

CANCER'S IP*

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The state of publicly funded science is in peril. Instead, new biomedical research efforts—in particular, the recent funding of a “Cancer Moonshot”—have focused on employing public-private partnerships, joint ventures between private industry and public agencies, as being more politically palatable. Yet, public-private partnerships like the Cancer Moonshot center on the production of public goods: scientific information. Using private incentives in this context presents numerous puzzles for both intellectual property law and information policy. This Article examines whether—and to what extent—intellectual property and information policy can be appropriately tailored to the goals of public-private partnerships. It shows that the success of the Cancer Moonshot, and other similar public-private partnerships, turns on data-sharing—the production, disclosure, and ultimate use of data. Consequently, encouraging private participation in data-sharing will likely require some form of patents, trade secrets, and regulatory exclusivities, appropriately limited to further the program’s public aims. The Article concludes by using the Cancer Moonshot to draw broader lessons about this new turn in research funding, public-private partnerships

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generally, and considerations of data privacy, scientific reproducibility, and transaction costs.

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“The only bipartisan thing left in America is the fight against cancer.”

—Former Vice President Joe Biden¹

INTRODUCTION

In a time of unprecedented political polarization around scientific research and funding, both sides seem to readily agree on one thing: curing cancer. In December 2016, former President Obama, for the last major bill-signing of his presidency, signed into law the 21st Century Cures Act² with “overwhelming bipartisan support,” the most significant overhaul of the U.S. Food and Drug Administration (“FDA”) in decades.³ The Act included \$1.8 billion of federal funding towards a remarkable new initiative: a “moonshot” to cure cancer.⁴ As currently structured, the Moonshot is a wide-ranging effort empowered to “mak[e] the most of Federal investments, targeted incentives, private sector efforts from industry and philanthropy, patient engagement initiatives, and other mechanisms to support cancer research and enable progress in treatment and care.”⁵ But unlike other government research programs—like the Moonshot’s namesake effort to put a man on the moon in 1969—“curing” cancer has no clear endpoint.⁶ Rather, the core of the Cancer Moonshot’s engine produces *information* about the disease to

1. Rick Berke, *Joe Biden Urges SXSW Crowd to Put Innovation to Work to Cure Cancer*, STAT (Mar. 12, 2017), <https://www.statnews.com/2017/03/12/joe-biden-cancer-moonshot-sxsw/> [<https://perma.cc/Z9R4-7WSX>].

2. 21st Century Cures Act, Pub. L. No. 144-255, 130 Stat. 1033 (2016).

3. Jeannie Baumann, *Obama Signs Bill to Speed Medical Breakthroughs, Boost NIH Funding*, BLOOMBERG BNA (Dec. 13, 2016), <https://www.bna.com/obama-signs-bill-n73014448613/> [<https://perma.cc/NK7W-4LS4>]; Adam Gaffney, *Congress Just Quietly Handed Drug Companies a Dangerous Victory*, NEW REPUBLIC (Dec. 14, 2016), <https://newrepublic.com/article/139328/congress-just-quietly-handed-drug-companies-dangerous-victory> [<https://perma.cc/SA2W-LVEJ>] (comparing the Act to the FDA’s 1962 Kefauver-Harris Amendments).

4. 21st Century Cures Act § 1001(b)(2)(A), 130; *Obama Signs 21st Century Cures Act into Law*, STAT (Dec. 13, 2016), <https://www.statnews.com/2016/12/13/21st-century-cures-obama-signs/> [<https://perma.cc/SHB6-85N2>]; see also Address Before a Joint Session of the Congress on the State of the Union, 2016 DAILY COMP. PRES. DOC. 12 (Jan. 12, 2016).

5. Memorandum on the White House Cancer Moonshot Task Force, 2016 DAILY COMP. PRES. DOC. 24 (Jan. 28, 2016) [hereinafter Memorandum].

6. See Jarle Breivik, *We Won’t Cure Cancer*, N.Y. TIMES, May 27, 2016, at A21 (“Every time we cure a person of cancer, we produce a person with an increased probability of getting cancer again. It is the Catch-22 of oncology. If this is such a basic fact, why are we still talking about moonshots?”).

“use the power of *data* to generate real solutions for treating cancer.”⁷ To achieve this, the Cancer Moonshot will be structured as a series of public-private partnerships; joint efforts between private industry and public agencies to achieve public goals.⁸

In economic terms, the Moonshot’s goal of collaboration between the public and private sectors seeks to produce a public good: scientific information.⁹ And like all truly public goods, scientific information lacks two of the core elements of property, excludability and rivalrousness.¹⁰ Unless they keep such information secret, researchers cannot exclude others from making use of their findings and the use of scientific information by one researcher does not rival another’s ability to make use of the same. The Moonshot’s call to develop cancer information, therefore, presents numerous puzzles for both intellectual property law and information policy. What incentives can be deployed to encourage private participation? What form of intellectual property, if any, is appropriate for producing scientific information? How should the information generated from such a project be standardized? Who will be responsible for safeguarding sensitive health information derived from a public-private partnership? Using cancer research as an emblem of the difficulties in encouraging the private production of scientific

7. Greg Simon, *The Cancer Moonshot: Achieving Lift Off*, MEDIUM (May 24, 2016), <https://medium.com/cancer-moonshot/the-cancer-moonshot-achieving-lift-off-aa22a1b37c43#.9rn90d3mc> [<https://perma.cc/VTF8-NPFQ>] (emphasis added).

8. See Martha Minow, *Public and Private Partnerships: Accounting for the New Religion*, 116 HARV. L. REV. 1229, 1237 (2003) (discussing the aims of public-private partnerships); *FACT SHEET: At Cancer Moonshot Summit, Vice President Biden Announces New Actions to Accelerate Progress Toward Ending Cancer As We Know It*, WHITE HOUSE (June 28, 2016), <https://obamawhitehouse.archives.gov/the-press-office/2016/06/28/fact-sheet-cancer-moonshot-summit-vice-president-biden-announces-new> [<https://perma.cc/KD35-XFWG>]; see also Press Release, Nat’l Cancer Inst., New Drug Formulary Will Help Expedite Use of Agents in Clinical Trials (Jan. 11, 2017), <https://www.cancer.gov/news-events/press-releases/2017/nci-formulary-launch> [<https://perma.cc/N39J-Z3XZ>].

9. See Paul M. Romer, *Endogenous Technological Change*, 98 J. POL. ECON. S71, S74 (1990) (“By definition, public goods are both nonrival and nonexcludable. Because they are nonexcludable, they cannot be privately provided or traded in markets. Public goods can be introduced into a model of price-taking behavior by assuming the existence of a government that can levy taxes. Basic scientific research is an example of a public good that could be provided in this way and that is relevant for modeling growth.”).

10. Jorge L. Contreras, *Constructing the Genome Commons*, in GOVERNING KNOWLEDGE COMMONS 99 (Brett M. Frischmann, Michael J. Madison & Katherine J. Strandburg eds., 2014) (defining a “public good,” like the sequence of the human genome, as “a resource provisioned by the state that is susceptible to neither exclusion nor depletion by use”); Romer, *supra* note 9, at S74.

information, this Article answers these questions through a synthesis of intellectual property and information policy—here, cancer's IP.¹¹

Cancer's special salience to information policy derives, in part, from its vast complexity, a “colossal diversity” of typology, genetics, environmental factors, and idiosyncrasies.¹² Since the turn of this century—when genetic sequencing became a routine and mature technology¹³—cancer researchers have recognized the disease as “complex almost beyond measure.”¹⁴ As a consequence, “cancer research has seen an increasing trend towards high-throughput techniques and translational approaches”¹⁵—that is, a move from traditional laboratory and clinical practices into the realm of “big data.”¹⁶ This signals an epochal shift in cancer research, a field

11. To be certain, numerous other incentive regimes may come to bear on the success of the Cancer Moonshot, including drug-price rebate programs, demand-side treatment innovation, and R&D tax credits. *See generally* Rebecca S. Eisenberg & W. Nicholson Price II, *Promoting Healthcare Innovation on the Demand Side*, 4 J.L. & BIOSCIENCES 3 (2017) (examining promotion of innovation by health insurers); Daniel Jacob Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303 (2013) (discussing R&D tax credits); Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J.L. & TECH. 153 (2016) (discussing rebates). But these are, simply, not the focus of this Article. Instead, this Article's aim is limited to unpacking, and hopefully resolving, the immediate complexities governing currently existent incentive regimes—e.g., intellectual property—on the Cancer Moonshot and other public-private partnerships.

12. *See* SIDDHARTHA MUKHERJEE, *THE EMPEROR OF ALL MALADIES: A BIOGRAPHY OF CANCER* 173 (Schribner ed. 2010) (“[C]ancer, a shape-shifting disease of colossal diversity, [has been] recast as a single, monolithic entity.”).

13. *See* Elaine R. Mardis, *The Impact of Next-Generation Sequencing Technology on Genetics*, 24 TRENDS IN GENETICS 133, 133 (2008) (“[S]equencing of DNA has undergone a steady metamorphosis from a cottage industry into a large-scale production enterprise that requires a specialized and devoted infrastructure of robotics, bioinformatics, computer databases and instrumentation.”); Michael L. Metzker, *Sequencing Technologies—The Next Generation*, 11 NATURE REV. GENETICS 31, 31 (2010) (“The major advance offered by [Next Generation Sequencing technology] is the ability to produce an enormous volume of data cheaply This feature expands the realm of experimentation beyond just determining the order of bases”); Erwin van Dijk et al., *Ten Years of Next-Generation Sequencing Technology*, 30 TRENDS IN GENETICS 418, 418–19 (2014) (describing the evolution of genetic sequencing techniques).

14. Douglas Hanahan & Robert A. Weinberg, *The Hallmarks of Cancer*, 100 CELL 57, 57 (2000).

15. Aisyah Mohd Noor et al., *Big Data: The Challenge for Small Research Groups in the Era of Cancer Genomics*, 113 BRIT. J. CANCER 1405, 1405 (2015).

16. *See, e.g.*, The International Cancer Genome Consortium, *International Network of Cancer Genome Projects*, 464 NATURE 993, 993 (2010) (predicting the benefits of cancer research using large datasets); Peng Jiang & X. Shirley Liu, *Big Data Mining Yields Novel Insights on Cancer*, 47 NATURE GENETICS 103, 103 (2015) (reviewing several big data approaches to cancer research); Joseph R. Nevins, *New Breast Cancer Genes—Discovery at the Intersection of Complex Data Sets*, 12 CANCER CELL 497, 497 (2007) (describing the role of big data in uncovering breast cancer risk genes); Noor et al., *supra* note 15, at 1405 (discussing big data and cancer research).

previously known better for its trial-and-error approach to clinical research than any greater understanding of the disease.¹⁷ By contrast, the object of much current cancer research is not the immediate development of treatments but the creation of “complex data sets . . . coupled with powerful analytical methods to extract a level of detail . . . not achievable with the once powerful methods of molecular biology.”¹⁸ Current cancer research, therefore, centers less on producing therapeutic innovations—new drugs, medical devices, and other tangible things used to treat cancer—and more on *information*.¹⁹

Understanding cancer as information exposes a number of challenges for encouraging private investment in research, especially investment structured within public-private partnerships. Traditional intellectual property protections seem ill-suited to support investment in projects like the Cancer Moonshot. Patents, for example, do not protect claims to scientific information—an increasingly powerful stricture after a series of recent Supreme Court cases concerning patent eligibility.²⁰ Where patents do cover the fruits of cancer research, patent law requires such discoveries to be disclosed before they can be appropriately verified, contributing to a burgeoning problem of scientific irreproducibility.²¹ And patents’ short term

17. See MUKHERJEE, *supra* note 12, at 206 (describing the research strategy of the National Cancer Institute in the 1970s as “empirical—throwing chemicals at cancer cells in test tubes to identify cancer killers The biology of cancer was still poorly understood. But the notion that even relatively indiscriminate cytotoxic agents discovered largely by accident would cure cancer had captivated oncology”).

