circumstances" exception should cover essentially every drug, thus vitiating the provision.[149] Senior FDA officials, including Commissioner Frank Young and Chief Counsel Thomas Scarlett, joined Hatch to assert in testimony and letters cited repeatedly in the legislative history that "extraordinary circumstances" should be construed, in light of supposedly clear and settled FDA rules and norms developed in the 1970s and early 1980s, to mean that safety and effectiveness data should remain secret for most every drug approval after enactment of section 104.[150] In response, Waxman and the subcommittee he chaired offered only tepid, confusing explanations of the data transparency section 104 was meant to promise—perhaps because emphasizing the impact of section 104 would have cost the bill crucial votes.[151] It was only in October 1984, after the Act had passed the House and Senate and awaited President Reagan's signature, that Waxman offered remarks that squarely challenged the pro-secrecy interpretations of Hatch and FDA leadership: "Section 104 creates a strong presumption that the data covered by the section will be available to the public."[152] In practice, Hatch's view has prevailed over Waxman's. The FDA has hewn to the position that "extraordinary circumstances" apply to essentially all drugs,[153] and today it keeps companies' safety and effectiveness data secret except when disclosure

149. Fisher's 1986 article provides an excellent play-by-play of maneuvering by Hatch and Senator Dennis DeConcini to create legislative history suggesting "extraordinary circumstances" apply to essentially every drug approval. Fisher, *supra* note 132, at 281–84; *see also* O'Reilly, *supra* note 132, at 16–21; Eisenberg, *supra* note 105, at 482–86; Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269, 297–98 (1985).

150. Fisher, *supra* note 132, at 283–84; O'Reilly, *supra* note 132, at 19–21; Eisenberg, *supra* note 105, at 484–85. But even FDA Chief Counsel Thomas Scarlett separately acknowledged section 104's plain meaning, in a quote to news media offered as the bill was under debate: "'[I]t may very well be that "extraordinary circumstances" will not be found to exist merely by reason of the possibility' of commercial use of the data for competition in a foreign country." *ANDA/Patent Bill's Data Disclosure Section Should Clarify When FDA Can Withhold Safety & Efficacy Information on ANDA-Suitable Pioneers, FDA's Scarlesays*, CITELINE: PINK SHEET (July 2, 1984), https://scrip.citeline.com/PS006801 [https://perma.cc/S38Z-STTZ].

151. *See* O'Reilly, *supra* note 132, at 18–19; Fisher, *supra* note 132, at 285.

152. 130 CONG. REC. 31729 (1984); *see also id.* at 31729–30 (challenging FDA leadership's pro-secrecy interpretation of the agency's own rules and practices).

153. *See* Eisenberg, supra note 37, at 381; Erika Lietzan, *A New Framework for Assessing Clinical Data Transparency Initiatives*, 18 MARQ. INTELL. PROP. L. REV. 33, 42–43 (2014).

is mandated by other statute[154] or when forced by dogged FOIA requesters to disclose partial data sets.[155]

Why has the FDA chosen secrecy? There seems to be no conspiracy. The primary answer, at least, appears to be the FDA's reluctance to take on new work. The Hatch–Waxman Act's legislative history shows pharmaceutical industry commentators and a member of Congress observing that to manage a substantial new data disclosure program would impose new burdens on an agency already struggling to fulfill FOIA requests and otherwise manage its mountains of information.[156] The same is true of the contemporary FDA. Even before the second Trump Administration, the FDA's managers of information were busy and loath to take on new disclosure programs.[157]

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154. For example, a 2007 statute commands the FDA to publish summaries of safety and effectiveness data in drug applications and a summary of its own analysis, soon after every new drug approval. Matthew Herder, Christopher J. Morten & Peter Doshi, *Integrated Drug Reviews at the US Food and Drug Administration—Legal Concerns and Knowledge Lost*, 180 JAMA INTERNAL MED. 629, 629–30 (2020).

155. Kapczynski and I recently published a summary of the mechanics of how FDA responds to and fulfills, in part, FOIA requests for safety and effectiveness data. Morten & Kapczynski, *supra* note 38, at 520–27. Peter Lurie and Allison Zieve published in 2006 an even more thorough account of FDA's disclosure practices, including its responses to FOIA requests for safety and effectiveness data. *See generally* Peter Lurie & Allison Zieve, *Sometimes the Silence Can Be Like the Thunder: Access to Pharmaceutical Data at the FDA*, 69 LAW & CONTEMP. PROBS. 85 (2006). For an important recent circuit decision governing FDA's release of safety and effectiveness data, see generally *Seife v. FDA*, 43 F.4th 231 (2d Cir. 2022).

156. *See, e.g.*, H.R. REP. NO. 98-857, at 74 (1984) (statement of Thomas J. Bliley, Jr.) ("[Section 104] has significant resource implications for FDA. Under the Freedom of Information Act, FDA is obligated to respond to requests for documents in its files, including the voluminous safety and effectiveness data made available by the bill, ordinarily within ten days. Since the enactment of the FOI Act, FDA has consistently received more requests for documents than virtually any other Federal agency. In 1983, FDA received over 39,000 FOI requests. . . . I fail to see how the public benefits by having FDA be forced to divert scarce technical personnel and resources to processing FDA requests and ANDAs, at the expense of new drug applications and other important public health functions."); *Hatch–Waxman Act Hearing*, *supra* note 139, at 107 (1984) (statement of Verne Willaman, Member, Exec. Comm., Johnson & Johnson) ("[T]he disclosure provision [of section 104] would add to FDA's already enormous burden under the Freedom of Information Act. It is difficult to see how the public benefits by having FDA resources diverted to giving foreign competitors valuable research information at the expense of approving drug applications."); *id.* at 122 ("Since the enactment of FOIA, FDA has consistently received more requests for documents than virtually any other Federal agency. In 1983, FDA received over 39,000 FOIA requests. . . . It is difficult to see how the public benefits by the FDA being forced to divert scarce resources to processing FOIA requests and ANDAs at the expense of new drug applications."). As of 2011, the FDA "house[d] the largest known repository of clinical data" in the world. U.S. FOOD & DRUG ADMIN., U.S. DEP'T HEALTH & HUM. SERVS., DRIVING BIOMEDICAL INNOVATION: INITIATIVES TO IMPROVE PRODUCTS FOR PATIENTS 22 (2011), https://www.celebrationofscience.org/assets/Uploads/DrivingBiomedicalInnovation-ImprovingProductsforPatients.pdf [https://perma.cc/U2XC-XHGA].

157. *See* Eisenberg, *supra* note 105, at 483–84 (quoting the FDA's Transparency Task Force "lament[ing]" in 2010 that "[i]n practice, the[] provisions [of section 104] have been difficult to implement"); Morten & Kapczynski, *supra* note 38, at 521, 528, 543 (arguing high FOIA compliance costs could be avoided by making proactive public disclosures). *See generally* Laurence

Part III will revisit the important lesson learned here: Minimizing administrative burden on the FDA and USPTO is key to any successful information disclosure program.

This history reveals two main insights: First, to many observers at the time, section 104 of the Hatch–Waxman Act promised a new era of data transparency at FDA—complete or near complete disclosure of safety and effectiveness data on drugs when those drugs go generic. In Eisenberg's words, section 104 appears to be a "statutory directive that secrecy will end once permissible free riding begins."[158] That promise is unfulfilled and widely forgotten today. But it remains true that the same Act that created patent term extensions contemplated major new disclosure requirements alongside them.[159] If Hatch–Waxman's framers did not explicitly paint the precise picture of patent-law-as-transparency-law laid out in Part I, they nevertheless painted both new patent protections and new transparency obligations onto the same canvas.

Second, the plain text of section 104 might matter in an era in which "we're all textualists now,"[160] legislative history is deprecated,[161] and agencies' own longstanding interpretations of federal statutes they administer merit less judicial deference.[162] The plain text of section 104—now codified at 21 U.S.C. § 355(*l*)—permits the FDA to withhold data from public disclosure only when "extraordinary circumstances are shown." The term "extraordinary circumstances" is defined nowhere in the entire Hatch–Waxman Act; nor does any definition of the term exist elsewhere in the Food, Drug, and Cosmetic Act or the Patent Act.[163] Per the contemporary Supreme Court, in such a circumstance, the plain and ordinary meaning of "extraordinary" must control.

Tai, *A Tale of Two Transparency Attempts at FDA*, 68 FOOD & DRUG L.J. 423 (2013) (analyzing FDA's FOIA statistics between 1997–2012).

158. Eisenberg, *supra* note 105, at 485.

159. I recognize that section 104 does not directly tether disclosure to the grant of an extension. I explain below, in Section III, why I think tethering disclosure to the grant of patent term extension nonetheless makes good policy sense.

160. Justice Kagan made this statement in 2015, then rescinded it in 2022, as Kevin Tobia has documented. Kevin Tobia, *We're Not All Textualists Now*, 78 N.Y.U. ANN. SURV. AM. L. 243, 253–59 (2023). Justice Gorsuch restated it in 2024. Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244, 2291 n.6 (2024) (Gorsuch, J., concurring).

161. *See, e.g.*, William N. Eskridge, Jr., Brian G. Slocum & Kevin Tobia, *Textualism's Defining Moment*, 123 COLUM. L. REV. 1611, 1668–70 (2023) (documenting textualists' deprecation and minimal reliance upon legislative history). For a recent Supreme Court statutory construction case emphasizing plain text and deprecating reliance on legislative history, in the context of transparency law, see *Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356, 2364–65 (2019).

162. *See generally Loper Bright Enters.*, 144 S. Ct. at 2265–73. Some scholars have argued this trend began even before *Loper Bright* formally overruled *Chevron*. *See, e.g.*, Ryan D. Doerfler, *Late-Stage Textualism*, 2021 SUP. CT. REV. 267, 295–301; Nathan Richardson, *Deference Is Dead (Long Live* Chevron*)*, 73 RUTGERS U. L. REV. 441, 485–93 (2021).

163. Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269, 298 (1985) ("The statute does not define the term 'extraordinary circumstances.'").

Hatch's engineering of the legislative history should be irrelevant; today's Court has said it "will never allow [legislative history] to be used to 'muddy' the meaning of 'clear statutory language.'"[164] The plain statutory text may have material doctrinal consequences. For example, section 104's plain text undermines claims that disclosure of this data in exchange for patent term extension could effect a taking. Part IV discusses these doctrinal consequences in more depth.

B. TODAY'S ONE-SIDED BARGAIN: USPTO EXTENDS PATENT TERMS WITHOUT PRODUCING NEW DISCLOSURE

This Section explains how patent term extension works today. To quote the USPTO, section 201 of the Hatch–Waxman Act, as codified at 35 U.S.C. § 156, "enables the owners of patents on certain human drugs, food or color additives, medical devices, animal drugs, and veterinary biological products to restore to the terms of those patents some of the time lost while awaiting premarket government approval from a regulatory agency"[165]—namely, the FDA or USDA.

This Section briefly explains why patent term extensions are, as a matter of statutory law and current regulatory practice, properly conceived as new grants of patent term rather than part of the original patent grant. It then explains the rules of eligibility for and duration of patent term extension.[166] It then explains the process by which these agencies together deliberate over and grant patent term extensions. Finally, it also explains the "duty of disclosure" that attaches to patent term extension. The Hatch–Waxman Act expressly delegated to the USPTO broad authority to attach disclosure requirements to patent term extension, which the USPTO has so far chosen to do very little with, meaning that patent term extensions produce essentially no interesting disclosure on the part of the patent owner.

1. Patent Term Extensions as New Grants of Exclusivity

The Hatch–Waxman Act uses both the phrases "patent term extension" and "patent term restoration." Many scholars[167] and the FDA (but not the

164. *Food Mktg. Inst.*, 139 S. Ct. at 2364 (quoting Milner v. Dep't of Navy, 562 U.S. 562, 572 (2011)).

165. U.S. PAT. & TRADEMARK OFF., MANUAL OF PATENT EXAMINING PROCEDURE § 2750 (9th ed. rev. 2024). In 1988, Congress further amended the Patent Act to make patents on animal drugs (including veterinary biologics) eligible for term extension. *See* Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, tit. II, § 201, 102 Stat. 3971, 3984 (1988) (codified as amended at 35 U.S.C. §§ 156, 271). Patent term extensions on animal drugs seem to be few and rare, perhaps because the comparatively weak generic animal drug industry has posed less of a threat to the brand-name "innovator" animal drug industry. *See, e.g.*, Katie Burns, *The Slow Rise of Generic Animal Drugs*, AM. VETERINARY MED. ASS'N (June 15, 2016), https://www.avma.org/javma-news/2016-07-01/slow-rise-generic-animal-drugs [https://perma.cc/N3LC-2QSB].