18. Nevins, *supra* note 16, at 497.

19. See, e.g., Jennifer Abbasi, *NCI Launches Cancer Patient Data Repository*, 316 JAMA 384, 384 (2016) (announcing the National Cancer Institute’s plans to house a “genomic data commons”); John Z. Ayanian et al., *Understanding Cancer Treatment and Outcomes: The Cancer Care Outcomes Research and Surveillance Consortium*, 22 J. CLINICAL ONCOLOGY 2992, 2992 (2004) (announcing canCORS, a cancer dataset comprising “a new model for studying cancer care: a large, distributed, multidisciplinary team of investigators collecting shared data”); S. Bamford et al., *The COSMIC (Catalogue of Somatic Mutations in Cancer) Database and Website*, 91 BRIT. J. CANCER 355, 355 (2004) (announcing COSMIC, a database then containing “a comprehensive view of all previously reported somatic mutations in cancer”); Joel Saltz et al., *caGrid: Design and Implementation of the Core Architecture of the Cancer Biomedical Informatics Grid*, 22 BIOINFORMATICS 1910, 1910 (2006) (“The complexity of cancer is prompting researchers to find new ways to synthesize information from diverse data sources and to carry out coordinated research efforts that span multiple institutions.”).

20. *Alice Corp. Pty. v. CLS Bank Int’l*, 134 S. Ct. 2347 (2014); *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 566 U.S. 902 (2013); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 561 U.S. 1040 (2012); *Bilski v. Kappos*, 561 U.S. 593 (2010).

21. See generally Jacob S. Sherkow, *Patent Law’s Reproducibility Paradox*, 66 DUKE L.J. 845, 848 (2017) (examining how “the availability of patents for the products of clinical research appears to hamper or even actively dissuade reproducibility”).

length, relative to the lengths and costs of clinical trials, skews research incentives toward later-stage—and less scientifically valuable—cancer research.²² Other forms of intellectual property currently suffer from similar deficiencies. Trade secrets fail to guard—and therefore, fails to encourage the production of—basic information about cancer.²³ But where they do operate, they raise significant public health and policy concerns.²⁴ And regulatory exclusivities—such as FDA warrants for shelters from market competition—protect only fully developed products, not the underlying scientific information about how such products work.²⁵

22. See Eric Budish, Benjamin N. Roin & Heidi Williams, *Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials*, 105 AM. ECON. REV. 2044, 2045–46 (2015) (assessing how patent terms skew the lengths of clinical trials).

23. See Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 194 (1987) (“Once [a trade secret] becomes generally known to other scientists through independent discovery, the first discoverer loses protection.”); J.H. Reichman & Pamela Samuelson, *Intellectual Property Rights in Data?*, 50 VAND. L. REV. 51, 60 (1997) (explaining that reverse-engineered scientific information fits poorly within trade secret law as it “provide[s] innovators and investors with no exclusive property rights”); David A. Rice, *Public Goods, Private Contract and Public Policy: Federal Preemption of Software License Prohibitions Against Reverse Engineering*, 53 U. PITT. L. REV. 543, 557 (1992) (“Other advances in science and technology may gain more limited protection, but cannot be wholly withdrawn from the public domain as a matter of proprietary right. Trade secrets, for example, are not protected against independent discovery or against being ascertained with the aid of reverse engineering.”).

24. See John M. Conley, Robert Cook-Deegan & Gabriel Lázaro-Muñoz, *Myriad After Myriad: The Proprietary Data Dilemma*, 15 N.C. J.L. & TECH. 597, 600 (2014) (“Whether clinical data should be protected as trade secrets, despite the fact that access to this information can have important health consequences for individual patients, is a profound ethical and legal dilemma.”); Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL’Y L. & ETHICS 717, 720 (2005) (“[T]rade secrecy greatly compromises the social value of the information as a resource for improving public health and for promoting further R&D.”); W. Nicholson Price II, *Black-Box Medicine*, 28 HARV. J.L. & TECH. 419, 434 (2015) (“[A] machine-learning algorithm can examine data, determine a relationship, and state it, but the underlying biological relationship is too complex to be amenable to scientific understanding or clinical trials.”); John T. Wilbanks & Eric J. Topol, *Stop the Privatization of Health Data*, 535 NATURE 345, 346–47 (2016) (discussing some of the problems with privatizing health data).

25. See W. Nicholson Price II, *Big Data, Patents, and the Future of Medicine*, 37 CARDOZO L. REV. 1401, 1447–48 (2016) (limiting the “advantage[s] to regulatory exclusivity comes only if exclusivity is coupled with a disclosure requirement”); W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491, 556 (2014) (discussing “significant concerns with product-based regulatory exclusivity, centered on appropriately valuing the innovation”); W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1023 (2016) (arguing that regulatory exclusivities, in some instances, “undermine[] efforts to advance fundamental knowledge about how biologics function and are best produced”); John R. Thomas, *The End of “Patent Medicines”? Thoughts on the Rise of Regulatory Exclusivities*, 70 FOOD & DRUG L.J. 39,

These difficulties suggest a serious misalignment between current IP structures and the objective of information-seeking public-private partnerships: efficiently “creat[ing] and disseminat[ing] knowledge, [including the] optimization of publishing data and results.”²⁶ Without sufficient private incentives to participate in knowledge creation, such partnerships will almost certainly fail.²⁷ But with *inappropriate* private incentives—incentives that privatize too much knowledge or disclose too little—public-private partnerships similarly fail to uphold their bargain to the public.²⁸ The success of public-private partnerships, like the Cancer Moonshot, therefore rest, at least in part, on aligning some form of private rights with the greater public good.

For the Cancer Moonshot specifically, this means data-sharing—or in Former Vice President Biden’s words, “breaking down some of the research that is trapped inside of silos, . . . shar[ing] information with drug companies, and drug companies being willing to be more forthcoming in sharing information.”²⁹ This is easier said than done. Current data-sharing efforts suffer from licensing thicket, a lack of interoperability, and strictures from grant-making agencies.³⁰ There

43 (2015) (“FDA-administered regulatory exclusivities are of commensurate scope with the drugs they approve.”); *see also* Yaniv Heled, *Regulatory Competitive Shelters in the Area of Personalized Medicine*, 21 B.U. J. SCI. & TECH. L. 287, 287 n.3 (2015) (describing FDA-awarded exclusivities as “regulatory competitive shelters” as “competitive advantages resulting from statutory bars on regulatory action”).

26. Constance E. Bagley & Christina D. Tvarnø, *Pharmaceutical Public-Private Partnerships: Moving from the Bench to the Bedside*, 4 HARV. BUS. L. REV. 373, 384 (2014); *see also* Liza S. Vertinsky, *Patents, Partnerships, and the Pre-Competitive Collaboration Myth in Pharmaceutical Innovation*, 48 U.C. DAVIS L. REV. 1509, 1531–37 (2015) (enumerating what public-private partnerships offer to the public).

27. *See* Vertinsky, *supra* note 26, at 1517 (“[Policymakers] need to find ways of mitigating the negative effects of market incentives on cooperation without removing market incentives altogether from this process. This requires strategies for confronting and reducing the tensions between private and public incentives to create and share knowledge.”).

28. *See id.* at 1516 (describing policymakers as “[w]ary of the challenges that patents and other market-based incentives can create for public-private partnerships”).

29. David A. Graham, *What Is the Point of Joe Biden’s Cancer ‘Moonshot’?*, ATLANTIC (Feb. 11, 2016), <http://www.theatlantic.com/politics/archive/2016/02/biden-cancer-moonshot-duke/462288/> [<https://perma.cc/CU5F-22BH>].

30. *See, e.g.*, Final NIH Genomic Data Sharing Policy, 79 Fed. Reg. 51,345, 51,348 (Aug. 28, 2014) (describing restrictions on disclosing genetic data for health privacy reasons); Ryan Abbott, *The Sentinel Initiative as a Cultural Commons*, in GOVERNING MEDICAL RESEARCH COMMONS 121 (Katherine J. Strandburg et al. eds., Cambridge University Press 2017) (discussing barriers to data sharing in the pharmaceutical and biotech contexts); Simon Oxenham, *Legal Maze Threatens to Slow Data Science*, 536 NATURE 16, 16–17 (2016) (describing the data licensing difficulties of Hetionet, a metadata set of “drugs, genes and diseases”); Victoria Stodden, *Reproducing Statistical Results*, 2 ANN. REV. STAT. & APPLICATION 1, 14 (2015) (“Evolving community standards and peer review cannot be relied upon to solve all dissemination issues, as some, such as

likely exists no elegant solution to resolving all of these issues while maintaining fidelity to the purpose—and success—of public-private partnerships. But breaking down broader mandates for data-sharing into discrete components—namely, the production of cancer data, the disclosure of cancer data, and the use of cancer data to generate new therapies—may prove more manageable. Compartmentalizing data-sharing this way provides policy makers the flexibility to appropriately tailor intellectual property and information policy incentives for the Cancer Moonshot, as well as other public-private partnerships.

Part I of this Article describes cancer's informational complexity, including the costs of developing such information and recent efforts to employ public-private partnerships in uncovering it. Part II then examines one of the broader difficulties in structuring public-private partnerships to tackle informational problems like cancer—namely, the misalignment between intellectual property incentives and data production. It shows that patents likely fail to cover the most important advances in the field or, oppositely, encourage only the disclosure of thin, short-term data. It also discusses the impropriety of levying trade secrets for public goods and the ineffectiveness of regulatory exclusivities for basic, robust data about scientific phenomena. Part III then attempts to align these disparate regimes. It counsels the recognition of projects like the Cancer Moonshot as grand data-sharing efforts. And it compartmentalizes their tasks as the production, disclosure, and use of the information they generate—each of which can be separately encouraged by relatively inexpensive alterations to the intellectual property and information policy regimes. Lastly, Part III uses this analysis to draw greater conclusions about some of the difficulties facing information-seeking public-private partnerships.

I. CANCER'S INFORMATION

A. *Cancer's Informational Complexity*

Cancer is a complex disease, “complex almost beyond measure.”³¹ Indeed, what we call “cancer” is, in actuality, a multitude

licensing for code and data, require coordinated action to ensure that goals such as interoperability are met.”)