166. 37 C.F.R. §§ 1.710–1.720 (2024).

167. *E.g.*, Lietzan & Acri, *supra* note 17, at 1333–37; Lietzan et al., *supra* note 25, at 425–27; Cárdenas-Navia, *supra* note 112, at 1311–13.

USPTO)[168] tend to use the term "restoration," which can imply that patent term extensions are somehow promised as part of the original patent grant—a right inherent to the patent system or a remedy for some regulatory wrong.

But patent term extensions are not part of the original patent grant. Patent term extensions are new grants of patent exclusivity—new bargains with the public.

Across all fields of technology, most patent owners do not enjoy the full duration of their patents, because patent owners typically file their patents before the patented product is ready for market—sometimes years before.[169] The House Energy and Commerce Committee noted as much in its final report on the Hatch–Waxman Act: "Although the patent term in the United States is 17 years,[170] the period during the patent term in which products are marketed (the effective patent term) is usually less than 17 years because patents often are obtained before products are ready to be marketed."[171] The FDA and USDA are not unique among federal regulatory agencies in that they keep certain patented products off the market unless and until the manufacturers of those products convince the agencies to allow them on; other federal regulators wield the same power, including the Environmental Protection Agency (as to pesticides) and the Federal Aviation Administration (as to commercial airplanes).[172]

Pharmaceutical and medical device companies sought, and ultimately got, from Congress special provisions of patent law to allow them to extend their patents and thus "restore" some of the time "lost" to regulatory review. During debate over the Hatch–Waxman Act, pharmaceutical companies produced evidence that development and approval times were increasing, effective patent life was declining, and the entire R&D-based pharmaceutical industry was at risk of failure.[173] On this basis, these companies (and others regulated by the FDA and USDA) argued for and got patent term extensions.[174] As Al Engelberg has observed, "[n]o other industry enjoys such a government subsidy."[175] Manufacturers of pesticides and commercial

168. Thomas, *supra* note 119, at 1041.

169. *See, e.g.*, Mark A. Lemley, *Ready for Patenting*, 96 B.U. L. REV. 1171, 1173 (2016) (explaining that patent law "encourages an inventor to file first and figure out later how (or even if) the invention works for its intended purpose").

170. In 1984, the standard term of a U.S. patent was seventeen years from issuance. Amendments to the Patent Act in the 1990s shifted the standard term of a U.S. patent to twenty years from the effective filing date. Today, it remains true that most patents are filed well before the patented invention is ready for market. *Id.*

171. H.R. REP. NO. 98-857, at 17 (1984).

172. *See* Christopher J. Morten, *Publicizing Corporate Secrets*, 171 U. PA. L. REV. 1319, 1336 (2023); Lietzan, *supra* note 112, at 69 (discussing the Environmental Protection Agency).

173. Lietzan, *supra* note 112, at 74–91, 98–107.

174. *Id.*; *see also* H.R. REP. NO. 98-857, at 17–18.

175. Engelberg, *supra* note 112, at 421.

aircraft today likewise "lose" some of their effective patent term to regulator-mandated testing and review but receive no patent term extensions.

Congress seems to have been sympathetic, as a *policy* matter, to the concept of "restoring" "lost" patent term, but Congress declined, as a *doctrinal* matter, to make extended patent terms on pharmaceutical or medical device patents part of the original grant of these patents. Instead, Congress expressly legislated patent term extensions into existence as a new grant. The Act itself does not award patent term extensions as a matter of right; it does not mandate or even permit the USPTO to work with the FDA or USDA on their own initiatives to calculate and award patent term extensions commensurate with regulatory delay. Instead, the Act establishes an elaborate application process for patent term extension—analogous with the application process used for patents themselves—that places the burden entirely on applicants to prove an entitlement to the extension sought.[176] The Act authorizes the USPTO to charge fees in exchange for the benefit of patent term extensions,[177] and the USPTO has charged a fee in exchange for patent term extension since at least 1987.[178] Pursuant to authority expressly delegated by the Hatch–Waxman Act,[179] the USPTO has promulgated elaborate rules as to what an application for patent term extension must contain.[180] Consistent with this concept of patent term extensions as new benefits rather than remedies or rights attached to the original patent, the House Energy and Commerce Committee's final report on the Hatch–Waxman Act repeatedly describes patent term extensions as a "*new* incentive" for patent owners.[181]

All this is to say, as a matter not just of theory but of statutory law and current regulatory practice, patent term extensions are properly conceived as new grants of patent term rather than part of the original patent grant. That fact tees up this Article's proposal for a new informational bargain in exchange for the new grant of patent term—the proposal of Part III.

176. 35 U.S.C. § 156(d), (e).

177. *Id.* § 156(h).

178. Rules for Extension of Patent Term, 52 Fed. Reg. 9386 (Mar. 24, 1987) (to be codified at 37 C.F.R pt. 1); *see also* 37 C.F.R. § 1.740(a)(14) (2024).

179. 35 U.S.C. § 156(d)(1)(E), (d)(4).

180. 37 C.F.R. § 1.740.

181. H.R. REP. NO. 98-857, at 15, 18 (1984) (emphasis added).

2. Eligibility for and Duration of Patent Term Extension

Courts and commentators have variously described the rules for eligibility for and duration of patent term extension as "complex,"[182] "complicated,"[183] even "unfathomable."[184] I do not attempt to survey them here; the work of Lietzan and her coauthors has provided terrific, detailed analysis of how the eligibility and duration rules play out in USPTO practice,[185] and the rules' details don't affect materially the second patent bargain proposed in Part III. Instead I offer just a few key takeaways on eligibility and duration.

On eligibility: As Lietzan and Acri have outlined, a patent must meet three criteria to be eligible for extension. First, the active ingredient in the product approved by the FDA or USDA must not have been approved previously.[186] Second, each regulatory approval process (and associated regulatory review period) may create one and only one eligibility for extension, which may be applied to one and only one patent.[187] Third, the patent in question must not already have been extended (i.e., because it happens to cover another, separate FDA-approved product).[188] Once a patent term extension is granted, it is "limited to any use approved for the product" in question.[189] In other words, the patent term extension does not extend to other products that the extended patent happens to cover.

On duration: Patent term extension typically extends the patent's term by an amount equal to *half* the time the patented product spent in clinical trials and other testing (the "testing phase") plus the *full* time the regulator spends reviewing the application for approval (the "approval phase"), up to a maximum of five years, or a maximum of fourteen years after product approval, whichever is shorter.[190] The testing phase occurs first and is typically primarily preoccupied with creation of evidence establishing the

182. Boehringer Ingelheim Pharma GMBH & Co. KG v. FDA, 195 F. Supp. 3d 366, 379 (D.D.C. 2016); Terry G. Mahn & Tina Murphy, *Introduction to Patent Term Extensions (PTE)*, FISH & RICHARDSON INSIGHTS (July 31, 2020), https://www.fr.com/insights/ip-law-essentials/intro-patent-term-extension [https://perma.cc/5THV-DRKA]; Lietzan, *Patent Term Restoration – Denied!*, *supra* note 33.

183. Sukhatme & Bloche, *supra* note 43, at 1034.

184. RICHARD J. WARBURG, AM. HEALTH LAWS. ASS'N, P12050113, PATENT LAWS WITH PROFOUND EFFECTS ON HEALTHCARE AND BIOTECHNOLOGY (2001).

185. *See* Lietzan, *Patent Term Restoration – Denied!*, *supra* note 33; Lietzan & Acri, *supra* note 17, at 1333–37; Lietzan et al., *supra* note 25, at 425–27, 436–40.

186. 35 U.S.C. § 156(a)(5)(A). Already-approved products containing salts or esters of the active ingredient also disqualify patent term extension. *See* Lietzan & Acri, *supra* note 17, at 1334. Most of the litigation over patent term extension has turned on this question of eligibility.

187. 35 U.S.C. § 156(a)(5)(B); *see* Lietzan & Acri, *supra* note 17, at 1334–35.

188. 35 U.S.C. § 156(a)(2), (a)(4).

189. *Id.* § 156(b)(1).

190. *Id.* § 156(c), (g); 37 C.F.R. § 1.775 (2024) (for FDA-regulated drugs); 21 C.F.R. § 60.22 (distinguishing the "testing phase" and "approval phase") (2025); MPEP, *supra* note 165, § 2757 (same).

safety and effectiveness of the product; the approval phase occurs second, upon filing of an application for approval with the regulatory, and is typically primarily preoccupied with review of that data (though some testing can and usually does continue during this time).[191] The sum of the testing phase and approval phase are, together, deemed the "regulatory review period."[192] Any delay during the regulatory review period attributable to the patent owner (rather than the regulator) is subtracted from the calculated extension.[193] The average patent term extension has a duration of about two-and-a-half or three years.[194]

There are more details of eligibility for and duration of patent term extension that I will skip, as they do not bear significantly on the wisdom or feasibility of the second patent bargain proposed by this Article.[195] The remainder of this Section will focus instead on the *process* of patent term extension, especially its timing, the close collaboration of USPTO and FDA it entails, and the minimal amount of new *disclosure* it currently produces.

3. The Process and Timing of Patent Term Extension

The Hatch–Waxman Act requires that the USPTO work closely with the FDA (or USDA) throughout the extension process.[196] Shortly after enactment of the Act, the USPTO and FDA jointly published memoranda of understanding outlining their process,[197] and the agencies have promulgated detailed rules.[198] The agencies work together closely today.[199]

The typical process of patent term extension goes like this: By statute, a patent owner seeking patent term extension must file an application for

191. 21 C.F.R. § 60.22.

192. 35 U.S.C. § 156(g); 21 C.F.R. § 60.22.

193. 35 U.S.C. § 156(c)(1).

194. Lemley & Reinecke, *supra* note 17, at 708 (reporting average and median duration of patent term extensions across all industries as 2.87 years (1048 days) and 2.70 (986 days), respectively); Lietzan & Acri, *supra* note 17, at 1346–47 (reporting the average and median duration of patent term extensions on patents on FDA-approved drugs in the article's dataset to be 2.87 and 2.59 years, respectively, and slightly longer for more recent extensions); Beall et al., *supra* note 112, at 21 (reporting a median duration of 2.75 years of extensions of patents on a smaller dataset of drugs).

195. For example, any portions of the regulatory review period that occur prior to patent issuance do not count toward the calculated duration of a patent term extension. 35 U.S.C. § 156(c).

196. *Id.* § 156(d)(2)(A)–(B) (requiring various exchanges of information and determinations between the Director of the USPTO and, as appropriate, the Secretary of Agriculture (USDA) or the Secretary of Health & Human Services (FDA)).

197. *See generally* Memorandum of Understanding Between the Patent and Trademark Office and the Food and Drug Administration, 52 Fed. Reg. 17830 (May 12, 1987).

198. 21 C.F.R. § 60 (2025); 37 C.F.R. §§ 1.710–1.791 (2024).

199. In a recent article, John Thomas observed, aptly, a general "lack of formal engagement [between FDA and USPTO] in the everyday administration of pharmaceutical intellectual property law." Thomas, *supra* note 119, at 1030. The one exception is administration of patent term extension. *Id.*

extension with the USPTO within sixty days of approval of the regulated product covered by the patent.[200] The USPTO conducts an initial review to ensure the application contains all the necessary parts,[201] and then forwards the application to the FDA. The FDA then determines whether the patented product was indeed the subject of an FDA approval process, whether the application for extension was filed within sixty days of product approval, and whether the product is indeed a new product.[202] If the FDA answers "yes" to all three questions, the patent is presumptively eligible for an extension, and the agencies shift their attention to the question of the appropriate duration of extension. The FDA will then verify the critical dates in the patent term extension application—the "regulatory review period" and its component "testing phase" and "approval phase"—and publish its calculations.[203] Assuming no challenge to those calculations, the FDA will then send USPTO a letter summarizing its final calculation of the regulatory review period.[204] The USPTO then conducts a final review[205]: It confirms that the applicant has complied with the agency's duty of disclosure[206] (more on this below), uses the official regulatory review period to determine the appropriate duration of extension,[207] and issues a Notice of Final Determination.[208] The Notice of Final Determination provides the patent owner with a window of time—typically one month—to object to any part of the USPTO's determination, including its calculation of the appropriate duration of extension.[209] Assuming no objection, the USPTO then issues a certificate of extension.[210]

Upon issuance of the certificate of extension, the extension is official.[211] The patent's expiration date is officially postponed; the American public, through the USPTO, confers an additional period of patent protection to

200. 35 U.S.C. § 156(d)(1).