31. Hanahan & Weinberg, *supra* note 14, at 57.

of hundreds of separate diseases with no single etiological source.³² The link—perhaps the only link—shared by this collection of diseases is unchecked cellular growth: the tumor or neoplasm.³³ For better or for worse, “cancer, a shape-shifting disease of colossal diversity [has been] recast as a single, monolithic entity.”³⁴

Traditional cancer research—if it may be called that—was therefore mostly superficial. Throughout the nineteenth and twentieth centuries, physicians principally categorized tumors simply by which organ they grew on—and little else. In 1848, the development of various cellular stains and the microtome—a precision instrument for cutting slices of paraffin-fixed tissue—rapidly increased our understanding of tissue systems and gave rise to better descriptions of various tumors.³⁵ But these advances did little to elucidate cancer’s cause. Even as late as the 1960s, clinicians had little understanding of what, molecularly, cancer *was* or how tumors originated.³⁶

By contrast, understanding cancer today is an effort to understand its cause: how normal cellular growth and division—a tightly regulated process with numerous safety checkpoints—can explode in a voracious malignancy.³⁷ And within cancer’s multitude,

32. See MEL GREAVES, *CANCER: THE EVOLUTIONARY LEGACY* 3 (2000) (“The illness we call cancer has extraordinarily diverse features including its causation, underlying pathology, clinical symptoms, therapeutic response, and outcome or chance of cure.”); MUKHERJEE, *supra* note 12, at 155 (“[One patient’s] lymphoma and [another’s] pancreatic cancer were both, of course ‘cancers,’ malignant proliferations of cells. But the diseases could not have been further apart in their trajectories and personalities. Even referring to them by the same name, *cancer*, felt like some sort of medical anachronism”); MUKHERJEE, *supra* note 12, at 332 (“Cancer is, in truth, a variety of diseases.”) (quoting Barnett S. Kramer & Richard D. Klausner, *Grappling With Cancer—Defeatism Versus The Reality of Progress*, 337 *NEW ENG. J. MED.* 931, 932–33 (1997))).

33. See MUKHERJEE, *supra* note 12, at 15–16 (“[T]he quintessential disease of pathological hyperplasia—cancer [Rudolf] Virchow called it *neoplasia*—novel, inexplicable, distorted growth”).

34. *Id.* at 173.

35. Erwin H. Ackerknecht, *Historical Notes on Cancer*, 2 *MED. HIST.* 114, 116 (1958) (“Oncology made a tremendous step forward through the flourishing of pathological anatomy, especially in France, at the beginning of the nineteenth century and the shift from the mere study of organ changes to that of the tissues composing the organs.”); Giuseppe Musumeci, *Past, Present and Future: Overview on Histology and Histopathology*, 1 *J. HISTOLOGY & HISTOPATHOLOGY* 1, 1 (2014) (discussing the invention of the microtome).

36. MUKHERJEE, *supra* note 12, at 155.

37. Michael B. Kastan & Jiri Bartek, *Cell-Cycle Checkpoints and Cancer*, 432 *NATURE* 316, 320 (2004) (“As the checkpoint and repair pathways facilitate cellular responses to DNA damage . . . it is reasonable to speculate that alterations in these pathways increase the risk of cancer developing.”); see also Hanahan & Weinberg, *supra* note 14, at 66 (describing cellular order as “guaranteed by . . . watchmen, manning so-

there appears to be a virtually limitless variety of causes. Smoking, for example, has been shown to cause several types of lung cancer.³⁸ Certain mutations in the *TP53* gene appear to be correlated to a particular variety of kidney cancer: clear cell renal cell carcinoma.³⁹ And the human papilloma viruses seem to be a necessary component to cervical cancer.⁴⁰ Overall, cancers arise from a wide and disparate variety of mechanisms including genetics, infections, environment, behavior, time, and just plain bad luck.⁴¹

Even within an individual incidence of cancer—a single tumor, residing in a single individual—the offending neoplasm can be remarkably heterogeneous, or even unique among its type.⁴² Each tumor may very well contain genetic mutations not seen in other tumors—or, more complicated yet, mutations in only parts of the tumor, hidden from an analysis of the whole.⁴³ And because every cancer patient's unique genetic and medical makeup contribute to the development of their cancers, each tumor is, in a very real sense, a novel composition.⁴⁴ Further, cancers are not static: they evolve in

called checkpoints, that operate at critical times in the cell's life"); Leland H. Hartwell & Michael B. Kastan, *Cell Cycle Control and Cancer*, 266 *SCI.* 1821, 1821 (1994) ("The passage of cells from one stage of the cell cycle to another is tightly regulated by a wealth of controls . . .").

38. 83 WORLD HEALTH ORG. & INT'L AGENCY FOR RES. ON CANCER, IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS: TOBACCO SMOKE AND INVOLUNTARY SMOKING 33 (2004), <http://monographs.iarc.fr/ENG/Monographs/vol83/mono83.pdf> [<https://perma.cc/QLX9-NDQM>].

39. Mark Bi et al., *Genomic Characterization of Sarcomatoid Transformation in Clear Cell Renal Cell Carcinoma*, 113 *PROC. NAT'L ACAD. SCI. USA* 2170, 2170 (2016).

40. Jan. M. M. Walboomers et al., *Human Papillomavirus Is a Necessary Cause of Invasive Cervical Cancer Worldwide*, 189 *J. PATHOLOGY* 12, 12 (1999).

41. See Sharon Begley, *Most Cancers Due to 'Bad Luck'? Not so Fast, Says Study*, *STAT* (Dec. 16, 2015), <https://www.statnews.com/2015/12/16/cancers-bad-luck/> [<https://perma.cc/VQQ4-LKPK>] (describing competing studies on the role that random mutations, i.e., "luck," factor into cancer development). Compare Cristian Tomasetti & Bert Vogelstein, *Variation in Cancer Risk Among Tissues Can Be Explained by the Number of Stem Cell Divisions*, 347 *SCI.* 78, 78 (2015) (substantiating the role of random mutations in cancer development) with Song Wu et al., *Substantial Contribution of Extrinsic Risk Factors to Cancer Development*, 529 *NATURE* 43, 43–44 (2016) (substantiating the role of extrinsic factors in cancer development).

42. Breivik, *supra* note 6, at A21 ("There are so many different types of cancer, so many different genes and biochemical mechanisms, and every patient is different.").

43. See Dan L. Longo, *Tumor Heterogeneity and Personalized Medicine*, 366 *NEW ENG. J. MED.* 956, 956 (2012) ("About two thirds of the mutations that were found in single biopsies were not uniformly detectable throughout all the sampled regions of the same patient's tumor . . . Thus, a single tumor biopsy, the standard of tumor diagnosis and the cornerstone of personalized-medicine decisions, cannot be considered representative of the landscape of genomic abnormalities in a tumor.").

44. See GREAVES, *supra* note 32, at 3 ("In a sense, every patient's cancer is unique . . ."); Shuji Ogino, Charles S. Fuchs & Edward Giovannucci, *How Many Molecular*

every sense of the word, often being selected for drug resistance as a function of medical treatment.⁴⁵ Any attempt to understand any given cancer at a given time is likely to be merely a snapshot of its growth and differentiation.⁴⁶

Perhaps because of this diversity, broader principles of cancer have proven difficult to identify. In 2000, cancer researchers Douglas Hanahan and Robert Weinberg attempted to categorize all cancers according to roughly six cellular characteristics and announced that conceptual simplicity would begin to emerge from the past quarter-century of data.⁴⁷ The small number of these organizing principles gave them hope that “those researching the cancer problem will be practicing a dramatically different type of science than we have experienced over the past 25 years.”⁴⁸ Yet, only a decade later, the authors, spurred by new developments in the field, felt obligated to add two additional hallmarks to their original six.⁴⁹ Other researchers have since added more.⁵⁰

Subtypes? Implications of the Unique Tumor Principle in Personalized Medicine, 12 EXPERT REV. MOLECULAR DIAGNOSTICS 621, 622 (“As each individual human being is unique, each tumor is unique.”).

45. Samuel Aparicio & Carlos Caldas, *The Implications of Clonal Genome Evolution for Cancer Medicine*, 368 NEW ENG. J. MED. 842, 842 (2013) (“Darwin’s theory of evolution was originally developed in the context of speciation. It has proved to be a fundamental property of biologic systems, including human cancers.”); Pornpimol Charoentong, et al., *Bioinformatics for Cancer Immunology and Immunotherapy*, 61 CANCER IMMUNOLOGY IMMUNOTHERAPY 1885, 1897 (2012) (“Cancer progression is an evolutionary process that results from accumulation of genetic and epigenetic variations in a single somatic cell.”); Hanahan & Weinberg, *supra* note 14, at 57 (“[O]bservations of human cancers and animal models argue that tumor development proceeds via a process formally analogous to Darwinian evolution, in which a succession of genetic changes, each conferring one or another type of growth advantage, leads to the progressive conversion of normal human cells into cancer cells.”).

46. See Aparicio & Caldas, *supra* note 45, at 846–47 (noting the need of “tumor monitoring” as tumor mutations are a moving target).

47. See Hanahan & Weinberg, *supra* note 14, at 57 (“We suggest that the vast catalog of cancer cell genotypes is a manifestation of six essential alterations in cell physiology that collectively dictate malignant growth . . . self-sufficiency in growth signals, insensitivity to growth-inhibitory (antigrowth) signals, evasion of programmed cell death (apoptosis), limitless replicative potential, sustained angiogenesis, and tissue invasion and metastasis We foresee cancer research developing into a logical science, where the complexities of the disease, described in the laboratory and clinic, will become understandable in terms of a small number of underlying principles.”).

48. *Id.*

49. Douglas Hanahan & Robert A. Weinberg, *Hallmarks of Cancer: The Next Generation*, 144 CELL 646, 646 (2011) (adding “reprogramming of energy metabolism and evading immune destruction” to the list of hallmarks).

50. *E.g.*, Federica Cavallo et al., 2011: *The Immune Hallmarks of Cancer*, 60 CANCER IMMUNOLOGY IMMUNOTHERAPY 319, 319 (2011) (adding “effective procedures to activate immune reactivity; characterization of not-disposable oncoantigens; and

This intractability in assessing and understanding “cancer” sets it apart from almost all other diseases.⁵¹ Physicians, perhaps better known for describing human illnesses in cold, clinical language, have long been moved to poetry in describing cancer’s guile: it is “the emperor of all maladies, the king of terrors,”⁵² “an obscene and demonic predator, an invincible grim reaper,”⁵³ a “hidden assassin.”⁵⁴ Cancer remains, if not unique in its difficulty, supremely peerless: diverse, complex, mysterious, intractable, and, for each patient, personal.

B. Understanding Cancer’s Information

At its core, the modern endeavor to understand cancer’s complexity is one of information: uncovering data, facts, or statistics describing the disease’s sufferers or components of tumors.⁵⁵ This parallels research into other complex phenomena that seeks to make sense of “the number and variety of an item’s constituent elements and of the elaborateness of their interrelational structure.”⁵⁶ Cancer research today accordingly focuses on determining and quantifying

counteraction of immune suppression.”); T. Dalmay & D.R. Edwards, *MicroRNAs and the Hallmarks of Cancer*, 25 *ONCOGENE* 6170, 6170–72 (2006) (aberrant microRNA regulation of tissue architecture); Maozhen Tian, Jason R. Neil & William P. Schiemann, *Transforming Growth Factor- β and the Hallmarks of Cancer*, 23 *CELLULAR SIGNALLING* 951, 959 (2011) (TGF- β sensitivity).

51. See Erika Check Hayden, *Cancer Complexity Slows Quest for Cure*, 455 *NATURE* 148, 148 (2008) (discussing the unique difficulties arising from cancer’s complexity); Peter J. Neumann, Sarah K. Bliss & James D. Chambers, *Therapies For Advanced Cancers Pose a Special Challenge for Health Technology Assessment Organizations in Many Countries*, 31 *HEALTH AFF.* 700, 700 (2012) (“[H]ealth technology assessment organizations are struggling with cancer’s ‘exceptionalism.’”); Jennifer K. Pilchta et al., *What’s New in Genetic Testing for Cancer Susceptibility?*, 30 *ONCOLOGY* 787, 787 (2016) (assessing the “complexity of clinical management . . . genetic testing, risk assessment, and large-scale population screening, [as] present[ing] unique challenges.”); see also Teneille R. Brown, *Denying Death*, 57 *ARIZ. L. REV.* 977, 982 (2015) (“In many ways, cancer is different. Cancer hijacks our bodies’ natural production systems and makes them go haywire. Cancer cells sinisterly take refuge in hidden corners of our bodies and then cleverly mutate to evade new drug treatments.”).

52. MUKHERJEE, *supra* note 12, at xiv.

53. GREAVES, *supra* note 32, at 3 (describing Susan Sontag’s depiction of cancer in her book, *SUSAN SONTAG, ILLNESS AS METAPHOR*, 1978)).

54. *Id.* at 109 (quoting poem by W.H. Auden, *Miss Gee*, in *ANOTHER TIME* 62 (1937)).

55. See PEDRO J. GUTIÉRREZ, IRMA H. RUSSO & JOE RUSSO, *THE EVOLUTION OF THE USE OF MATHEMATICS IN CANCER RESEARCH* 158–165 (2012) (demonstrating the statistical modeling of tumors); Vivien Marx, *The Big Challenges of Big Data*, 498 *NATURE* 255, 255 (2013) (describing cancer as a “big data” challenge); Michael R. Stratton, Peter J. Campbell & P. Andrew Futreal, *The Cancer Genome*, 458 *NATURE* 719, 719 (2009) (characterizing cancer genetics as an “explosion of information”).

56. NICHOLAS RESCHER, *COMPLEXITY: A PHILOSOPHICAL OVERVIEW* 1 (1998).

these elements, such as: which populations are most susceptible to the disease;⁵⁷ environmental factors or human behaviors that contribute to it;⁵⁸ how changes in cellular function affect cancer's progression;⁵⁹ and which genes play a role in tumors' genesis.⁶⁰ To that end, efforts to understand cancer both focus on information and produce it—cancer research generates data about components of the disease and synthesizes existing data to produce new understandings about its causes.⁶¹ Understanding cancer is understanding cancer's *information*.

This drive to understand cancer through producing and synthesizing information is perhaps best illustrated by the International Agency for Research on Cancer's ("IARC") Monographs on the Evaluation of Carcinogenic Risks to Humans.⁶² IARC—an arm of the World Health Organization ("WHO")—periodically establishes working groups of several dozen to hundreds of scientists to evaluate published research on the carcinogenic effect of chemicals, foods, and human behavior.⁶³ Through committee meetings, it crafts a report that weighs all of the published evidence of the particular agent studied and then assigns the agent to one of five risk groups: (1) carcinogenic to humans; (2A) probably carcinogenic to humans; (2B) possibly carcinogenic to humans; (3) not classifiable as to its carcinogenicity to humans; and (4) probably not carcinogenic to humans.⁶⁴ As an example, IARC recently completed a report of the

57. See, e.g., Jeffery P. Struewing et al., *The Risk of Cancer Associated with Specific Mutations of BRCA1 and BRCA2 Among Ashkenazi Jews*, 336 NEW ENG. J. MED. 1401, 1401 (1997).

58. See, e.g., David C. Whiteman & Louise F. Wilson, *The Fractions of Cancer Attributable to Modifiable Factors: A Global Review*, 44 CANCER EPIDEMIOLOGY 203, 203 (2016).

59. See, e.g., A. Janssen & R.H. Medema, *Mitosis as an Anti-Cancer Target*, 30 ONCOGENE 2799, 2799 (2011).

60. See, e.g., Stratton et al., *supra* note 55, at 719.

61. See, e.g., Marx, *supra* note 55, at 257 (charting a "data explosion" for genetic sequencing information); Stratton et al., *supra* note 55, at 723 ("[T]he arrival of second-generation sequencing technologies promises a new era for cancer genomics. These platforms currently generate billions of bases of DNA sequence per week, yields that are predicted to increase rapidly over the next couple of years."); Whiteman & Wilson, *supra* note 58 at 203 (demonstrating the data created from a synthesis of global cancer information).

62. See generally WORLD HEALTH ORG. & INT'L AGENCY FOR RES. ON CANCER, *Preamble to IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS* (2006), <http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf> [<https://perma.cc/UYL5-NR62>] (describing the monograph system).

63. *Id.* at 5–6.

64. *Id.* at 22–23. For a criticism of IARC's classification system, see Ed Yong, *Beefing With the World Health Organization's Cancer Warnings*, ATLANTIC (Oct. 26, 2015), <http://www.theatlantic.com/health/archive/2015/10/why-is-the-world-health-organization-so-bad-at-communicating-cancer-risk/412468/> [<https://perma.cc/X2HA-DX3F>].

role of glyphosate—the pesticide famously found in Monsanto's Roundup—in human cancers.⁶⁵ It analyzed the methodology and results of roughly two dozen studies—cohort, case-control, and meta-analyses in humans—as well as other experimental studies in mice and rats.⁶⁶ It reviewed the possible mechanisms of action for glyphosate to damage cellular DNA.⁶⁷ And it concluded that glyphosate is “probably” carcinogenic to humans, based on limited evidence of its association with one form of human cancer, more substantial evidence of its carcinogenicity in animals, and plausible mechanisms of action for the chemical “operat[ing] through two key characteristics of known human carcinogens.”⁶⁸ IARC reports, like the one on glyphosate, frequently review hundreds of studies and commonly consist of close to 1,000 pages.⁶⁹ As of July 6, 2016, IARC has produced 999 of these reports.⁷⁰ Significantly, the WHO does not study any other disease with such depth.⁷¹

Information underlies reports like IARC's—the myriad biochemical, genetic, and cellular pathways involved in the origins and progression of tumors. Because cancer is, in effect, “a runaway cell-cycle engine,”⁷² researchers often examine which of these elements are responsible for aberrations in the cell-cycle—whether they wrongly drive a cell forward in its replication cycle,⁷³ fail to stop a replicating cell from further replicating,⁷⁴ or incorrectly signal other

65. 112 WORLD HEALTH ORG. & INT'L AGENCY FOR RES. ON CANCER, IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS: SOME ORGANOPHOSPHATE INSECTICIDES AND HERBICIDES (2015), <http://monographs.iarc.fr/ENG/Monographs/vol112/mono112.pdf> [<https://perma.cc/LC9A-FPW6>].

66. *Id.* at 331–61.

67. *Id.* at 365–86.

68. *Id.* at 398 (“Glyphosate is *probably carcinogenic to humans (Group 2A)*.”).

69. *E.g.*, WORLD HEALTH ORG. & INT'L AGENCY FOR RES. ON CANCER, *supra* note 38 (comprising 1,473 pages, including a 24-page, single-spaced bibliography).

70. *See Agents Classified by the IARC Monographs, Volumes 1–120*, INT'L AGENCY FOR RES. ON CANCER, LIST OF CLASSIFICATIONS, <http://monographs.iarc.fr/ENG/Classification/> (last modified Oct. 27, 2017) [<https://perma.cc/8YD5-GRM7>].

71. A recent list of the WHO's programs includes only a single research agency: IARC. *See Programmes and Projects*, WORLD HEALTH ORG., <http://www.who.int/entity/en/> [<http://perma.cc/HL8V-ZJRV>].

72. *See* Andrew W. Murray, *Creative Blocks: Cell-Cycle Checkpoints and Feedback Controls*, 359 NATURE 599, 599 (1992).

73. *E.g.*, William R. Taylor & George R. Stark, *Regulation of the G2/M Transition by p53*, 20 ONCOGENE 1803, 1803 (2001) (describing the role of a protein, p53, in driving replication in a cancerous cell).

74. *E.g.*, Charles J. Sherr, *Cancer Cell Cycles*, 274 SCI. 1672, 1672 (1996) (reviewing genes responsible for the continuous replication of cancer cells).

cells to begin the replication process.⁷⁵ To date, researchers have identified innumerable pathways responsible for cellular replication, each involving dozens of proteins engaged in countless interactions with one another.⁷⁶ Researchers then frequently continue this work by using the data generated in past studies to identify even more genes and cellular pathways responsible for “tumorigenesis.”⁷⁷

This broad view of cancer places the disease within the framework of “-omics,” a suffix used to identify areas of study encompassing enormously large informational scales.⁷⁸ The human genome, for example, is the collection of roughly all 20,000 known human genes.⁷⁹ Genomics is, therefore, the study of the interactions among them.⁸⁰ At omics-level scales, science begins to fade from laboratory benches and moves toward computers. Researchers, facing data from tens of thousands of elements, with a gargantuan number of interactions among them, cannot possibly examine them all. Instead, “techniques developed in fields such as computer science and statistics [are used] to facilitate understanding . . . [of] the biologic systems being studied.”⁸¹

75. E.g., Francis Rodier et al., *Persistent DNA Damage Signalling Triggers Senescence-Associated Inflammatory Cytokine Secretion*, 11 NATURE CELL BIOLOGY 973, 973 (2009) (finding an inflammation signaling response in some types of cancer cells).

76. See H. Billur Engin, Jason F. Kreisberg & Hannah Carter, *Structure-Based Analysis Reveals Cancer Missense Mutations Target Protein Interaction Interfaces*, 11 PLOS ONE e0152929 1, 2 (2016).

77. E.g., *id.*

78. WILLIAM C.S. CHO, *Preface to AN OMICS PERSPECTIVE ON CANCER RESEARCH* v (William C.S. Cho ed., 2010) (“Postgenome science is characterized by omics data related to genome, transcriptome, epigenome, proteome, metabolome and interactome. In the omics era, it is a revolution in cancer research which fundamentally shifts the strategy from piece-by-piece to global analysis and from hypothesis-driven to discovery-based research.”).

79. Jyoti Madhusoodanan, *Human Gene Set Shrinks Again*, SCIENTIST (July 8, 2014) (citing Iakes Ezkurdia, *Multiple Evidence Strands Suggest That There May Be as Few as 19,000 Human Protein-Coding Genes*, 23 HUM. MOLECULAR GENETICS 5866, 5866 (2014)), <http://www.the-scientist.com/?articles.view/articleNo/40441/title/Human-Gene-Set-Shrinks-Again/> [<http://perma.cc/4SD5-RKJF>].

80. John Quackenbush, *Microarray Analysis and Tumor Classification*, 354 NEW ENG. J. MED. 2463, 2470 (2006) (“Genomics is the study of genomes and the complete collection of genes that they contain.”); Nick Campbell & Mary Muers, *About This Site: Omics*, OMICSGATEWAY (July 2011), <http://www.nature.com/omics/about/index.html> [<http://perma.cc/E4SC-8BB7>] (“Omics is a general term for a broad discipline of science and engineering for analyzing the interactions of biological information objects in various ‘omes.’”).

81. Quackenbush, *supra* note 80, at 2470.

The same is true for data concerning cancer, or “oncogenomics.”⁸² Oncogenomics seeks “the integration of complete genome analyses . . . so that accurate models of the molecular basis of cancer can be built.”⁸³ And in contrast to traditional clinical research—case reports from physicians about patients—oncogenomics requires the expertise of statisticians, data scientists, and quantitative molecular biologists.⁸⁴ Studying cancer’s information is consequently more of a *data* science than a *laboratory* science.