201. 37 C.F.R. § 1.750 (2024); *see also* MPEP, *supra* note 165, § 2755.

202. 21 C.F.R. § 60.10 (2025).

203. *Id.* §§ 60.20, 60.22, 60.28. The statute permits third parties to challenge both the patent owner's and the FDA's calculation of the appropriate duration of patent term extension via a petition process. 35 U.S.C. § 156(d)(2)(B). These petitions are rare. *See* Kyle Dolinsky & N. Nicole Stakleff, *Due Diligence: Calculating the Regulatory Review Period for Patent Term Extension*, JDSUPRA (May 26, 2017), https://www.jdsupra.com/legalnews/due-diligence-calculating-the-14422 [https://perma.cc/4BZ5-JEPG] ("To date, it appears that only four due diligence petitions have even been filed, and only one was actually decided by FDA.").

204. 21 C.F.R. § 20.26 (2025).

205. 37 C.F.R. §§ 1.720, 1.750 (2024).

206. 35 U.S.C. § 156(d)(4); 37 C.F.R. § 1.765.

207. 37 C.F.R. § 1.750.

208. *Id.*; *see also* MPEP, *supra* note 165, § 2758.

209. *See* 37 C.F.R. § 1.750; MPEP, *supra* note 165, § 2758. The USPTO can conclude at this stage that the patent is altogether ineligible for extension; the patent owner then has an opportunity to request reconsideration.

210. 37 C.F.R. § 1.780; MPEP, *supra* note 165, § 2759.

211. 37 C.F.R. § 1.780.

the patent owner. The entire patent term extension process is documented and made public in the patent's prosecution history.

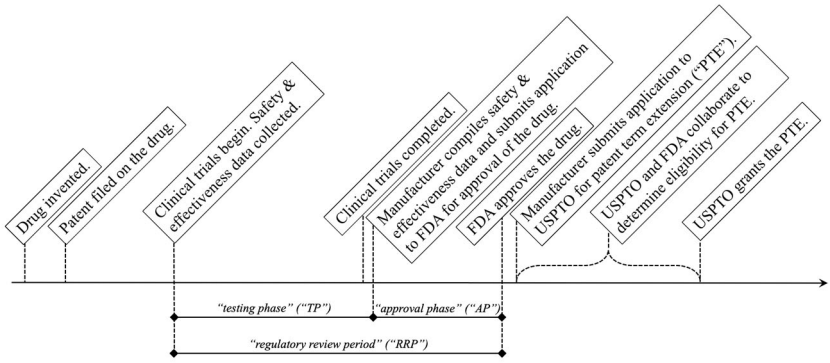
This process of patent term extension necessarily takes place after the filing of the patent on the regulated product that enjoys extension—typically *many* years after. For pharmaceuticals, an average of about twelve or thirteen years elapse between filing of the patent and filing of the patent term extension application.[212] Patent term extension applications must be filed quickly after regulatory approval—within sixty days.[213] The USPTO and FDA together then take an average of about three years to grant the extension.[214] All told, fifteen or sixteen years might elapse from first patent filing to grant of the patent term extension. Figure 1 presents a timeline of patent term extension on an FDA-approved product.

212. Lietzan has calculated that an average of 5.61 years elapse between filing date of the first patent covering a drug or a method of its use and the date that clinical trials begin. Erika Lietzan, *The Drug Innovation Paradox*, 83 MO. L. REV. 39, 86 (2018). Lietzan and Acri have calculated that on average, 6.04 years pass between the date that clinical trials begin and the date that sufficient safety and effectiveness data has been gathered to merit FDA approval. Lietzan & Acri, *supra* note 17, at 1346. They have also calculated that the FDA takes an average of 1.5 years to approve applications, once filed. *Id.* at 1346 n.144. This suggests a total duration from first patent filing to FDA approval of 13.15 years (5.61+6.04+1.5). Cárdenas-Navia estimates "an average of 12.3 years between when a patent application is filed and when FDA approval is granted for the corresponding product." Cárdenas-Navia, *supra* note 112, at 1320.

213. 35 U.S.C. § 156(d)(1); 21 C.F.R. § 60.10(a)(4) (2025); 37 C.F.R. § 1.720(f) (2024).

214. *See* Cárdenas-Navia, *supra* note 112, at 1320 ("[I]t takes an average of 2.9 years from when the FDA approves a product until the USPTO issues a Certificate of Extension for the corresponding patent . . . ."); Letter from Brian H. Batzli, Pres., Am. Intell. Prop. L. Ass'n, on Joint USPTO-FDA Collaboration Initiatives to Kathi Vidal, Dir., U.S. Pat. & Trademark Off. 8 (2023), https://www.aipla.org/docs/default-source/advocacy/aipla-comments-on-uspto-fda-collaboration-2-6-2023-corrected-version-031023.pdf?sfvrsn=86be6a25_1 [https://perma.cc/3WBW8MW6] ("This process is often lengthy and can take approximately three years from initial filing of PTE application to granting of a PTE certificate.").

Figure 1. Timeline of Patent Term Extension ("PTE") on an FDA-Approved Product



Typical duration of PTE = RRP - ½TP, up to a maximum of 5 years and 14 years from the date of FDA approval of the drug.

When complete, the patent term extension process officially links the extended patent with the approved product it covers and with the safety and effectiveness testing carried out to obtain that approval. For example, the Notice of Final Determination associated with Ozempic and its patent term extension states that:

> A determination has been made that U.S. Patent No. 8,129,343, claims of which cover the product and method of using the product known by the trademark OZEMPIC® (semaglutide), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,040 days [2.85 years].[215]

The Notice of Final Determination further reveals that the "testing phase" of Ozempic's development—during which data on its safety and effectiveness were gathered and submitted to the FDA to support approval—lasted 2,970 days, or a bit over eight years.[216] By USPTO regulation, all applicants for patent term extension must submit a description "of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities"[217]—i.e., an accounting of testing of safety and effectiveness and other properties of the approved product. The patent term extension application for Ozempic, for example, includes several pages of documentation of testing carried out by Ozempic's

215. Notice of Final Determination, U.S. Patent No. 8,129,343, at 1 (Apr. 20, 2021), https://data.uspto.gov/patent-file-wrapper/search/details/11908834/documents [https://perma.cc/55X7-M3DL].

216. *Id.*

217. 37 C.F.R. § 1.740(a)(11) (2024).

manufacturer and the dates upon which data was submitted to the FDA[218]—though no documentation of the *results* of this testing.

4. The Duty of Disclosure in Patent Term Extension: Strong in Theory, Negligible in Current Practice

The section of the Hatch–Waxman Act that created patent term extension, section 201, imposes a duty of disclosure on the part of all applicants for patent term extension. Congress explicitly, broadly, and concisely delegated authority to the USPTO to define this duty: "An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Director [of the USPTO]."[219] And the Act expressly permits the USPTO to deny patent term extension applications on the basis of failure to comply with this duty.[220] To quote the Federal Circuit, "the Director of the PTO is charged with deciding whether the patent is entitled to term extension, a decision" that encompasses the question of compliance with the duty of disclosure and "which is given 'great deference'" by the court.[221]

Section 201 was fiercely debated, but that fierce debate focused on the need for, and appropriate duration of, patent term extension,[222] not on the duty of disclosure. The legislative history says little about the duty of disclosure that attaches to patent term extension.[223]

De jure, the USPTO has construed the duty of disclosure to have real teeth. Per the official USPTO rule,

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218. Transmittal Letter for Application for Patent Term Extension Under 35 U.S.C. § 156, U.S. Patent No. 8,129,343, at tabs 7–8 (Jan. 19, 2018), https://data.uspto.gov/patent-file-wrapper/search/details/11908834/documents [https://perma.cc/7TZ2-NHV8].

219. 35 U.S.C. § 156(d)(4); *see also id.* § 156(d)(1)(E) (dictating that a patent term extension application shall contain "such patent or other information as the Director may require").

220. *See id.* § 156(e)(1) ("A determination that a patent is eligible for extension may be made by the Director solely on the basis of the representations contained in the application for the extension. If the Director determines that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d) have been complied with, the Director shall issue to the applicant for the extension of the term of the patent a certificate of extension . . . .").

221. Pfizer, Inc. v. Ranbaxy Lab'ys Ltd., 457 F.3d 1284, 1290 (Fed. Cir. 2006) (quoting Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392, 399 (Fed. Cir. 1990)).

222. *See supra* Part I and Section II.A.

223. The final House Energy and Commerce Committee report does include this brief passage:

> The applicant [for patent term extension] would be subject to any disclosure requirements prescribed by the Commissioner. The Committee expects that those requirements would subject the applicant to at least the same duty of disclosure, and the penalties and loss of rights for violation of the duty of disclosure, which governs all patent application proceedings before the Patents and Trademarks Office.

H.R. REP. NO. 98-857, at 41 (1984).

> If it is established by clear and convincing evidence that any fraud was practiced or attempted on the Office or the Secretary in connection with the patent term extension proceeding or that there was any violation of the duty of disclosure through bad faith or gross negligence in connection with the patent term extension proceeding, a final determination will be made pursuant to § 1.750 that the patent is not eligible for extension.[224]

One might think, then, that patent term extensions and their documentation should produce some sort of interesting information disclosure—perhaps even including some substantive details of the testing and regulatory approval that, in the patent owner's view, make the patent eligible for extension and dictate the appropriate duration of extension. But, de facto, the duty of disclosure is of negligible importance. That is so because the USPTO has construed the duty of disclosure vaguely and never enforced it.[225] The USPTO's rule requires the patent owner and its agents to disclose "material information adverse to a determination of entitlement to the extension sought" and defines "material information," rather circularly, as information "where there is a substantial likelihood that the Office or the Secretary would consider it important in determinations to be made in the patent term extension proceeding."[226] The USPTO has not elaborated on this definition,[227] and the agency has apparently never denied an application for term extension of a drug patent for failure to comply with the duty of disclosure.[228] It is unclear what, in the USPTO's view, would actually violate the duty of disclosure; perhaps intentional withholding of information revealing that the patent in question is ineligible for extension or that the applicant has exaggerated the appropriate extension of duration.[229]

The punch line is this: Today's patent term extension process reveals essentially no new technical information about the regulated product covered by the extended patent. Consider, again, Ozempic: We know from its patent term extension documentation[230] (and even more from FDA

224. 37 C.F.R. § 1.765(c) (2024).

225. *See id.* § 1.765(a) (defining the "[d]uty of disclosure in patent term extension proceedings").

226. *Id.*

227. *See, e.g.*, MPEP, *supra* note 165, § 2762 ("2762 Duty of Disclosure in Patent Term Extension Proceedings") (restating the rule without elaborating on it).

228. *See* Lietzan, *Patent Term Restoration – Denied!*, *supra* note 33 (indicating that the 122 drugs that did not get patent term extensions were denied or dismissed for reasons other than failure to comply with the duty of disclosure).

229. *See* Pfizer, Inc. v. Ranbaxy Laby's Ltd., 457 F.3d 1284, 1290–91 (Fed. Cir. 2006) (suggesting that intentional withholding of statements by the patent owner indicating that the patent upon which extension is sought does not actually cover the approved product could constitute a breach of the duty of disclosure).

230. Application for Patent Term Extension Tabs 7–8, at 131–41, Novo Nordisk A/S, U.S. Patent No. 8,129,343 (Jan. 19, 2018), https://data.uspto.gov/patent-file-wrapper/search/details/11908834/documents [https://perma.cc/MUZ2-A5SS].

publications)[231] that the testing of safety and effectiveness that formed the basis of the FDA's approval decision took place between 2008 and 2017. But we don't have all, or most, of the safety and effectiveness data itself, in either the patent term extension documents or directly from the FDA.

But before we leave the duty of disclosure in patent term extension, one last point: The Hatch–Waxman Act's broad and explicit delegation of authority to the USPTO to define this duty remains in the statute.[232] I return to the duty of disclosure and this grant of authority in Section III.A, which considers how a second patent bargain to unlock safety and effectiveness data might actually be struck.

III. STRIKING THE SECOND PATENT BARGAIN

This Part lays the prescriptive and doctrinal foundation of the second patent bargain. Section III.A proposes in concrete terms a fair and practical bargain: Whenever the USPTO extends a patent on an FDA-approved product, the FDA should release some of its archives of safety and effectiveness data on that product (with minimal redactions for privacy and trade secrecy). Section III.B shows two potential paths of law reform to make this bargain law of the land: a first path through revision of FDA and USPTO rules and a second through amendment of federal statute.