As an illustration of this point, take the size and structure of oncogenomic databases. These frequently consist of vast arrays of information concerning tumor genetics, some of which house sampling information from more than 100,000 subjects.⁸⁵ The Catalogue of Somatic Mutations in Cancer (“COSMIC”) database, for example, contains genetic information from over 370,000 tumors as part of more than 1.5 million individual experiments.⁸⁶ These databases have become objects of study themselves, with researchers compiling resources to analyze, annotate, and visualize their data.⁸⁷ Indeed, cancer research has become so informationally rich that its output is now routinely studied by data scientists unrelated to cancer research.⁸⁸ Somewhat controversially, a great deal of cancer research now concerns mining this previously collected data to determine new

82. Robert L. Strausberg et al., *Oncogenomics and the Development of New Cancer Therapies*, 429 NATURE 469, 470 (2004) (“Database development and analysis tools . . . will be equally important for the development and population of a database of the molecular biology of cancer.”).

83. *Id.*

84. See R. David Hawkins, Gary C. Hon & Bing Ren, *Next-Generation Genomics: An Integrative Approach*, 11 NATURE REV. GENETICS 476, 478 (2010) (discussing the requirement of data integration in the era of next-generation genomics).

85. See Athanasia Pavlopoulou, Demetrios A. Spandidos & Ioannis Michalopoulos, *Human Cancer Databases (Review)*, 33 ONCOLOGY REP. 3, 4 (2014) (reviewing sample sizes of various cancer databases).

86. Simon A. Forbes et al., *COSMIC (The Catalogue of Somatic Mutations in Cancer): A Resource to Investigate Acquired Mutations in Human Cancer*, 38 NUCLEIC ACIDS RES. D652, D652 (2009) (describing a database with 370,000 samples).

87. See, e.g., Michael P. Schroeder, Abel Gonzalez-Perez & Nuria Lopez-Bigas, *Visualizing Multidimensional Cancer Genomics Data*, 5 GENOME MED. 9, 10 (describing one such compilation and visualization project).

88. See, e.g., David Haussler et al., *A Million Cancer Genome Warehouse 3–5* (Univ. Cal. Berkley Dep’t Elec. Eng’g & Comput. Scis., Technical Report No. UCB/EECS-2012-211), <https://www2.eecs.berkeley.edu/Pubs/TechRpts/2012/EECS-2012-211.pdf> [<http://perma.cc/34HM-9WT2>]; Mehmet Koyutürk, *Using Protein Interaction Networks to Understand Complex Diseases*, 45 COMPUTER 31, 31 (2012); A. Lex et al., *StratomeX: Visual Analysis of Large-Scale Heterogeneous Genomics Data for Cancer Subtype Characterization*, 31 COMPUTER GRAPHICS F. 1175, 1175 (2012).

linkages between genetics and the disease.⁸⁹ This all highlights the recent turn in cancer research: that it is now as much an informational endeavor as it is an empirically clinical one.

C. *The Cost of Developing Cancer Information*

Developing information about cancer is both time-intensive and costly. Sourcing patients, providing treatment, excising tumors, analyzing samples, and conducting further research on those samples requires long commitments of time, effort, and expertise.⁹⁰ A typical clinical cancer research protocol may take a decade to complete.⁹¹ It also requires a good deal of money. The National Cancer Institute (“NCI”), responsible for roughly eighty percent of U.S. cancer research spending,⁹² received \$5.389 billion in appropriations in 2017.⁹³ That equals roughly seventy percent of the total budget of the National Science Foundation, an agency devoted to funding research in virtually every non-health-related science, from astronomy to zoology.⁹⁴

89. See, e.g., Simon A. Forbes et al., *COSMIC: Mining Complete Cancer Genomes in the Catalogue of Somatic Mutations in Cancer*, 39 NUCLEIC ACIDS RES. D945, D945 (2010) (describing data mining techniques for the COSMIC database). An editorial in the *New England Journal of Medicine* has fomented a recent controversy over the practice of data sharing and data mining, calling some researchers “research parasites.” Dan L. Longo & Jeffrey M. Drazen, *Data Sharing*, 374 NEW ENG. J. MED. 276, 276 (2016). Other prominent researchers in the field have criticized the editorial as “deeply troubling,” “deranged,” and an act of “condescension.” *Data Sharing, Data Scientists, and “Parasites,”* GENOMEWEB (Jan. 25, 2016), <https://www.genomeweb.com/scan/data-sharing-data-scientists-and-parasites> [<https://perma.cc/2H3B-LJPG> (dark archive)].

90. See Aylin Sertkaya et al., *Examination of Clinical Trial Costs and Barriers for Drug Development*, ERG 4.3–4.26 (July 25, 2014), https://aspe.hhs.gov/sites/default/files/pdf/77166/rpt_erg.pdf [<http://perma.cc/QXC6-4KN8>] (describing some of the barriers to clinical trials).

91. See, e.g., Jack Cuzick et al., *Effect of Anastrozole and Tamoxifen as Adjuvant Treatment for Early-Stage Breast Cancer: 10-Year Analysis of the ATAC Trial*, 11 LANCET ONCOLOGY 1135, 1135 (2010) (noting breast cancer “median follow-up of 120 months”); Kristina R. Dahlstrom et al., *An Evolution in Demographics, Treatment, and Outcomes of Oropharyngeal Cancer at a Major Cancer Center*, 119 CANCER 81, 81 (2013) (noting the median survival rate oropharyngeal cancer is 120 months); Wilma D. Heemsbergen et al., *Long-Term Results of the Dutch Randomized Prostate Cancer Trial: Impact of Dose-Escalation on Local, Biochemical, Clinical Failure, and Survival*, 110 RADIOTHERAPY & ONCOLOGY 104, 104 (2014) (noting prostate cancer “median follow-up of 110 months”).

92. Seth Eckhouse, Grant Lewison & Richard Sullivan, *Trends in the Global Funding and Activity of Cancer Research*, 2 MOLECULAR ONCOLOGY 20, 20 (2008) (estimating NCI’s spending to be roughly 83% of cancer research spending in the United States).

93. *NCI Budget and Appropriations*, NAT’L CANCER INST. (Apr. 19, 2016), <http://www.cancer.gov/about-nci/budget> [<https://perma.cc/N8WU-DFMM>].

94. *What We Do*, NAT’L SCI. FOUND. (Sept. 3, 2017), <https://www.nsf.gov/about/what.jsp> [<http://perma.cc/XFF2-MFXU>] (describing the goals and purpose of the National Science Foundation).

Currently, the cost of cancer research is spread across multiple domains, none of which are cheap. Academic research laboratories often pair with their clinical counterparts to genetically sequence patient tumors—a process that experienced an exponential *decrease* in cost since 2007.⁹⁵ Nonetheless, whole genome sequencing of a single sample still costs roughly \$1,000 on the retail market, a sum that can quickly become extraordinary when multiplied across several samples from thousands of patients.⁹⁶ Research laboratories running studies on this data, funded by government or private grants, typically bear these costs.⁹⁷ As just one example, the NCI awarded a \$2.8 million grant for a project focused on the whole genome sequencing of 1,200 samples from a leukemia variant—a grant that ultimately resulted in a publication in *Nature*.⁹⁸ That grant was one of almost seventy whole genome sequencing studies funded by the NCI in 2013 alone.⁹⁹

Besides the cost of sequencing itself, there is also the cost of housing and securing sequencing information. These data costs can similarly be substantial. Using one popular genetic data service, Strand NGS, whole genome sequencing data files from 1,000 samples can expand to as large as 300 terabytes¹⁰⁰—currently the size of 300 typical computer hard drives.¹⁰¹ Storing and securing this data can

95. See *DNA Sequencing Costs: Data*, NAT'L HUM. GENOME RES. INST. (last updated Oct. 31, 2017), <https://www.genome.gov/27541954/dna-sequencing-costs-data/> [<http://perma.cc/HC94-4YSJ>] (charting the decrease in sequencing cost from 2001 to 2015).

96. *HiSeq X Ten System*, ILLUMINA, <https://www.illumina.com/systems/sequencing-platforms/hiseq-x.html> [<http://perma.cc/J87M-9L3Q>] (“The system consists of a set of 10 HiSeq X ultra-high-throughput instruments that deliver over 18,000 human genomes per year at the price of \$1000 per genome.”).

97. See Elaine R. Mardis, *The \$1,000 Genome, the \$100,000 Analysis?*, 2 *GENOME MED.* 84, 84 (2010) (noting that while the cost of sequencing is often paid for by research laboratories, the cost-bearer for sequencing *analysis* is frequently unclear).

98. See Li Ding et al., *Clonal Evolution in Relapsed Acute Myeloid Leukaemia Revealed by Whole-Genome Sequencing*, 481 *NATURE* 506, 510 (2012); *Genomics of Acute Myelogenous Leukemia*, NAT'L CANCER INST. (2013), <http://fundedresearch.cancer.gov/nciportfolio/search/details?action=abstract&grantNum=2P01CA101937-10&grantID=8475986&grtSCDC=FY%202013&absID=8475986&absSCDC=PUB2013> [<https://perma.cc/6QFN-4JB9>].

99. See *Advanced Search*, NCI FUNDED RES. PORTFOLIO, http://fundedresearch.cancer.gov/nciportfolio/search/SearchForm?formType=advanced&action=clear&field=keywords#keywords_field [<http://perma.cc/J6H7-C2NR>] (searching for grants in fiscal year 2013 with keywords “whole genome sequencing” or “whole genome sequence”).

100. *Guide to Storage and Computation Requirements*, STRANDNGS, <http://www.strandngs.com/support/ngs-data-storage-requirements> [<http://perma.cc/F2AZ-C2U7>].

101. See Joel Santo Domingo, *SSD vs. HDD: What's the Difference?*, *PCMAG* (Jun. 9, 2017, 4:01 PM), <https://www.pcmag.com/article2/0,2817,2404258,00.asp> [<http://perma.cc/7MTG-K2UN>].

then easily cost thousands of dollars per month.¹⁰² A recent report from *STAT* pegged the cost of storing information from the Cancer Genome Atlas, for example, to be \$2 million *per year*.¹⁰³

More traditionally, FDA-mandated clinical trials for new cancer therapeutics remain one of the richer, yet more expensive, sources of data of cancer information.¹⁰⁴ In a typical cancer clinical trial, a therapeutic developer divides a subject population into several treatment “arms” to determine whether a new treatment will have a beneficial effect, often relative to a current, standard treatment.¹⁰⁵ In doing so, the therapeutic developer often generates reams of data concerning the subjects’ genetics, physiology, and behavior, including valuable information concerning patients’ (and their tumors’) genetics, biochemistry, and cellular makeup.¹⁰⁶ This information, in turn, then often requires years’ worth of follow-up to determine whether the therapy (or its control) had any effect on the disease.¹⁰⁷ From start to finish, a typical cancer clinical trial costs roughly \$40 million and takes between six-and-a-half to eight-and-a-half years.¹⁰⁸

Clinical trials have several drawbacks, not the least of which is their length: they are often not run *long enough* to generate some of the most robust and important data to researchers.¹⁰⁹ Longitudinal data—measurements of fixed variables over prolonged periods of

102. See *Pricing: Genomics*, GOOGLE CLOUD PLATFORM, (last updated Dec. 13, 2017) <https://cloud.google.com/genomics/pricing> [http://perma.cc/FW6F-CDVG] (listing the annual cost of storage of a single, average human genome to be \$25.00).

103. Sharon Begley, *Cancer Research Moves to the Cloud to Improve Patient Care*, *STAT* (Feb. 17, 2016), <https://www.statnews.com/2016/02/17/cancer-research-cloud-computing/> [http://perma.cc/9HBM-5RSU].

104. See Kathy L. Hudson, Michael S. Lauer & Francis S. Collins, *Toward a New Era of Trust and Transparency in Clinical Trials*, 316 *JAMA* 1353, 1353 (2016) (describing clinical trials as responsible for the “generation of robust evidence about treatments or preventive interventions in routine clinical care”).

105. See Richard Simon, *The Use of Genomics in Clinical Trial Design*, 14 *CLINICAL CANCER RES.* 5984, 5984 (2008) (describing variations of cancer clinical trials).

106. See, e.g., U.S. Patent No. 9,350,802 (filed June 22, 2012) (describing a method of transferring data generated from clinical trials).

107. See, e.g., Jack Cuzick et al., *supra* note 91, at 1135; Kristina R. Dahlstrom et al., *supra* note 91, at 81, 90; Wilma D. Heemsbergen et al., *supra* note 91, at 104.

108. Sertkaya et al., *supra* note 90, at 1, 3.

109. See Budish, Roin & Williams, *supra* note 22, at 2074 (“[C]onsistent with the idea that the patent system should offer zero incentive to develop drug compounds that take longer than 20 years to develop, very few trials in our data have a reported length of 20 years or longer.”).

time—frequently serve as the gold standard in clinical research.¹¹⁰ In the cancer context, longitudinal data typically focuses on several standard measurements of treatment patients—survival period, remission, tumor genetics, and so on—taken over the course of several years, to accurately assess whether the patients have, in fact, survived their cancers.¹¹¹ Because of the long time periods involved, longitudinal studies are often publicly funded.¹¹² For instance, the NCI currently shepherds the well-known National Surgical Adjuvant Breast and Bowel Project (“NSABP”), a series of decades’ long longitudinal studies on cancer treatments.¹¹³ One NSABP project, NSABP-04, consisted of a thorough, *twenty-five year* longitudinal study concerning breast cancer patients’ survival expectancies after massive surgical interventions, like radical mastectomies¹¹⁴ (it concluded that radical surgery provided no additional benefit, overturning decades of oncological wisdom).¹¹⁵ By as late as 2011, the NSABP cost between \$15 and \$30 million per year.¹¹⁶

And even after all of a project’s clinical research has been performed, there remains the possibility—and cost—of secondary research, or research reexamining the same data, under different hypotheses, statistical tools, and global analyses.¹¹⁷ The costs of

110. See Scott L. Zeger & Kung-Yee Liang, *Longitudinal Data Analysis for Discrete and Continuous Outcomes*, 42 BIOMETRICS 121, 122 (1986) (introducing “general estimating equations” for clinical statistics).

111. See GEERT VERBEKE & GEERT MOLENBERGHS, *LINEAR MIXED MODELS FOR LONGITUDINAL DATA* 15 (2009) (describing a longitudinal cancer study tracking “duration of response, time to progression, [and] survival,” among other variables); *id.* at 415–16 (discussing the measuring of interdam variability as capturing tumor genetics).

112. See Budish et al., *supra* note 22, at 2074 (“Of the approximately 120 clinical trials longer than 20 years that have non-missing data on sponsorship, essentially 100 percent are publicly funded.”); Wilbanks & Topol, *supra* note 24, at 347 (“Pharmaceutical firms have long sequestered limited types of hard-to-obtain data, for instance on how specific chemicals affect certain blood measurements in clinical trials. But they generally lack longitudinal health data about individuals outside the studies that they run, and often cannot connect a participant in one trial to the same participant in another.”).

113. *National Surgical Adjuvant Breast and Bowel Project: Over 50 Years of Clinical Trial History*, NSABP, <http://www.nsabp.pitt.edu> [<http://perma.cc/S45T-GS6U>].

114. Bernard Fisher et al., *Twenty-Five-Year Follow-Up of a Randomized Trial Comparing Radical Mastectomy, Total Mastectomy, and Total Mastectomy Followed by Irradiation*, 347 NEW ENG. J. MED. 567, 567 (2002); see also MUKHERJEE, *supra* note 12, at 200–01 (describing NSABP-04).

115. See Fisher et al., *supra* note 114, at 567; MUKHERJEE, *supra* note 12, at 200–01.

116. *2011 Fact Book*, NAT’L CANCER INST. (2011), <https://www.cancer.gov/about-nci/budget/fact-book/archive/2011-fact-book.pdf> [<https://perma.cc/WG7B-MJP7>] (budget information about the center ended in 2012).

117. Angela K. Green et al., *The Project Data Sphere Initiative: Accelerating Cancer Research by Sharing Data*, 20 ONCOLOGIST 464, 465 (2015) (“[A]dvancements in

secondary research are essentially the data costs of the original research repeated with the additional costs of computer equipment, data scientists, statisticians, and information technology professionals.¹¹⁸ Furthermore, there are costs in ensuring the confidentiality of any information obtained from the original dataset¹¹⁹ and potentially licensing fees for private datasets.¹²⁰ In 2013, the Director of Kansas State University's Johnson Cancer Research Center, Rob Denell, praised a series of private donations to make up some of these costs.¹²¹ To paraphrase Professor Denell: cancer research ain't cheap.¹²²

D. *Public-Private Partnerships and the Cancer Moonshot*

Given the cost and uncertainty involved in developing cancer information, cancer research has historically been funded through grants, both private and public. In the nineteenth century, cancer research suffered from a lack of “government support—local, state, or national—for biological scientists.”¹²³ As a result, the private largesse of the Gilded Age funded research hospitals studying the disease, including the United States' first such specialized facility, the New York Cancer Hospital, in 1890.¹²⁴ Today, private funding comprises a large part of the global cancer research budget—roughly \$1 billion in the United States alone.¹²⁵ A substantial portion of that goes to research by pharmaceutical development companies in an effort to usher their products to the marketplace.¹²⁶ But, in a historical parallel, today's New Gilded Age similarly funds cancer research through

statistical methods for secondary database analysis offer many tools for reanalyzing data arising from disparate trials, such as propensity score matching.”).

118. See Alexander K. Smith et al., *Conducting High-Value Secondary Dataset Analysis: An Introductory Guide and Resources*, 26 J. GEN. INTERNAL MED. 920, 923–26 (2011) (describing some of the costs associated with secondary analyses).

119. See *id.* at 923 (“Some datasets . . . require multiple layers of permission and security, and in some cases data must be analyzed in a central data processing center. If the project requires linking new data to an existing database, this linkage will add to the time needed to complete the project and probably require enhanced data security.”).

120. See *infra* notes 381–86 and accompanying text.

121. Marcia Locke, *Private Donations Let Cancer Research Center Award \$466,600 for Research, Training*, K-STATE NEWS (May 9, 2013), <http://www.k-state.edu/media/newsreleases/may13/canceryear5913.html> [<http://perma.cc/XM2M-HRZ9>].

122. *Id.* (“‘Saving lives through cancer research isn't cheap,’ said Rob Denell, director of the university's Johnson Cancer Research Center and distinguished professor of biology.”).

123. JAMES T. PATTERSON, *THE DREAD DISEASE* 22 (1987).

124. See *id.*

125. Eckhouse et al., *supra* note 92, at 25.

126. See *id.* at 21–22.

large, singular grants.¹²⁷ Like the Astors of last century, Sean Parker, the internet billionaire, recently announced a \$250 million grant effort devoted to cancer research.¹²⁸

On the public side of the ledger, cancer research through grant funding largely began in 1938 with the establishment of—and \$400,000 of appropriations funding awarded to—the National Cancer Institute.¹²⁹ The NCI's work and budget slowly but steadily increased in the intervening decades until 1971, when President Nixon declared a “War on Cancer”—increasing the Institute's budget by \$100 million.¹³⁰ As of this writing, the NCI's budget constitutes \$5.389 billion,¹³¹ sixteen percent of the NIH's total budget,¹³² with funding relatively split between intramural and extramural research.¹³³ It is fair to say that current academic research on cancer is largely a product of the NCI.¹³⁴

The success of these funding efforts, however, has been mixed. Research efforts—alongside breakthrough advances in genomics and information technology—have produced more information about cancer than previously dreamed of.¹³⁵ But the parallel development of

127. See Ron Winslow, *Sean Parker Turns to Cancer Research*, WALL ST. J. (Apr. 17, 2016), <https://www.wsj.com/articles/sean-parker-turns-to-cancer-research-1460521518> [<https://perma.cc/C8FN-UQ75> (staff-uploaded archive)] (describing the cancer philanthropy of Sean Parker, Michael Bloomberg, and Sidney Kimmel).

128. *Id.*

129. NAT'L INSTS. HEALTH, HISTORY OF CONGRESSIONAL APPROPRIATIONS, 1938–1949, <https://officeofbudget.od.nih.gov/pdfs/FY08/FY08%20COMPLETED/appic3806%20%20transposed%2038%20-%2049.pdf> [<https://perma.cc/TWL4-EWZM>].

130. See NAT'L CANCER INST., 1972 FACT BOOK 22 (1972), <http://www.cancer.gov/about-nci/budget/fact-book/archive/1971-fact-book.pdf> [<https://perma.cc/DQ5T-XGVF>]; *National Cancer Act of 1971*, NAT'L CANCER INST., https://ntp.cancer.gov/timeline/flash/milestones/M4_Nixon.htm [<https://perma.cc/3S23-W4NZ>].

131. *NCI Budget and Appropriations*, NAT'L CANCER INST. (last updated Nov. 28, 2017), <http://www.cancer.gov/about-nci/budget> [<https://perma.cc/S4FZ-5QQB>].

132. *HHS FY2016 Budget in Brief*, HHS.GOV, <http://www.hhs.gov/about/budget/budget-in-brief/nih/index.html> [<https://perma.cc/XM3M-2RKL>].

133. *NCI Budget Fact Book*, NAT'L CANCER INST., <http://www.cancer.gov/about-nci/budget/fact-book> [<https://perma.cc/HU42-R2JY>]. NIH defines “intramural research” as research “done by scientists employed by the Federal government,” while extramural research “is done across the United States and in some foreign countries by investigators who have been awarded grants through the NIH grant program.” *Frequently Asked Questions About NHGRI Research*, NAT'L INSTS. HEALTH, <https://www.genome.gov/12011002/about-nhgri-research-fact-sheet/> [<https://perma.cc/Y2DB-CJ44>].

134. See G. Steven McMillan, Francis Narin & David L. Deeds, *An Analysis of the Critical Role of Public Science in Innovation: The Case of Biotechnology*, 29 RES. POL'Y 1, 6 (2000) (calculating the National Cancer Institute to be the largest paper-producing research organization in the United States, apart from Harvard University, and the single greatest source of funding acknowledgements in published materials).

135. See Robert L. Grossman et al., *Toward a Shared Vision for Cancer Genomic Data*, 375 NEW ENG. J. MED. 1109, 1111 (2016) (“The recent explosion of cancer genome

public and private funding mechanisms shows a lack of coordination between the two systems, and even within them.¹³⁶ Cancer information seems to be increasingly siloed in public and private granaries, and even then, compartmentalized and divided by discipline.¹³⁷ Nixon's War on Cancer was perhaps the first attempt to break down these barriers, by establishing the National Cancer Advisory Board ("NCAB"), "a presidentially appointed committee of 18 members, to assist NCI in developing its programs."¹³⁸ But, historically, the NCAB has included university research professors at the expense of industry representatives.¹³⁹ Today, the board consists entirely of academics and clinicians.¹⁴⁰ Within the NCI, true coordination between the public and private sectors remains pervasively weak.¹⁴¹ And Nixon's War on Cancer, like other wars fought by him, has been widely viewed as a failure.¹⁴²

analysis has left in its wake a trail of data ambiguity that must be addressed and rectified.").