A. REIMAGINING THE QUID PRO QUO: STRIKING A CONTEMPORARY SECOND PATENT BARGAIN

How should we strike a second patent bargain that is fair and effective?

On *what* disclosure to require in exchange for patent term extension: The FDA and USPTO should work together to disclose three sections or components of drug and device applications: (1) clinical overviews; (2) clinical summaries; and (3) clinical study reports ("CSRs"), including two standard appendices attached to CSRs: (a) study protocols; and (b) statistical analysis plans. This information is in the "sweet spot" of risk and reward, as I explain below, it is highly useful to noncommercial information users but extremely unlikely to reveal personal information about individual patients and essentially useless to would-be free riders.

What exactly is this information?[233] The clinical overview is—as the name suggests—an overview of *all* the trial data and other clinical data in an

231. *See, e.g.*, CTR. FOR DRUG EVALUATION & RSCH., APPLICATION NUMBER: 209637ORIG1S000 CLINICAL REVIEW 36–38 (2017), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209637Orig1s000MedR.pdf [https://perma.cc/84RM-HX5C] (clinical review published upon FDA approval of Ozempic in 2017). Pages 36–38 document eight trials conducted to generate evidence of safety and effectiveness. *Id.*

232. *See* 35 U.S.C. § 156(e)(1).

233. For a more detailed taxonomy of the information contained in clinical overviews, clinical summaries, CSRs, protocols, and statistical analysis plans, see Alexander C. Egilman et al.,

application. Per the FDA, the clinical overview "is intended to provide a critical analysis of the clinical data" in the application as a whole.[234] The clinical overview presents critical perspective; it explains, inter alia, why a product was developed by its manufacturer, how it compares to competitor products, any "particular efficacy or safety issues encountered in development and how they have been evaluated and resolved," why certain patient populations are to be excluded from the product's FDA-approved ("on-label") uses, how "benefits" and "risks" are defined, and much more.[235] By contrast, the clinical summary presents clinical data without commentary—"just the facts, ma'am." The clinical summary provides an easy-to-use digest of all the clinical data in a product application.[236] Finally, CSRs are detailed summaries of individual clinical trials, including whether a given trial met or failed to meet its predetermined safety and effectiveness endpoints. CSRs include, as standard appendices, trial protocols, which specify precisely how studies are conducted, and statistical analysis plans, which specify how trial data is interpreted.[237] Protocols and statistical analysis plans are valuable in that they permit independent researchers to spot mistakes, selective reporting, and alteration of clinical trial outcomes (i.e., fraud).[238] A 2025 meta-analysis found that CSRs often reveal tested products have smaller benefits and greater harms than those depicted in the (more selective) medical literature.[239]

These three informational components are highly useful for independent research on safety, effectiveness, cost-effectiveness and value, the integrity of FDA decision-making, and more.[240] Researchers have used these components

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Transparency of Regulatory Data Across the European Medicines Agency, Health Canada, and US Food and Drug Administration, 49 J.L. MED. & ETHICS 456, 458 (2021).

234. CTR. FOR BIOLOGICS EVALUATION & RSCH., U.S. DEP'T OF HEALTH & HUM. SERVS., M4E(R2): THE CTD — EFFICACY GUIDANCE FOR INDUSTRY 7 (2017), https://www.fda.gov/media/93569/download [https://perma.cc/S753-9FCC].

235. *Id.* at 7–8, 13–18.

236. *Id.* at 20–43.

237. *Id.* at 57.

238. *See, e.g.*, John P.A. Ioannidis, Arthur L. Caplan & Rafael Dal-Ré, *Outcome Reporting Bias in Clinical Trials: Why Monitoring Matters*, BRIT. MED. J. 4 (Feb. 14, 2017), https://www.bmj.com/content/356/bmj.j408 [https://perma.cc/SAL4-Q2RE].

239. J. K. Aronson & I. J. Onakpoya, *Clinical Study Reports—A Systematic Review with Thematic Synthesis: Part 2. Studying Benefits, Harms, and the Benefit to Harm Balance of Pharmacological Interventions*, TRIALS 8–9 (2025), https://link.springer.com/content/pdf/10.1186/s13063-024-08671-z.pdf [https://perma.cc/S9NH-LMLN] ("CSRs should . . . ideally be included when the benefit to harm balance of any therapeutic intervention that has been subjected to clinical trial is being estimated.").

240. *See generally* Alexander C. Egilman, Joseph S. Ross & Matthew Herder, *Optimizing the Data Available via Health Canada's Clinical Information Portal*, 193 CAN. MED. ASS'N J. E1305 (2021) (describing Health Canada's public disclosure of these sections of product applications and the research done with them); HEALTH CAN., PUBLIC RELEASE OF CLINICAL INFORMATION IN DRUG SUBMISSIONS AND MEDICAL DEVICE APPLICATIONS 2 (2017), https://www.canada.ca/content/dam/hc-sc/documents/programs/public-release-clinical-information-drug-submissions-medical-device

to identify safety and effectiveness problems with cholesterol-lowering statins,[241] to show that Canada's drug regulator approved Purdue Pharma's oxycodone product (OxyContin) without properly assessing risks of misuse and addiction,[242] to argue that oseltamivir (Tamiflu) fails to meaningfully prevent the spread of the flu, reduce hospital admissions, or minimize flu complications, making the drug cost-ineffective,[243] and more. As Canada's drug regulator put it when announcing its own information disclosure program, these components provide "far more comprehensive [clinical information on safety and effectiveness] than that found in other sources including publications in scientific or medical journals, clinical trial registries," and other publicly accessible sources.[244] In short, these components fuel precisely the sort of independent research that advocates of data transparency envisioned when championing inclusion of section 104 in the Hatch–Waxman Act, including (to quote Public Citizen again) revelation of "dangers neither disclosed by the drug manufacturers nor detected by FDA."[245] These components are the very same components that the researchers seek.

Clinical overviews, clinical summaries, and CSRs are already in the FDA's hands. The FDA holds a massive trove of safety and effectiveness data on medical products[246]—"the largest known repository of clinical data" in the world.[247] Clinical overviews, clinical summaries, and CSRs sit within this enormous repository; they are prepared by manufacturers and then submitted to the FDA in applications for approval of a new drug[248] or device.[249] The FDA already maintains all this data in highly organized,

-applications.pdf [https://perma.cc/ZE2Z-JRX5] ("2. Policy Rationale," enumerating benefits of disclosure of these specific components of product applications).

241. Peter Doshi, Kyungwan Hong, Sarah Tanveer & Tom Jefferson, *Assessing Muscle-Related Adverse Events in Randomized Trials of Statins*, 37 J. GEN. INTERNAL MED. 3498, 3498–99 (2022) (using safety and effectiveness data obtained from the European Medicines Agency and Health Canada to raise new questions about the safety of statins).

242. Pappin et al., *supra* note 65, at 585.

243. Richard Van Noorden, *Report Disputes Benefit of Stockpiling Tamiflu*, NATURE (Apr. 10, 2014), https://rdcu.be/eZL1K [https://perma.cc/A2YU-VWJW]; T. Jefferson et al., *Neuraminidase Inhibitors for Preventing and Treating Influenza in Adults and Children (Review)*, COCHRANE DATABASE SYSTEMATIC REV. 25, https://pmc.ncbi.nlm.nih.gov/articles/PMC6464969/pdf/CD008965.pdf [https://perma.cc/NM9S-H3JA].

244. HEALTH CAN., *supra* note 240, at 1.

245. *Hatch–Waxman Act Hearing*, *supra* note 139, at 260 (Testimony of Louise S. Greenfield & Janet S. Hathaway, Staff Att'ys with Pub. Citizen's Cong. Watch and William B. Schultz, Att'y with Pub. Citizen Litig. Grp.). *See generally supra* Section II.A.

246. Morten & Kapczynski, *supra* note 38, at 510–14.

247. U.S. FOOD & DRUG ADMIN., *supra* note 156, at 22.

248. CTR. FOR BIOLOGICS EVALUATION & RSCH., *supra* note 234, at 2.

249. *PMA Application Contents*, U.S. FOOD & DRUG ADMIN. (Apr. 22, 2024), https://www.fda.gov/medical-devices/premarket-approval-pma/pma-application-contents [https://perma.cc/DJR5-UDGL].

indexed form and already discloses bits and pieces of it (e.g., CSRs) to dogged FOIA requesters.[250] That the FDA already discloses clinical overviews, clinical summaries, and CSRs, albeit reluctantly and inconsistently, underscores the fact that these documents do not generally contain trade secrets.[251]

Publishing information already in the FDA's files has many benefits. For one, pulling from the FDA's existing files lessens burdens on patent owner and agency alike; neither need generate or format new information. At the same time, publishing data held by the FDA eliminates concerns over data quality and compliance. The data that companies submit to the FDA is of high quality: It is certified by the companies that submit it and independently verified by the FDA. Companies have very strong incentives to submit complete, correct data to the FDA because errors and fraud may be punished with refusal of product approval, criminal prosecution and imprisonment, mass tort liability, and more.[252] The same is unfortunately not true for data in patents.[253] There *is* a systematic compliance and enforcement problem vis-à-vis the first patent bargain, arising from, inter alia, the fact that the maximal penalty for inclusion of incomplete or false data in a patent is typically invalidity or unenforceability of the patent—severe but less devastating consequences.[254] Publishing information already in the FDA's

250. Morten & Kapczynski, *supra* note 38, at 520–27, 541–43.

251. *Id.* at 534–38.

252. For drug products, see, for example, Press Release, FDA, Statement on Data Accuracy Issues with Recently Approved Gene Therapy (Aug. 6, 2019), https://www.fda.gov/news-events/press-announcements/statement-data-accuracy-issues-recently-approved-gene-therapy [https://perma.cc/7MTV-V3AZ] (threatening "civil or criminal penalties" for knowing submission of false data in a drug application). For medical devices, see, for example, Press Release, FDA, Fraudulent and Unreliable Laboratory Testing Data in Premarket Submissions: FDA Reminds Medical Device Manufacturers to Scrutinize Third-Party-Generated Data (Feb. 20, 2024), https://www.fda.gov/medical-devices/industry-medical-devices/fraudulent-and-unreliable-laboratory-testing-data-premarket-submissions-fda-reminds-medical-device [https://perma.cc/5MKG-MFSU]. *See also* Press Release, U.S. Dep't of Just., Former Employee of Medical Device Manufacturer Sentenced for Forging Two FDA Letters that Led to Illegal Sale of Medical Devices (Jan. 24, 2024), https://www.justice.gov/opa/pr/former-employee-medical-device-manufacturer-sentenced-forging-two-fda-letters-led-illegal [https://perma.cc/JL3X-Q59K]; Daniel Feith, Deputy Att'y Gen., Dep't of Just., Remarks at the FDLI Enforcement, Litigation, and Compliance Conference (Dec. 15, 2020), https://www.justice.gov/archives/opa/speech/deputy-assistant-attorney-general-daniel-feith-delivers-remarks-fdli-enforcement [https://perma.cc/DN4H-9CNF] ("[T]he Consumer Protection Branch has prioritized enforcement against entities and individuals that have engaged in fraud or deception in conducting clinical trials. Disturbingly, one published study found that one in six researchers involved in clinical drug trials reported that they were personally aware of fabrication in research. Therefore, in partnership with FDA's Office of Criminal Investigations, we are aggressively investigating and prosecuting misconduct ranging from falsifying and altering trial results and other data, to concealing conflicts of interest, to making misrepresentations in submissions to the FDA.").

253. *See supra* note 92 and accompanying text.

254. *See* S. Sean Tu, Caroline Leadmon, C. Joseph Ross Daval & Aaron S. Kesselheim, *Inequitable Conduct and Invalidation of Patents Related to Food and Drug Administration-Regulated Products*, 330 JAMA 2119, 2119–21 (2023) (documenting a small number of patents deemed

files will also make it harder for the *FDA* to hide information that might embarrass the agency—e.g., information showing an approval decision was based on faulty science.[255]

There are also benefits of international harmony. The FDA's counterparts in the European Union and Canada today publish precisely this information—clinical overviews, clinical summaries, CSRs, protocols, and statistical analysis plans, with minimal redactions.[256] The data portals maintained by the European Medicines Agency ("EMA")[257] and Health Canada[258] as well as the National Institutes of Health's ("NIH") ClinicalTrials.gov database[259] show how to render this kind of information readily comprehensible, with FAQs and glossaries to help journalists, physicians, patients, and other audiences make meaningful use of the data. (Of course, the data portals maintained by the EMA and Health Canada lack data on many drugs and devices, including controversial products approved by the U.S. FDA but not approved elsewhere, including lecanemab (Leqembi) and eteplirsen (Exondys 51).)

Clinical overviews, clinical summaries, and CSRs are the "sweet spot" of safety and effectiveness data disclosure because they fuel this research without compromising patient privacy or the competitive positions of the

unenforceable for inequitable conduct arising from patent owner's withholding of negative data from the USPTO and from the public). *But see In re* Lipitor Antitrust Litig., 868 F.3d 231, 266–68 (holding that antitrust liability could conceivably arise from abuse of a patent procured via submission of fraudulent data to the USPTO).

255. See, for example, Justice Breyer describing agencies' "skittishness" about revealing their own mistakes: "[G]iven the temptation, common across the private and public sectors, to regard as secret all information that need not be disclosed, I fear the majority's reading will deprive the public of information for reasons no better than convenience, skittishness, or bureaucratic inertia." Food Mktg. Inst. v. Argus Leader Media, 139 S. Ct. 2356, 2368 (2019) (Breyer, J., concurring in part).

256. Egilman et al., *supra* note 233, at 462; Morten et al., *Researcher Access to Social Media Data*, *supra* note 45, at 186–89; *see also EMA Policy 0070: Back on the Road to Transparency*, PROPHARMA (Sept. 5, 2023), https://www.propharmagroup.com/thought-leadership/ema-policy-0070-back-on-the-road-to-transparency [https://perma.cc/Z3WE-69UU] (recent update on European Medicines Agency's ("EMA") safety and efficacy data transparency program). Clinical trial data itself is harmonized globally; the EMA and Health Canada receive, review, and publish data in the same format that the FDA receives and reviews. *CDER Data Standards Program*, U.S. FOOD & DRUG ADMIN. (Dec. 23, 2025), https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/cder-data-standards-program [https://perma.cc/QXL4-KRQG]; *Electronic Common Technical Document (eCTD)*, U.S. FOOD & DRUG ADMIN. (Oct. 4, 2024), https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd [https://perma.cc/XE7S-JEV6]; Jagadeeswara Rao Gaddale, *Clinical Data Acquisition Standards Harmonization Importance and Benefits in Clinical Data Management*, 6 PERSPS. CLINICAL RSCH. 179, 180 (2015).

257. *Clinical Data*, EUR. MEDS. AGENCY, https://clinicaldata.ema.europa.eu/web/cdp/home [https://perma.cc/6YZK-V5HR].

258. *Clinical Information on Drugs and Medical Devices*, HEALTH CAN., https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/clinical-information-drugs-health-products.html [https://perma.cc/4LB8-J94S].

259. *ClinicalTrials.gov*, NAT'L LIBR. MED., https://clinicaltrials.gov [https://perma.cc/DNE6-49UJ].

companies that generate and submit this data. Medical data from clinical trials is particularly sensitive, as it can be used to exploit or discriminate—imagine insurers using a person's clinical trial data to deny coverage on the basis that the person's future treatment is likely to be expensive.[260] The FDA currently, and properly, requires redaction of any data that "constitutes a clearly unwarranted invasion of personal privacy,"[261] such as names and birthdays, before public release. The data transparency programs maintained by Health Canada and EMA likewise redact and otherwise de-identify personally identifiable information.[262] Happily, clinical overviews, clinical summaries, CSRs, protocols, and statistical analysis plans are *summaries* (and metadata about those summaries) that reveal little or no information on individual patients in the first place.[263] Health Canada, the EMA, and the FDA (in responses to FOIA requests) have all developed workable methods to anonymize CSRs to the extent they do reveal individuals' health data—e.g., in tables of patient outcomes.[264]

What about protecting the competitive and intellectual property interests of the companies who generated this information? Recall the concern voiced by representatives of the brand-name pharmaceutical industry during debate on section 104 of the Hatch–Waxman Act[265] over generic companies copying safety and effectiveness data and free riding on it for approval in other countries (regardless of the timing of generic approval in the United States). This concern can be allayed.[266] First, many important foreign drug

260. Specialty credit rating agencies already create and sell health reports on individual people. *See, e.g.*, Ann Carrns, *Consumers Can Check on Data Beyond Their Credit Reports*, N.Y. TIMES (Jan. 15, 2014), https://www.nytimes.com/2014/01/15/your-money/consumers-can-check-on-data-beyond-their-credit-reports.html (on file with the *Iowa Law Review*). For analysis of the sensitivity of health data, see generally I. Glenn Cohen & Michelle M. Mello, *Big Data, Big Tech, and Protecting Patient Privacy*, 322 JAMA 1141 (2019) (discussing the use of artificial intelligence to analyze health data); W. Nicholson Price II & I. Glenn Cohen, *Privacy in the Age of Medical Big Data*, 25 NATURE MED. 37 (2019) (same); Efthimios Parasidis, Elizabeth Pike & Deven McGraw, *A Belmont Report for Health Data*, 380 NEW ENG. J. MED. 1493 (2019) ("A majority of people believe that there should be limits on the use of their health data."); and BIG DATA, HEALTH LAW, AND BIOETHICS (I. Glenn Cohen, Holly Fernandez Lynch, Effy Vayena & Urs Gasser eds., 2018) (highlighting how many aspects of daily life could be considered health data).

261. 21 C.F.R. § 20.63 (2025); *see also id.* § 20.82(b)(2).

262. *See* Egilman et al., *supra* note 233, at 462.

263. CSRs typically include, as appendices, case report forms that describe the health of individual patients, but these are unnecessary to most independent research and should not be disclosed.

264. *See* Janice Branson et al., *Evaluating the Re-identification Risk of a Clinical Study Report Anonymized Under EMA Policy 0070 and Health Canada Regulations*, TRIALS 2 (2020), https://link.springer.com/content/pdf/10.1186/s13063-020-4120-y.pdf [https://perma.cc/2BBW-RDAJ]; Egilman et al., *supra* note 233, at 464–65.

265. *See supra* Section II.A.

266. There are reasons to question whether free riding in other countries is itself inherently harmful to the American public or should be a focus of U.S. innovation law and policy. *See, e.g.*,

regulators, including China's and India's, do not rely on this summary data when approving generic applications.[267] Second, FDA and USPTO could require that all users who access the summary data attest that they will not use the data for regulatory approval in other countries.[268] Health Canada and the EMA require such attestation from users of the clinical overviews, clinical summaries, and CSRs they disclose,[269] and after years of disclosure by these agencies, there are no known examples of companies attempting to free ride on information to obtain approval from another country's drug regulator. Third, the FDA and USPTO could "watermark" the information they disclose, making clear to foreign regulators the source of the information—as Health Canada and the EMA do.[270]

Clinical overviews, clinical summaries, and CSRs do not typically contain trade secret information.[271] There is nonetheless a good reason to permit companies to request some minimal redaction of clinical overviews, clinical summaries, CSRs, protocols, and statistical analysis plans before public

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Daniel J. Hemel & Lisa Larrimore Ouellette, *Knowledge Goods and Nation-States*, 101 MINN. L. REV. 167, 179–81 (2016).

267. *See* Amy Kapczynski, The Interaction Between Open Trial Data and Drug Regulation in Selected Developing Countries 3 (2014) (unpublished manuscript), https://law.yale.edu/sites/default/files/area/center/ghjp/documents/kapczynski_interaction_between_open_data_report_for_nam_.pdf [https://perma.cc/P235-TRRT]; *see also* Cynthia M. Ho, *Avoiding the TRIPS Trap: A Path to Domestic Disclosure of Clinical Drug Data Consistent with International Norms*, 54 CORNELL INT'L L.J. 479, 509–10 (2021) (summarizing EU law's view of the modest amount of trade secret data within clinical study reports and industry acquiescence to this view).

268. *See* Ho, *supra* note 267, at 531 ("How can a country take steps to protect against the risk that a competitor will use disclosed data to obtain regulatory approval in another country? A country could make disclosure contingent on a promise not to use the data for subsequent regulatory approval processes."). Ho points out that requiring such an attestation may help ensure that the data disclosure program comports with obligations imposed by Article 39 of the TRIPS Agreement. For further analysis of the interplay of drug regulators' disclosure of safety and effectiveness data and the TRIPS Agreement, see CARLOS MARÍA CORREA, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT 14 (2002), https://www.southcentre.int/wp-content/uploads/2019/02/Bk_2002_Protection-of-Data-Submitted-for-Pharmaceuticals-Registration_EN.pdf [https://perma.cc/JD85-VD2G]; Trudo Lemmens & Candice Telfer, *Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency*, 38 AM. J.L. & MED. 63, 82–87 (2012); and WORLD HEALTH ORG., DATA EXCLUSIVITY AND OTHER "TRIPS-PLUS" MEASURES 2–3 (2017), https://iris.who.int/bitstreams/7c03d66c-7594-4e1f-aed1-c53c1a039d51/download [https://perma.cc/AC5A-HDMP].

269. *Public Release of Clinical Information: Guidance Document*, HEALTH CAN., https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/profile-public-release-clinical-information-guidance/document.html [https://perma.cc/9UVC-9MZY] (Appendix H: Terms of Use requiring users to represent and warrant "that your access to Clinical Information is solely for non-commercial purposes"); *Terms of Use*, EUR. MED. AGENCY: CLINICAL DATA, https://clinicaldata.ema.europa.eu/web/cdp/termsofuse [https://perma.cc/PN4X-3QW2] (EMA's terms of use state that "the intended use of the clinical data is for general and non-commercial purposes. . . . the clinical data is for academic and other non-commercial research purposes").

270. Ho, *supra* note 267, at 538.

271. Morten & Kapczynski, *supra* note 38, at 534–38.

disclosure: These documents sometimes contain not just information on the patented product but also information on other things. For example, clinical study reports and clinical trial protocols may detail how companies design and run clinical trials, conduct laboratory assays, and so on. Such information is not directly relevant to the patented product's properties, and such information sometimes—not always—meets the requirements for trade secret protection. If so, it may justifiably be redacted on that basis. The EMA offers helpful guidance here: Under EU law, only information that bears "innovative features" qualifies for redaction.[272] An advisory committee of the EMA enumerated examples of the relatively few subcategories of safety and effectiveness data likely to bear such features, such as new assay methodologies for biomarkers, methods to pursue newly validated endpoints, and novel trial designs that make proof of effectiveness faster and more economical.[273] The NIH has adopted a similar view: This information can be redacted as a trade secret.[274]

Of course, there is risk of a different kind of financial harm, not from free-riding competition but from lost sales upon discovery of toxicity, lack of efficacy, or other problems with the product. But this sort of private loss is exactly the sort patent law and law generally should promote, not fear. As the Supreme Court has said:

> If . . . a public disclosure of [trade secret] data reveals, for example, the harmful side effects of the [trade secret owner's] product and causes the [owner] to suffer a decline in the potential profits from sales of the product, that decline in profits stems from a decrease in the value of the [product] to consumers, rather than from the

272. EUR. MEDS. AGENCY, EXTERNAL GUIDANCE ON THE IMPLEMENTATION OF THE EUROPEAN MEDICINES AGENCY POLICY ON THE PUBLICATION OF CLINICAL DATA FOR MEDICINAL PRODUCTS FOR HUMAN USE 54–59 (2018), https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data_en-3.pdf [https://perma.cc/28UL-6ZQK]; *see* Ho, *supra* note 267, at 507–08 (summarizing EU law's view of the modest amount of trade secret data within clinical study reports through an example of industry acquiescence to this view).

273. CLINICAL TRIAL ADVISORY GRP. ON RULES OF ENGAGEMENT, ADVICE TO THE EUROPEAN MEDICINES AGENCY ON RULES OF ENGAGEMENT FOR ACCESSING CLINICAL TRIAL DATA 1–2 (2013), https://web.archive.org/web/20180721140704/http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/04/WC500142859.pdf [https://perma.cc/7599-MPSN].