136. See NAT'L CANCER INST., THE FUTURE OF CANCER RESEARCH: ACCELERATING SCIENTIFIC INNOVATION (PRESIDENT'S CANCER PANEL ANNUAL REPORT 2010-2011) ii (2012) <https://deainfo.nci.nih.gov/advisory/pcp/annualreports/pcp10-11rpt/FullReport.pdf> [<https://perma.cc/2KN7-VXAB>]. ("In 2012, more than 40 years after passage of the [1971 National Cancer] Act, neither the scope of the [National Cancer Program] nor its leadership, coordination, or participants have ever been clearly defined. As a result, the NCP lacks a national vision and priorities, and the cancer research effort continues to be fragmented and largely uncoordinated. The application and dissemination of research advances remains uneven at best.").

137. See Alaina G. Levine, *Blurring the Lines Between Academic and Industrial Cancer Research*, SCIENCE (Mar. 29, 2013), <https://www.sciencemag.org/careers/features/2013/03/blurring-lines-between-academic-and-industrial-cancer-research> [<https://perma.cc/23JG-J7HG>] ("Depending on the type of cancer research, [scientists] can become quite siloed in academia," says [Jennifer] Malin Companies rely on collaboration across disciplines such as cancer biology, oncology, cellular biology, chemistry, and biotechnology." (first alteration in original)).

138. *National Cancer Act of 1971*, NAT'L CANCER INST., <http://www.cancer.gov/about-nci/legislative/history/national-cancer-act-1971> [<https://perma.cc/E8VS-DQH9>].

139. This conclusion is based on a review of the meeting minutes of the National Cancer Advisory Board from 1980 until today. See *National Cancer Advisory Board Meetings*, NAT'L CANCER INST., <http://deainfo.nci.nih.gov/advisory/ncab/ncabmeetings.htm> [<https://perma.cc/KDX5-5X3D>]; *NCAB Archive Meeting Information*, NAT'L CANCER INST., <http://deainfo.nci.nih.gov/advisory/ncab/archive/index.htm> [<https://perma.cc/DF7V-C9VG>].

140. See NATIONAL INSTITUTES OF HEALTH, NATIONAL CANCER INSTITUTE, NATIONAL CANCER ADVISORY BOARD (May 2017), <http://deainfo.nci.nih.gov/advisory/ncab/ncabpublicroster.pdf> [<https://perma.cc/MG7E-NVUC>].

141. See PRESIDENT'S COUNCIL OF ADVISORS ON SCI. & TECH., PRIORITIES FOR PERSONALIZED MEDICINE 2 (Sept. 2008), <https://www.hsdl.org/?view&did=234678> [<https://perma.cc/H9ME-QJD5>]. ("Historically, development [of genomics-based molecular diagnostics] has been the purview of industry rather than of government-supported academic science, which has instead focused on discovery research. . . . [I]n order to move genomic discoveries to practical application, public investment in the

Recently, however, public and private funders have been united in calls to solve these coordination problems through true public-private partnerships.¹⁴³ Indeed, “[n]early all major recent policy cancer research funding and policy initiatives have emphasised the public–private partnership route.”¹⁴⁴ Broadly defined, public-private partnerships are joint efforts between private industry and public agencies to achieve public goals.¹⁴⁵ They are, in many ways, an explicit recognition that certain problems are so large and unwieldy that neither sector has the appropriate incentives—owing to short-term political and shareholder appeasement—to work on the task alone.¹⁴⁶ Public-private partnerships may be publicly funded by an agency, as a lure for the expertise and efficiency of the private sector.¹⁴⁷ Or they may seek private funding in exchange for profitable participation in public (and publicity generating) work.¹⁴⁸ They also differ from other forms of public engagement with private entities, such as grants, prizes, or tax credits, in that they seek not just expertise but also organizational input and elbow grease from private participants.¹⁴⁹

translational research necessary to validate genomic/clinical correlations must be increased and also coordinated with industry investment.”).

142. See Alison Abbott, *On the Offensive*, 416 NATURE 470, 470 (2002) (“[S]ince President Richard Nixon launched his ‘war on cancer’ in 1971, a minority of experts has [sic] even begun to suggest that cancer has become science’s Vietnam.”).

143. See PRESIDENT’S COUNCIL OF ADVISORS ON SCI. & TECH., *supra* note 141, at 2; Bagley & Tvarnø, *supra* note 26, at 376 (discussing Bristol-Myers Squibb’s formation of the International Immuno-Oncology Network).

144. Eckhouse et al., *supra* note 92, at 31.

145. Gian Luca Burci, *Public/Private Partnerships in the Public Health Sector*, 6 INT’L ORGS. L. REV. 359, 361 (2009) (defining a public-private partnership as a “long-term collaborative arrangement among a group of diverse stakeholders, some of which of a public nature (e.g., government agencies and intergovernmental organizations) and others of a private nature (e.g., non-governmental organizations, private commercial companies, research institutes, professional associations, etc.) to jointly pursue a discreet public health goal”); Vertinsky, *supra* note 26, at 1515 n.23 (similarly defining public-private partnerships). In contrast to this Article, other commentators have included public universities on the public side of this ledger. See, e.g., Bagley & Tvarnø, *supra* note 26, at 376 n.13 (“[W]e define ‘public nature’ to include public universities and research institutes, and those private universities and research institutes that receive government funding for medical research.”).

146. See Bagley & Tvarnø, *supra* note 26, at 376–77 (“Partnerships of this sort . . . are designed to address the market’s failure to incentivize private firms to develop and market drugs that would not be profitable without government or NGO funding.”); *id.* at 379 (describing shareholder pressure on the current pharmaceutical development system).

147. See Vertinsky, *supra* note 26, at 1533 (describing public-private partnerships as sharing expertise).

148. See *id.* at 1532–33 (describing private incentives for public-private partnerships).

149. See Hemel & Ouellette, *supra* note 11, at 315–26 (describing prizes, patents, grants, and R&D tax incentives as one-way incentives for the production of goods).

Apart from cancer, these form part of a larger story of similar, recent partnerships in the health innovation space.¹⁵⁰

To be sure, public-private partnerships, as an organizational structure, are not new. Public-private partnerships have been deployed in attempts to solve large-scale infrastructure problems since at least the early nineteenth century.¹⁵¹ Where neither the public fisc nor the private sector can afford to fund the establishment of a project for the common good, public-private partnerships strive to marry public governance with market efficiencies.¹⁵² Ideally, at least. Public-private partnerships, like all forms of economic organization, suffer from their own problems, such as culture mismatches: “a lack of trust between the two groups, with resistance on both sides to share fully with the other, leading to informational asymmetry.”¹⁵³ Public-private partnerships often, despite their name, suffer from a lack of public accountability, with decisions between government and private actors cloistered in the shadows of appropriation decisions.¹⁵⁴ And perhaps most alarmingly, public-private partnerships often fail to fulfill the very public values under which they are established: public access to their products, market competition among private participants, and community representation.¹⁵⁵ For these reasons, Martha Minow has partially criticized the trend toward privatizing public governance as loosing upon the world “dangers of divisiveness and [a] loss of common institutions.”¹⁵⁶ Nonetheless, as with cancer research, public-private partnerships have recently been proposed as

150. See, e.g., Kevin Outterson et al., *Accelerating Global Innovation to Address Antibacterial Resistance: Introducing CARB-X*, 15 NATURE REV. DRUG DISCOVERY 589, 589 (2016) (announcing CARB-X, a public-private partnership to combat antibiotic resistance). See generally Vertinsky, *supra* note 26 (discussing the Alzheimer’s Disease Neuroimaging Initiative, the Accelerating Medicines Partnership, and Arch2POCM).

151. Minow, *supra* note 8, at 1237.

152. See CHARLES L. GLENN, *THE AMBIGUOUS EMBRACE: GOVERNMENT AND FAITH-BASED SCHOOLS AND SOCIAL AGENDAS* 25 (2000) (“New forms of competition are likely to result from such a devolution of responsibility from government to mediating structures, and this could produce some efficiencies.”).

153. Jay P. Kesan & Carol Hayes, *Thinking Through Active Defense in Cyberspace*, in PROCEEDINGS OF THE WORKSHOP ON DETERRING CYBERATTACKS: INFORMING STRATEGIES AND DEVELOPING OPTIONS FOR U.S. POLICY 338 (2010).

154. See Minow, *supra* note 8, at 1259–63 (discussing accountability issues with public private partnerships).

155. See *id.* at 1246.

156. See *id.* at 1246. Yeats has vividly imagined the collapse of systems and society. William Butler Yeats, *The Second Coming*, in THE COLLECTED POEMS OF W. B. YEATS 187 (Richard J. Finneran ed. 1996) (“Turning and turning in the widening gyre / The falcon cannot hear the falconer; / Things fall apart; the centre cannot hold; / Mere anarchy is loosed upon the world, / The blood-dimmed tide is loosed, and everywhere / The ceremony of innocence is drowned . . .”).

solutions to particularly heavy public policy problems including education,¹⁵⁷ health care,¹⁵⁸ and cybersecurity,¹⁵⁹ to name a few. In an age of dwindling public research dollars, affixing “-private” to public research programs at least provides hope that other actors will make up for research and development shortfalls.

As currently structured, the Cancer Moonshot is just such a public-private partnership.¹⁶⁰ The recently passed 21st Century Cures Act authorized \$1.8 billion in funding, primarily to engage and encourage pharmaceutical developers to turn their own resources toward studying cancer's complexity, disclosing that information to the public, and bringing potential treatments to trial.¹⁶¹ Organizationally, the Moonshot will be overseen by the Cancer Moonshot Task Force, an entity broadly focused on seven major problems with cancer research today: clinical trial enrollment, immunology and prevention, risk assessment, pediatric cancers, precision medicine, tumor evolutionary, and—importantly for this Article—data sharing.¹⁶² Unlike the NCAB, however, the Task Force has commissioned—and will likely commission in the future—implementation reports from both the public and private sectors. One such working group, the Enhanced Data Sharing Working Group, lists members from three different federal agencies, as well as Amazon, Google, Microsoft, and a variety of academic research institutions.¹⁶³ Using these working groups, the Cancer Moonshot will ideally select several discrete projects for joint completion between private industry and the NCI.¹⁶⁴ Furthermore, the Task Force will explicitly discuss—beyond the scientific hurdles they face—creative ways to fund their goals, and bring them—profitably—into the private sector.¹⁶⁵

157. Minow, *supra* note 8, at 1231–32 (describing several facets of public-private partnerships in education).

158. John V. Jacobi, *The Ends of Health Insurance*, 30 U.C. DAVIS L. REV. 311, 402 (1997) (describing a trend toward public-private partnerships in health care).

159. Kesan & Hayes, *supra* note 153, at 337–38 (describing the move toward cybersecurity Information Sharing and Analysis Centers).