274. *See* Clinical Trials Registration and Results Information Submission, 81 Fed. Reg. 64982, 64995 (Sept. 21, 2016) (to be codified at 42 C.F.R. pt. 11) (stating that opponents of mandatory disclosure of summary data from clinical trials have not "identified specific clinical trial results information that would be required to be submitted and that would meet the definition of a protected trade secret property interest for purposes of a takings analysis"); *id.* at 64996 ("[S]ection 402(j) of the PHS Act requires the trial results in summary form (rather than individual participant-level form), which we believe can be provided without disclosing trade secret or confidential commercial information."); *id.* at 65000 (authorizing limited redaction of trial protocols when a "responsible party believes that a protocol does contain trade secret and/or confidential commercial information . . . so long as the redaction does not include any specific information that is otherwise required to be submitted under this rule").

> destruction of an edge the [owner] had over its competitors, and cannot constitute the taking of a trade secret.[275]

It is orthodox intellectual property theory that intellectual property rights are intended to permit inventors to internalize some portion of the *value* of useful inventions and so spur creation of more useful inventions. Intellectual property rights are not supposed to permit inventors to hide the truth about inventions of low, zero, or even negative value. Whenever intellectual property rights conceal information about the value of inventions, they are malfunctioning.[276] The existing patent term system discordantly permits some companies—including Sarepta, whose perhaps useless drug eteplirsen was described in the Introduction—to extend lucrative patent rights on drugs and simultaneously to hide data that may show the patented drugs have no social value whatsoever. Striking the second patent bargain would force these companies to choose one or the other—extension or secrecy. It would represent a step toward better alignment of patent incentives and social value—and broadly disseminate information on that value, to boot.

On *when* to disclose: I propose that the FDA and USPTO should work together to disclose safety and effectiveness data on a given product on the same day the USPTO issues its certificate of patent term extension—i.e., on the day the patent term extension takes effect. To publicly disclose safety and effectiveness data on a product at the same time the product's patent term extension takes effect would mirror the mechanics of the first patent bargain: Inventors must disclose their inventions, and how to make and use them, in the text of their patents, no later than the day those patents issue and take legal force.[277] Public disclosure coincides with the public's grant of exclusive rights to the inventor; the quid pro quo is simultaneous. In this second patent bargain, just as in the first, the patent owner would retain the right to back out of the bargain up until the moment the benefit is conferred. If the patent owner decides that data secrecy is preferable to the new grant of exclusive rights, it can decline the patent term extension and keep the data secret.

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275. Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1011–12 n.15 (1984).

276. *See* Charles Tait Graves & Sonia K. Katyal, *From Trade Secrecy to Seclusion*, 109 GEO. L.J. 1337, 1400 (2021) ("It is essential, therefore, to reconsider the roots of trade secret law in terms of its effect on the broader flow of information and the risk of opacity."); Robin Feldman & Charles Tait Graves, *Naked Price and Pharmaceutical Trade Secret Overreach*, 22 YALE J.L. & TECH. 61, 109–11 (2020); Christopher J. Morten, Information & Inefficiency (July 2025) (unpublished manuscript) (on file with the *Iowa Law Review*).

277. 35 U.S.C. § 154(a)(2) (term of a patent runs from date of patent grant). In practice today, most inventions are disclosed in published patent applications prior to patent issuance, typically at eighteen months from patent application filing. *See id.* § 122(b); MPEP, *supra* note 165, § 1120. However, U.S. patent applicants still have the right, in some circumstances, to request that their applications not be published, keeping the details of their inventions secret until publication of the patent itself (upon patent issuance). 35 U.S.C. § 122(b); MPEP, *supra* note 165, § 1120.

Section II.B showed how the FDA and USPTO already collaborate closely through the patent term extension process. It would be easy enough for the FDA to begin redacting and otherwise preparing its files of safety and effectiveness data on a given product for public disclosure as the patent term extension application nears grant. For example, the FDA could begin preparing files for disclosure soon after it sends the USPTO its determination of the final regulatory review period;[278] the work would be synergistic, as the FDA already reviews the very same New Drug Application or Biologics License Application files that contain clinical overviews, clinical summaries, and CSRs to confirm the exact length of time the patented product spent in testing and in regulatory review. Expanding this kind of FDA–USPTO cooperation in information management was an explicit focus of the agencies' collaboration initiatives during the Biden Administration[279] (which appear to have been put on hold by the second Trump Administration[280]).

In separate writings, Eisenberg, Kapczynski, and I have argued that the FDA should simply disclose safety and effectiveness data from *all* product approvals, at the moment of approval or shortly thereafter, with minimal redaction, regardless of whether those products seek or receive patent term extensions.[281] Eisenberg has argued for a statutory amendment that would strike a different quid pro quo: broad and deep disclosure of this data to the public immediately upon product approval in exchange for new, enhanced data exclusivity rules that would further insulate innovator companies from free-riding competitors.[282] Kapczynski and I have argued that disclosure of this data upon product approval is both wise and legal under existing statute (pending thorough revision of rules promulgated by the FDA).[283] We argued against unconditioned disclosure to the broad public; we've argued instead that the FDA should publicize the data conditionally.[284] By "publicize," we mean that the FDA should closely govern access to and use of this data to discourage commercial and otherwise harmful users and uses, rather than disclose the data to all comers without restriction.[285] I still endorse, wholeheartedly, the proposal that Kapczynski and I laid out. (And I like Eisenberg's

278. 21 C.F.R. § 60.26 (2025).

279. *USPTO-FDA Joint Engagements*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/initiatives/uspto-fda-collaboration/engagements [https://perma.cc/6U7D-A5A2].

280. The agencies' webpage describing the collaboration initiatives appears to have been removed at some point in 2025. *See USPTO – FDA Collaboration Initiatives*, U.S. PAT. & TRADEMARK OFF. (Oct. 9, 2025), https://web.archive.org/web/20251009105843/https://www.uspto.gov/initiatives/fda-collaboration [https://perma.cc/8T2R-M57R] (archive of webpage).

281. Eisenberg, *supra* note 105, at 487; Morten & Kapczynski, *supra* note 38, at 509–10, 529–49 (arguing the policy benefits of data disclosure shortly after product approval, and describing FDA's legal authority to disclose data upon product approval).

282. Eisenberg, *supra* note 105, at 488–89.

283. Morten & Kapczynski, *supra* note 38, at 541–49.

284. *Id.*

285. *Id.*

proposal, too.) I think to demand controlled public disclosure of safety and effectiveness data from each and every FDA approval is itself a fair bargain—FDA approval itself and the regulatory exclusivities that come with it confer enormous benefits.[286] As the Supreme Court has observed, transparency obligations are an integral part of regulated markets: "[S]uch restrictions are the burdens we all must bear in exchange for the advantage of living and doing business in a civilized community."[287]

But I conceded in my article with Kapczynski[288] that our 2021 proposal implicates some legal challenges and some potential financial liability for the FDA, under the Takings Clause especially. As we spoke privately with agency leadership about the proposal of that article, I gradually came to understand that the prospect of takings litigation can foreclose agency action, even if the agency is likely to survive a takings challenge.

An impetus for this Article is to offer a disclosure proposal that agency leadership feel fully comfortable with. An advantage of the new proposal of this Article is that it directly and specifically tethers the disclosure mandate to an enormously valuable benefit: the patent term extension. As I explain in Part IV, that explicit quid pro quo should obviate completely any concerns on the part of the FDA or USPTO that disclosure could render the agencies vulnerable to legal challenge and liability.

And, of course, to link the grant of an extended patent term to public disclosure of late-stage safety and effectiveness data has sound basis in patent theory and doctrine, too, as Part I traced. For medical inventions, information on safety and effectiveness is often essential to understanding and evaluating the invention's utility, enablement, and nonobviousness, regardless of when that information is generated.[289] The obligation to disclose post-filing information on safety and effectiveness would commensurate closely with patent owners' rights to rely on the same information to obtain and defend their patents; responsibility would follow right. Owners of patents on pharmaceutical and other chemical inventions often rely on post-filing evidence of so-called "unexpected results" to establish the nonobviousness of their patents;[290] public disclosure of post-filing safety and effectiveness

286. *Id.*

287. Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1007 (1984) (citations and internal quotation marks omitted).

288. Morten & Kapczynski, *supra* note 38, at 549–55.

289. On utility, see, for example, *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1564 (Fed. Cir. 1996) ("[P]ractical utility may be shown by adequate evidence of any pharmacological activity."). On enablement, see, for example, *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1336–37 (Fed. Cir. 2003) (describing patent owner's use of post-filing publications to "demonstrate[] the extent of the enabling disclosure" in an asserted patent covering processes for making a biologic drug product). On nonobviousness, see, for example, Karshtedt, *supra* note 94, at 1647–50 (summarizing patent law's reliance on late-stage, post-filing evidence of inventions' properties for proof of unexpected results and other secondary considerations of nonobviousness).

290. Karshtedt, *supra* note 94, at 1647.

information would permit better and less biased analysis of this essential condition of patentability. Late-stage safety and effectiveness information is also vital to understanding the best mode of practicing medical inventions—another core requirement of patentability. As Lee recently reminded us, "[i]f a patent applicant has subjective knowledge of a best mode at the time of filing a patent application, the applicant must disclose it in an objectively adequate manner."[291] The same logic should apply equally at the time of filing an application for patent term extension: If an applicant for term extension knows the best mode of using an FDA-regulated product, safely and effectively, in various patient populations, it is already obliged to include that information in its application for FDA approval and should have to disclose the same information publicly if and when the extension is granted.

Finally, brand-name companies might argue that if safety and effectiveness data must be disclosed in exchange for patent term extension, the data should be disclosed no sooner than the date on which the first generic version of the drug is approved—i.e., the date on which commercial free riding on that data first becomes legal in the United States. Recall that section 104 of the Hatch–Waxman Act made generic approval a triggering event for disclosure of safety and effectiveness data.[292] Why not retain that trigger? I think to delay disclosure until generic approval is unnecessary. The trigger moment this Article proposes is the moment that a patent term extension is granted, typically two or three years after product approval and a few years prior to approval of the first generic.[293] At this moment, the product is guaranteed to be *doubly* protected from generic competition in the United States—protected both by the patent being extended and protected by the FDA's regulatory exclusivities, which last no less than five years from approval and often seven-and-a-half years.[294] These are ideal conditions for disclosure: Noncommercial research can take place while FDA and patent law shelter the product from free-riding competitors.[295] Since the regulatory and statutory proposals of this Article do not actually rely on the sweeping

291. Lee, *supra* note 4, at 49. The AIA dramatically weakened the best mode requirement by precluding defendants in patent infringement litigation from raising it as a basis of invalidity. 35 U.S.C. § 282(b)(3)(A). However, disclosure of the best mode remains "on the books" as a requirement for patentability, *see id.* § 112(a), and the USPTO continues to instruct its examiners to reject patent applications that fail to disclose the best mode. MPEP, *supra* note 165, § 2165.

292. 21 U.S.C. § 355(*l*)(1)(E). To be precise, the statute requires disclosure either on the date that a generic version is approved or, in the event that no generic has sought FDA approval, on the date that a generic *could* be approved, had a generic application been submitted to the FDA.

293. *See supra* Section II.B.3 (describing the process and timing of patent term extension).

294. Eisenberg, *supra* note 105, at 482; Sunand Kannappan, Jonathan J. Darrow, Aaron S. Kesselheim & Reed F. Beall, *The Timing of 30-Month Stay Expirations and Generic Entry: A Cohort Study of First Generics, 2013–2020*, 14 CLINICAL TRANSLATIONAL SCI. 1917, 1921–23 (2021).

295. Eisenberg, *supra* note 105, at 487 ("By providing an exclusionary right that survives public disclosure, the patent system protects innovators from free riders without the need for secrecy.").

but unfulfilled transparency promise of section 104, I think we should feel free to diverge from section 104's timing.

It is to the Article's specific regulatory and statutory proposals that I turn next.

B. Two Paths to a Second Patent Bargain

How do we make this second patent bargain the law?

1. A Path Through the Agencies: Revise Duty of Disclosure Rules

One potential path to a second patent bargain runs through the FDA and USPTO. This path would require only rule reform and no new action from Congress, but it might entail more risk than the agencies are willing to undertake.

Section II.B.4 explained that the Hatch–Waxman Act imposes a duty of disclosure on applicants for patent term extension; that the relevant provision of the Act delegates to the USPTO broad authority to define that duty; that the USPTO has construed the duty vaguely; and that the duty has little practical effect, as the agency has never actually denied a patent term extension application on the basis of failure to comply.

What if the USPTO revisited its broad statutory authority to impose disclosure obligations on patent term extension applicants? What if the USPTO required patent owners seeking patent term extensions to disclose, or to authorize the relevant regulator to disclose, some of the testing data in the product application that created the eligibility for patent term extension? More specifically, what if the USPTO required the companies seeking to extend patents on FDA-approved medicines, vaccines, and devices to permit the FDA to disclose the safety and effectiveness information described in Section III.A: (1) clinical overviews; (2) clinical summaries; and (3) CSRs?

To use patent term extension's duty of disclosure in this way might feel a bit odd.[296] Duties of disclosure in patent law are typically duties to disclose information *to the USPTO*, when that information bears in some way on the USPTO's decision-making—e.g., the agency's decision whether to grant a patent in the first place,[297] or to cancel a patent challenged at the Patent Trial and Appeal Board.[298] What I propose instead is to require the patent

296. Section 104 of the Hatch–Waxman Act, described in Section II.A, did of course mandate disclosure of this same safety and effectiveness data. But it mandates disclosure by the FDA, not disclosure by the USPTO; imagines disclosure of safety and effectiveness data for all FDA-approved drugs and vaccines, not disclosure of data on the subset of those products that enjoy patent term extension; and imagines delaying disclosure until a generic competitor has been approved or some other triggering event occurs, not disclosure earlier, at the moment of patent term extension. For the reasons presented in Section III.A and Part IV, I think disclosure by the USPTO of safety and effectiveness data on products that enjoy patent term extension at the moment of patent term extension makes the best practical and theoretical sense.

297. 37 C.F.R. § 1.56 (2024).

298. *Id.* § 42.11.

owner to authorize disclosure *to the public* of information sitting in the FDA's files, information that is not directly necessary or even relevant to the USPTO's decision on whether to grant or deny the extension. But it seems to me such disclosure, however unorthodox, would still comport with the Hatch–Waxman Act's broad dictate that "[a]n application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Director."[299]

For the USPTO to construe, via new regulation, patent term extension's duty of disclosure to require authorization of regulator-held disclosure of safety and effectiveness data might even survive court challenge, despite the federal courts' increasingly crabbed view of agency rulemaking and regulation generally. The Supreme Court's recent decision in *Loper Bright*, for example, extinguished federal courts' broad deference to agencies' interpretations of ambiguous statutes, but seems to have preserved deference in the event that the statutes in question "'expressly delegate[]' to an agency the authority to give meaning to a particular statutory term."[300] *Loper Bright* provided, in a footnote, two examples of statutes that apparently meet the requirements for express delegation and therefore confer discretion upon the recipient agencies; these anointed examples include delegatory language ("as such terms are defined and delimited by regulations of the Secretary" and "as defined by regulations which the Commission shall promulgate") similar to the Hatch–Waxman Act's ("[a]n application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Director.").[301] In an existing provision of federal statute, Congress even expressly authorized the USPTO to request that FDA and HHS "furnish full and complete information with respect to such questions relating to drugs as the Director may submit concerning any patent application."[302]

Any reconsideration and revision of rules by the USPTO would have to be done in close concert with the FDA. Disclosure of the safety and effectiveness information I propose in Section III.A, including verification of the safety and effectiveness information itself and verification of redactions for privacy and trade secrecy proposed by the patent owner, will require active participation of the FDA. To that end, the FDA would likely need to revise its own rules for management of patent term extension applications.[303] Rule

299. 35 U.S.C. § 156(d)(4).

300. Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244, 2263 (2024) (alteration in original) (quoting Batterton v. Francis, 432 U.S. 416, 425 (1977)).

301. *Id.* at 2263 n.5; 35 U.S.C. § 156(d)(4).

302. 21 U.S.C. § 372(d).

303. 21 C.F.R. pt. 60 (2025). The FDA might, at the same time, clarify its secrecy regulations to specify that any safety and effectiveness information authorized for disclosure by a patent owner in a patent term extension application will no longer be considered a trade secret or confidential commercial information subject to nondisclosure by the agency. *See id.* § 20.61.

reform at the FDA could be undertaken in coordination with the USPTO, as part of the agencies' aforementioned and ongoing Collaboration Initiatives.[304]

Of course, the *realpolitik* here is unfavorable. The FDA and the USPTO have historically been cautious about undertaking new transparency initiatives on their own[305] and reluctant to work together.[306] HHS Secretary Kennedy and FDA Commissioner Marty Makary took power promising "radical transparency" but have thus far inconsistently embraced public-facing transparency.[307]

Each agency has understandable incentives not to undertake the rule reform sketched here—litigation risk, manageable but nonzero new workload associated with managing the publication of safety and effectiveness information, and, for the FDA, risk of revealing of mistakes in the agency's own analysis and decision-making. As such, it might be more realistic to imagine Congress commanding the agencies to act via new legislation. It is to that possibility that I turn next.

2. Path Through Congress: Amend the Patent Act Again

A second potential path to a second patent bargain runs through Congress. Congress could simply amend section 201 of the Hatch–Waxman Act (now codified at 35 U.S.C. § 156) to condition patent term extension upon publication of some of the safety and effectiveness information that supported the regulatory approval that created the entitlement to patent term extension.

In my mind, two ingredients would make the statutory recipe successful. First, Congress should make the information publication program mandatory, not discretionary, on both the agencies and the companies they interact with. Other safety and effectiveness data transparency programs administered by the FDA have underperformed because the agency has had discretion to invest minimal resources.[308] Second, and closely related, Congress should appropriate the money the USPTO and FDA require to hire personnel needed to administer these programs.

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304. *FDA–USPTO Collaboration Initiatives*, U.S. FOOD & DRUG ADMIN. (Nov. 4, 2022), https://www.fda.gov/about-fda/reports/fda-uspto-collaboration-initiatives [https://perma.cc/KL4K-DHQP].

305. *See, e.g.*, Tai, *supra* note 157, at 426–33 (documenting resistance within FDA to Commissioner Margaret Hamburg's data-sharing initiatives); Simon Rowberry, *Digitizing the USPTO Patent Backfile*, 39 DIGIT. SCHOLARSHIP IN HUMANS. 335, 340 (2024) (describing the "long, difficult, history of digitization [of patent data] at the Patent Office").

306. Thomas, *supra* note 119, at 1029–31.

307. Jeneen Interlandi, *Inside the Collapse of the F.D.A.*, N.Y. TIMES (July 8, 2025), https://www.nytimes.com/2025/07/08/magazine/fda-collapse-rfk-kennedy.html (on file with the *Iowa Law Review*).

308. *See* Morten et al., *Researcher Access to Social Media Data*, *supra* note 45, at 169–74 (documenting important but modest success of safety and effectiveness data sharing on ClinicalTrials.gov because of meager enforcement by the FDA); Ramachandran et al., *supra* note 42, at 2131–32 (same).

An advantage of the second, legislative path over the first, regulatory one is that explicit congressional blessing for a second patent bargain will foreclose challenges under the Administrative Procedure Act that the USPTO and FDA have overstepped their statutory authority. However, a patent bargain reached via either path may face a separate legal challenge, under the Takings Clause. I address that concern head-on in the next Part.

IV. DEFENDING THE SECOND PATENT BARGAIN

This Part anticipates and responds to a potential counterargument against the Article's proposed second patent bargain—a counterargument grounded in contemporary constitutional doctrine. The Takings Clause of the U.S. Constitution is a potential barrier to new law mandating disclosure of safety and effectiveness data in exchange for patent term extension. Prominent scholars, including Richard Epstein and Lietzan, have argued that mandatory disclosure of safety and effectiveness data contained in drug applications effects a taking.[309]

Nowhere in the legislative history of the Hatch–Waxman Act is there any suggestion that section 104's mandate of disclosure of safety and effectiveness data could conceivably effect a taking.[310] But, in the decades since, takings challenges to agencies' information disclosure programs have increased—or at least *threats* of takings challenges have.[311] For example, in 2010, when the FDA considered disclosing more summary data from clinical trials of prescription drugs, the largest pharmaceutical industry lobbying group, PhRMA, alleged that "disclosure of trade secrets and confidential commercial information currently in FDA's hands or developed in reliance on the current statutory and regulatory scheme would constitute an

309. *See* Richard A. Epstein, *The Constitutional Protection of Trade Secrets and Patents Under the Biologics Price Competition and Innovation Act of 2009*, 66 FOOD & DRUG L.J. 285, 287, 304–28 (2011) (arguing, inter alia, that the Biologics Price Competition and Innovation Act of 2009, which permits follow–on "biosimilar" manufacturers to rely to some extent on clinical trial data submitted by brand-name companies, may work as an unconstitutional taking unless compensation is paid); Lietzan, *supra* note 153, at 72, 77 (arguing that "forcible disclosure [of trade secrets] constitutes a taking" and suggesting that the FDA should compensate companies whose data is shared with researchers).

310. However, there was substantial debate over whether the Act's separate ANDA provisions, which permit generic companies to "free ride" on safety and effectiveness data previously submitted by brand companies, work a taking. *See* Lourie, *Patent Term Restoration*, *supra* note 111, at 545; Lietzan, *supra* note 112, at 104–05.

311. Morten, *supra* note 169, at 1391. As I write, the FDA is being sued by a drug company for allegedly improperly revealing a different, more stringently protected category of data contained in the company's drug application—certain chemistry, manufacturing, and controls (CMC) information related to impurities, particle size, and dissolution. Vanda Pharms., Inc. v. United States, 169 Fed. Cl. 196, 201 (Fed. Cl. 2024). The case is now on appeal to the Federal Circuit (No. 25-1434).

unconstitutional taking requiring payment of just compensation."[312] FDA retreated.[313] Similarly, in 2016, as the NIH contemplated a rule requiring submission and publication of high-level summary data from clinical trials, the largest medical device industry lobbying group, AdvaMed threatened litigation, alleging that disclosure of this data would work a taking of its members' "trade secret and confidential commercial information."[314]

For these reasons, the Takings Clause is worth taking seriously. But it is not a real barrier to disclosure of safety and effectiveness information.

Note first that takings claims arising specifically from alleged regulatory interference with secret safety and effectiveness data seem more smoke than fire. NIH ultimately promulgated its clinical trial data sharing rule,[315] and neither the medical device nor the pharmaceutical industries sued in the years since. Outside the United States, two drug companies did sue the EMA, in an effort to enjoin that agency's policy of disclosing redacted clinical study reports (of just the sort this Article proposes), on the theory that disclosure would violate their intellectual property interests under European law.[316] The Court of Justice of the European Union ultimately sided with the agency,[317] and EMA's disclosure has continued.[318]

If a company were to bring a claim against the FDA or USPTO for disclosure of safety and effectiveness data, it would likely lose. First, it is not at all clear that the sort of safety and effectiveness data in drug applications that this Article proposes disclosure of even qualifies for the protections of the Takings Clause. The Fifth Amendment's Takings Clause guarantees that "private property" will not "be taken for public use, without just

312. Letter from Jeffrey K. Francer, Assistant Gen. Couns., Pharm. Rsch. & Mfrs. of Am., and Sascha Haverfield-Gross, Deputy Vice President Sci. & Regul. Affs., Pharm. Rsch. & Mfrs. of Am., Draft Proposals for Public Comment Regarding Disclosure Policies of the U.S. Food and Drug Administration (Docket No. FDA-2009-N-0247) (July 20, 2010), https://web.archive.org/web/20201223164140/https://www.regulations.gov/contentStreamer?documentId=FDA-2009-N-0247-0252&attachmentNumber=1&contentType=pdf [https://perma.cc/2JFK-UBPR]; *accord* TRANSPARENCY TASK FORCE, FDA, U.S. DEP'T OF HEALTH & HUM. SERVS., FDA TRANSPARENCY INITIATIVE: DRAFT PROPOSALS FOR PUBLIC COMMENT REGARDING DISCLOSURE POLICIES OF THE U.S. FOOD AND DRUG ADMINISTRATION 4–8 (2010), https://web.archive.org/web/20201016234033/http://www.lb7.uscourts.gov/documents/02c51292.pdf [https://perma.cc/7RPY-SAPL].

313. *See* Tai, *supra* note 157, at 434.

314. Erin Durkin, *Califf, Biden Task Force Tout NIH Rule Requiring Failed Trial Data Be Posted*, INSIDEHEALTHPOLICY.COM'S FDA WEEK, Oct. 21, 2016, at 1, 11.

315. 42 C.F.R. pt. 11 (2024).

316. Ed Silverman, *European Regulators Appeal Rulings that Prevent Release of Drug Data*, STAT NEWS (Sept. 29, 2016), https://www.statnews.com/pharmalot/2016/09/29/europe-appeals-drug-data-release (on file with the *Iowa Law Review*).

317. Case C-175/18, PTC Therapeutics Int'l v. Eur. Meds. Agency, ECLI:EU:C:2020:23, ¶ 64 (Jan. 22, 2020) (describing the very limited redactions); *see also id.* at ¶¶ 82, 91, 97 (rejecting the challenge to the release of clinical trial documents, concluding that the agency had broad discretion to release data, and that the company had not made a specific showing that the release would undermine its legitimate interests).

318. *See Clinical Data*, *supra* note 257.

compensation."[319] Not all rights and interests constitute protected "private property" eligible for protection under the Takings Clause;[320] while the Supreme Court and circuits have held some intangible assets—e.g., certain liens, contracts, and trade secrets—to be "private property" eligible for protection under the Takings Clause,[321] they have held that other intangible assets—e.g., federal welfare benefits—are not.[322] The Federal Circuit recently observed that the question of whether patents themselves constitute "private property" eligible for protection under the Takings Clause is an open one.[323]

The Court has never articulated a precise test to determine whether a given intangible asset qualifies as private property eligible for the Takings Clause's protection. However, its *Ruckelshaus v. Monsanto* decision identified a dispositive feature of trade secrets that make them protectable under the Takings Clause: State law treats them like property.[324] The same portions of *Monsanto* suggest that private secrets that do *not* meet the relevant state law definition of a trade secret are ineligible for protection under the Takings Clause and can be disclosed without troubling the Clause.[325] FOIA confirms this: For decades, federal agencies have disclosed information that meets the broader definition of "confidential commercial information" protected by FOIA exemption 4 but not the definition of a trade secret, without effecting a taking.[326]

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319. U.S. CONST. amend. V.

320. *See, e.g.*, Air Pegasus of D.C., Inc. v. United States, 424 F.3d 1206, 1212 (Fed. Cir. 2005) ("[A]s a threshold matter, the court must determine whether the claimant has established a property interest for purposes of the Fifth Amendment.").

321. Ruckelshaus v. Monsanto, 467 U.S. 986, 1003 (1984).

322. Bowen v. Gilliard, 483 U.S. 587, 604–05 (1987).

323. *See* Golden v. United States, 955 F.3d 981, 989 n.7 (Fed. Cir. 2020) ("Despite the Claims Court's express finding on the status of patent rights under the Fifth Amendment, we decline to address that question here.").

324. *See Monsanto*, 467 U.S. at 1001 ("Monsanto asserts that the health, safety, and environmental data it has submitted to EPA are property under Missouri law, which recognizes trade secrets, as defined in § 757, Comment *b*, of the Restatement of Torts, as property."); *id.* at 1003 ("That intangible property rights protected by state law are deserving of the protection of the Taking Clause has long been implicit in the thinking of this Court.").

325. *See* Pamela Samuelson, *Principles for Resolving Conflicts Between Trade Secrets and the First Amendment*, 58 HASTINGS L.J. 777, 809 (2007) ("While proponents of the trade-secrets-as-property conception tend to invoke *Ruckelshaus* [*v. Monsanto*] as supporting the property concept, a fuller review of the Court's ruling demonstrates that trade secret interests are balanced against other societal interests, and sometimes the larger societal interests override trade secret interests.").

326. *See, e.g.*, § 305.82-1 Exemption (b)(4) of the Freedom of Information Act (Recommendation No. 82-1), 47 Fed. Reg. 30702, 30703 (July 15, 1982) ("Agencies currently have discretion, subject to the limitations of the Trade Secrets Act (18 U.S.C. 1905), to release a submitter's exempt (b)(4) information, even though disclosure might cause damage to the submitter."); Food Mktg. Inst. v. Argus Leader Media, 139 S. Ct. 2356, 2362 (2019) (observing that FOIA's Exemption 4 provided the USDA with "*discretion* to withhold the requested data" and that USDA might "might just as easily choose to provide the data anyway," even if the exemption applies).

Recall that clinical study reports and other summary data from clinical trials are, in the view of the EMA, NIH, and other authorities, simply not trade secrets.[327] Disclosure of non-trade-secret information cannot violate the Takings Clause. Recall further that, under the second patent bargain proposed by this Article, affected companies would be permitted to redact any genuine trade secrets scattered among their safety and effectiveness data, such as innovative assays for biomarkers.[328] Thus the proposed patent bargain avoids offending the Takings Clause by avoiding disturbing any information eligible for its protection.

What if a court disagreed and concluded that safety and effectiveness data is, in fact, a trade secret eligible for the Takings Clause's protection? There is still no taking, so long as the FDA and USPTO take a single, simple step: They make no promise of ongoing confidentiality when they obtain the secret. *Monsanto* expressly held that agency disclosure of information obtained from a regulated entity can constitute a taking if and only if the agency provided an assurance of ongoing secrecy.[329] If no assurance of secrecy, disclosure effects no taking even if the information is a bona fide trade secret. That makes the takings analysis easy for a forward-looking second patent bargain: Takings liability can be averted simply by refraining from any assurances of secrecy. If and when the FDA and USPTO promulgate

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327. *See supra* Section III.A.

328. *See supra* Section III.A.

329. As the Court stated in *Monsanto*,

> [T]he statute . . . gave Monsanto explicit assurance that EPA was prohibited from disclosing publicly . . . any data submitted by an applicant if both the applicant and EPA determined the data to constitute trade secrets. Thus, . . . the Federal Government had explicitly guaranteed . . . an extensive measure of confidentiality and exclusive use. This explicit governmental guarantee formed the basis of a reasonable investment-backed expectation.

Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1011 (1984) (citation omitted); *see also id.* at 1007 ("[A]s long as Monsanto is aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate Government interest, a voluntary submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking."); Love Terminal Partners, L.P. v. United States, 889 F.3d 1331, 1345 (Fed. Cir. 2018) ("In *Ruckelshaus* [*v. Monsanto*], . . . the Supreme Court concluded that plaintiffs only had a reasonable expectation in the confidentiality of trade secrets disclosed to the EPA in pesticide registration applications to the extent that the relevant statute explicitly guaranteed confidentiality at the time of submission."); Elizabeth A. Rowe, *Striking a Balance: When Should Trade-Secret Law Shield Disclosures to the Government*, 96 IOWA L. REV. 791, 802 (2011) ("*Monsanto* is . . . a mixed bag for trade-secret owners . . . . There is a real risk that when a company submits business information to an agency and it falls into the hands of a competitor, a court could find there was no promise of confidentiality, and thus no taking."). In this regard, the takings analysis for corporate secrets and other secret information dovetails with broader regulatory takings doctrine, which focuses on "the character of the governmental action, its economic impact, and its interference with reasonable investment-backed expectations." PruneYard Shopping Ctr. v. Robins, 447 U.S. 74, 83 (1980). If the submitter of confidential information to the government receives no assurance of continuing secrecy, then it has no "reasonable investment-backed expectation" of the same. *Id.*

new rules to implement the second patent bargain, they should provide clear notice that portions of any new submission of safety and effectiveness data may be disclosed to the world upon grant of patent term extension connected to that submission.

The plain text of section 104 of the Hatch–Waxman Act[330] further undermines any industry argument that disclosure of safety and effectiveness data is unexpected; while the FDA has, as a matter of agency rule and practice, kept the vast majority of safety and effectiveness data secret since 1984, those rules and practices have arguably been inconsistent with section 104's plain text.[331] Secrecy has been living on borrowed time.

Could public disclosure of safety and effectiveness data in exchange for patent term extension impose an unconstitutional condition on drug and device companies?[332] In *Monsanto*, the Supreme Court held that when a regulatory mandate of information disclosure comes with a commensurate benefit, the regulatory "condition" is constitutional.[333] *Monsanto* declared (quoting Justice Brandeis) that such impositions on regulated entities "are the burdens we all must bear in exchange for the advantage of living and doing business in a civilized community."[334] *Monsanto*'s holding that regulators may condition regulatory benefits on mandatory disclosure of information

330. *See supra* Section II.A.

331. *See supra* Section II.A; *see also* Eisenberg, *supra* note 105, at 477–81.

332. *See, e.g.*, Epstein, *supra* note 309, at 304–13.

333. *See Monsanto*, 467 U.S. at 1007 ("[A] voluntary submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking.").

334. *Id.* (internal quotation marks and citations omitted); *see also* Corn Prods. Refin. Co. v. Eddy, 249 U.S. 427, 431 (1919) ("[A] manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold.").

remains good law.[335] Patent term extension is enormously valuable—typically worth millions or billions of dollars[336]—making this analysis easy.

CONCLUSION

This Article has argued for a second patent bargain, a new quid of disclosure in exchange for the quo of patent term extension. Patent term extension provides the American public with a golden opportunity to demand rich, detailed, late-stage, post-filing information on how to use, learn from, and otherwise benefit from the patented invention. As to patented drugs, vaccines, and medical devices that benefit from patent term extension, I've argued here that this information is already sitting in the FDA's files and could be made public practically and legally. To disclose this information would improve health care, accelerate science, help to hold both industry and the FDA accountable, and help inform patients and the broader public of the true value of patented medical products, without significantly disturbing the existing incentive structure for the companies that invent and develop these products.

In future work, I intend to expand on the theory that patent law can and should not only incentivize new inventions but also disseminate information on the *value* of those inventions, and to work through more potential applications of this theory. Consider, for example, whether the

335. This portion of *Monsanto* was reaffirmed in *Nollan v. California Coastal Commission*, 483 U.S. 825, 833 n.2 (1987) (holding that, in *Monsanto*, "we found merely that the Takings Clause was not violated by giving effect to the Government's announcement that application for '*the right to [the] valuable Government benefit*,' . . . of obtaining registration of an insecticide would confer upon the Government a license to use and disclose the trade secrets contained in the application." (citation omitted)). *Monsanto* was again cited as good law in the Court's conservative-led 2015 and 2019 takings decisions in *Horne* and *Knick*. *See* Horne v. Dep't of Agric., 576 U.S. 350, 365–66 (2015) (characterizing the regulations in *Monsanto* as creating a voluntary exchange of benefits); Knick v. Twp. of Scott, 139 S. Ct. 2162, 2173 (2019) (upholding language in *Monsanto*); *cf.* Cedar Point Nursery v. Hassid, 141 S. Ct. 2063, 2079 (2021) ("[T]he government may require property owners to cede a right of access as a condition of receiving certain benefits, without causing a taking. . . . When the government conditions the grant of a benefit such as a permit, license, or registration on allowing access for reasonable health and safety inspections, both the nexus and rough proportionality requirements of the constitutional conditions framework should not be difficult to satisfy."). There is an errant First Circuit decision from the early 2000s that declined to follow *Monsanto* faithfully: *Philip Morris, Inc. v. Reilly*, 312 F.3d 24, 47 & n.21 (1st Cir. 2002) (en banc) (concluding that a Massachusetts disclosure law imposed an unconstitutional condition, declining to follow *Monsanto*, and electing instead to apply the reasoning of a later Supreme Court decision, *Nollan*, 483 U.S. at 833 n.2). Even this errant decision acknowledged that disclosure of a trade secret to serve a significant state interest is constitutional when the disclosure is tethered to a substantial benefit. *Id.* at 44 (noting that Massachusetts' interest in promoting the health of its citizens could have been compelling enough to alter the court's holding, but nevertheless finding a taking because the regulation was not sufficiently tailored to achieve this interest); *id.* at 47 ("[A]s part of a regulatory scheme which confers some government benefit upon a manufacturer, *Monsanto* establishes that the government may require that manufacturer to relinquish its rights to a trade secret.").

336. *See supra* Introduction.

obligatory payment of maintenance fees at regular intervals after patent issuance—required to keep U.S. patents in force[337]—could be coupled with an obligation on the part of the patent owner to update the USPTO with post-filing information in the owner's possession on the safety, effectiveness, and other properties of the patented invention.[338] Consider also whether putting patent law in conversation with other fields of federal technology regulation, such as telecommunications, automotive, and aerospace, could yield other fruitful informational bargains. Moments in the lives of patents on internet technologies, self-driving cars, and passenger jets could perhaps act as triggers for disclosure of information on these products validated and held by the Federal Communications Commission, the National Highway Traffic Safety Administration, and the Federal Aviation Administration. New bargains could break logjams of corporate secrecy and rededicate the patent system to the production and dissemination of information that benefits the public.

337. 35 U.S.C. § 41(b).

338. Thomas recently suggested coupling the event of the payment of maintenance fees with a disclosure requirement. *See* Thomas, *supra* note 12, at 346. He suggests discounting maintenance fees for patent owners who notify the public of specific commercial products and services that embody their patents—i.e., "mark" their products. *See id.*