160. See *FACT SHEET*, *supra* note 8.

161. See *id.*; 21st Century Cures Act, Pub. L. No. 114-255, § 1001(b)(4)(c), 130 Stat. 1033, 1040–41 (2016).

162. See Memorandum, *supra* note 5.

163. See CANCER MOONSHOT BLUE RIBBON PANEL REPORT 2016, 62 (2016) <https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel/blue-ribbon-panel-report-2016.pdf> [<https://perma.cc/Y9AX-CGVD>].

164. See Memorandum, *supra* note 5.

165. See *id.* (charging the Task Force with, among other things, contemplating “targeted incentives [such as] private sector efforts from industry and philanthropy”).

The Moonshot goes beyond the mere funding of new research: it also seeks to use the imprimatur of non-research focused federal agencies as a lure for private participation in the project. The U.S. Patent and Trademark Office (“PTO”), for example, recently announced a program, “Patents 4 Patients,” that seeks to fast-track patent applications directed to cancer immunotherapies—a research area of particular interest to the Moonshot.¹⁶⁶ The program, originally slated to expire in June 2017, has since been extended—by the same statute creating the Moonshot, the 21st Century Cures Act.¹⁶⁷ The Moonshot also employs the FDA, in coordination with the NIH to review research into the connection between cancer and stem cells, providing—in theory—a coordinated approach to moving basic research from the laboratory to the clinic.¹⁶⁸

More broadly, Cancer Moonshot researchers and industry participants realize that their efforts are unlikely to produce a silver bullet: a single pill or vaccine set to cure cancer.¹⁶⁹ Rather, they recognize that the primary effort of the Moonshot, for all of the Working Groups involved, is to produce, share, and utilize robust information about cancer. In a speech at Duke University, former Vice President Biden noted that the purpose of the Moonshot was to “seek greater collaboration, greater sharing of information . . . [,] breaking down some of the research that is trapped inside of silos, and share information with drug companies, and drug companies being willing to be more forthcoming in sharing information.”¹⁷⁰ The heads of both the NCI and NIH similarly published a letter in the *New England Journal of Medicine*, noting that a “goal of the initiative will be to overcome barriers that often prevent collaboration and information sharing among the various groups working to defeat cancer and that limit access to state-of-the-art research.”¹⁷¹ And Greg Simon, a former executive at Pfizer and the current executive director of the Moonshot, wrote an opinion piece for *Medium* promising that the Moonshot would “use the power of *data* to generate real solutions

166. *Patents for Patients*, USPTO, <https://www.uspto.gov/patent/initiatives/patent-application-initiatives/patents-4-patients> [<https://perma.cc/64L2-JC9J>].

167. Extension of the Cancer Immunotherapy Pilot Program, 82 Fed. Reg. 28,645, 28,645–46 (June 23, 2017).

168. 21st Century Cures Act, Pub. L. No. 114-255, § 1001(b)(4)(D), 130 Stat. 1041 (2016).

169. See Simon, *supra* note 7 (“For one thing, there’s the matter of ‘cancer’ not being a single disease, but hundreds of diseases, with ‘cures’ taking many forms.”).

170. Graham, *supra* note 29, at 2.

171. Douglas R. Lowy & Francis S. Collins, *Aiming High—Changing the Trajectory for Cancer*, 374 NEW ENG. J. MED. 1901, 1902–03 (2016).

for treating cancer.”¹⁷² Whether industry agrees remains to be seen.¹⁷³ The key to making the Cancer Moonshot a success, where other efforts have failed, therefore likely lies in structuring the appropriate incentives to produce that data.

II. CANCER'S IP

Understanding that the product of public-private partnerships like the Cancer Moonshot is *data*—for example, protein information for 58,000 patients,¹⁷⁴ the genomic sequences of 600,000 people,¹⁷⁵ or molecular screens of 1.5 million historical cancer cases¹⁷⁶—presents numerous challenges for intellectual property and information policy. Who, if anyone, owns the underlying datasets? Should the information derived from such research be propertized, and if so, by whom? And, concerning public-private partnerships, will private enterprises be sufficiently encouraged to participate, and on what terms?

In particular, efforts to uncover cancer's information present a classic case of Kenneth J. Arrow's information paradox.¹⁷⁷ Although costly and difficult to create, once known information about cancer's mechanisms and modes of treatment can be used freely by anyone.

172. Simon, *supra* note 7 (emphasis added).

173. See David Winwood, *The 'Cancer Moonshot' May Succeed—If We Don't Weaken Patent Protections*, INT'L BUS. TIMES (Aug. 18, 2016, 6:55 PM), <http://www.ibtimes.com/cancer-moonshot-may-succeed-if-we-dont-weaken-patent-protections-opinion-2403922> [<https://perma.cc/9QN5-RVKK>] (preemptively criticizing the Moonshot for weakening patent protection for cancer therapies).

174. Press Release, The White House Office of the Vice President, FACT SHEET: At the Victoria Comprehensive Cancer Ctr., Vice President Biden Announces New Memoranda of Understanding Between the U.S. and Australia, New Funding as Part of Cancer Moonshot (July 16, 2016), <https://obamawhitehouse.archives.gov/the-press-office/2016/07/16/fact-sheet-victoria-comprehensive-cancer-center-vice-president-biden> [<https://perma.cc/QH9F-7H2K>].

175. Mark Warren, *The Cure for Cancer Is Data—Mountains of Data*, WIRED (Oct. 19, 2016, 6:55 AM), <http://www.wired.com/2016/10/eric-schadt-biodata-genomics-medical-research/> [<https://perma.cc/6BMB-Y2EK>].

176. Syapse, *Non-Profit Health Systems Form Cancer Data-Sharing Consortium*, GENOMEWEB (June 2, 2016), <https://www.genomeweb.com/cancer/syapse-non-profit-health-systems-form-cancer-data-sharing-consortium> [<https://perma.cc/Q7L3-Q6L7> (staff-uploaded archive)].

177. Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Inventive Activity*, in *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS* 609, 615 (Universities-National Bureau Committee for Economic Research, Committee on Economic Growth of the Social Science Research Council ed., 1962) (explaining that because information must be shared in order to advertise it to potential purchasers, the seller must either risk transferring his information without compensation or avoid sharing with anyone).

Without some right to the information itself, researchers may be discouraged from developing information about cancer in the first instance.¹⁷⁸ The traditional solution to Arrow's paradox has been intellectual property: government sanctioned property rights to information—namely, the right to exclude others from using that information in the marketplace.¹⁷⁹ This has been no less true in cancer research, where biopharmaceutical developers have typically relied on three forms of intellectual property: patents, trade secrets, and regulatory exclusivities.¹⁸⁰ Used together, these forms of intellectual property give rise to a system of exclusive rights in information about cancer, from the discovery of cancer's information to its use in commercially available treatments.¹⁸¹ But each form of intellectual property has significant shortcomings in the cancer context—legal, temporal, and practical deficiencies that make them less than ideal to develop and use information about cancer. This Section describes these intellectual property regimes and examines their deficiencies.

A. Patents

1. Patentable Subject Matter

In many respects, patents are a societal *quid pro quo*: inventors of new technological advances publicly disclose their creations in exchange for time-limited exclusionary rights to their inventions.¹⁸² At the same time, not all advances are thought to be “worth to the public

178. See *id.* at 615; see also Michael J. Burstein, *Exchanging Information Without Intellectual Property*, 91 TEX. L. REV. 227, 232–33 (2012) (examining the paradox, and its shortcomings, with respect to biotechnology); Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 126 (1999) (describing the paradox in the context of gene sequences); Ted Sichelman, *Commercializing Information With Intellectual Property*, 92 TEX. L. REV. SEE ALSO 35, 42–44 (2013) (further examining Burstein's work in the biotechnology context).

179. Dan L. Burk & Brett H. McDonnell, *The Goldilocks Hypothesis: Balancing Intellectual Property Rights at the Boundary of the Firm*, 2007 ILL. L. REV. 575, 585 (“By publicly disclosing technical information, while protecting it by exclusivity, patents circumvent the Arrow paradox.”); Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 81 n.15 (1994) (“Indeed, patents in general protect the licensor's property so that she can confidently offer it for sale. In other words, patents solve Arrow's Paradox.”).

180. See Arti K. Rai & Jacob S. Sherkow, *The Changing Life Science Patent Landscape*, 34 NATURE BIOTECHNOLOGY 292, 292–93 (2016) (discussing the historical use of these protections); Jacob S. Sherkow, *Protecting Products Versus Platforms*, 34 NATURE BIOTECHNOLOGY 462, 462–63 (2016) (discussing these protections for biotechnology companies, generally).

181. See *infra* Part II.A–C.

182. See Sherkow, *supra* note 21, at 865 n.128 and accompanying text (reviewing the history of this terminology).

the embarrassment of an exclusive patent.”¹⁸³ Some things, “like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge[,] . . . free to all men and reserved exclusively to none.”¹⁸⁴ To that end, patent law has long prohibited the patenting of “pure” information: mathematical equations, scientific principles, laws of nature, and the like.¹⁸⁵ These discoveries are ineligible for patent protection; they lack, in patent law parlance, patentable subject matter.¹⁸⁶

But separating what constitutes mere information as opposed to a practical application of it has proved to be one of the most difficult—if not *the* most difficult—questions in patent law.¹⁸⁷ Since 2010, the Supreme Court has issued a quartet of opinions attempting to delineate just that difference: *Bilski v. Kappos*;¹⁸⁸ *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*;¹⁸⁹ *Association for Molecular Pathology v. Myriad Genetics, Inc.*;¹⁹⁰ and *Alice Corp. Pty. v. CLS Bank International*.¹⁹¹ In *Bilski*, the Court affirmed the Patent Office’s rejection of a patent application claiming a method of commodities hedging as an unpatentable “concept . . . reduced to a

183. Letter from Thomas Jefferson to Isaac McPherson, (Aug. 13, 1813) in 13 THE WRITINGS OF THOMAS JEFFERSON 326, 335 (Albert Ellery Bergh & Monticello eds., 1904).

184. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

185. *See, e.g.*, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 70–71 (2012) (law of nature); *Gottschalk v. Benson*, 409 U.S. 63, 65 (1972) (mathematical formula); *Funk Bros.*, 333 U.S. at 130 (scientific principle). *See generally* Jacob S. Sherkow, *The Natural Complexity of Patent Eligibility*, 99 IOWA L. REV. 1137, 1144–55 (2014) (describing the contours of what, doctrinally, constitutes patent subject matter).

186. Sherkow, *supra* note 185, at 1139 (describing “patentable subject matter [as] a century-and-a-half old legal doctrine that limits the types of inventions that can be patented”). The doctrine is nominally codified in § 101 of the patent statute: “any new and useful process, machine, manufacture, or composition of matter, or any new useful improvement thereof.” 35 U.S.C. § 101 (2012). But in reality, it is ignored in favor of a long-established common gloss. Sherkow, *supra* note 185, at 1144–45 (discussing 35 U.S.C. § 101).

187. Sherkow, *supra* note 185, at 1140 (discussing the difficulties in applying the doctrine).

188. 561 U.S. 593 (2010).

189. 566 U.S. 66 (2012).

190. 569 U.S. 576 (2013).

191. 134 S. Ct. 2347 (2014). In addition, Justice Breyer’s 2006 dissent in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*—a per curiam dismissal of a writ of certiorari as improvidently granted—further explicated the contours of patent eligibility. 548 U.S. 124, 125–32 (2006) (Breyer, J., dissenting). The Supreme Court’s activity in this area looks diminished, however, after its recent denial of certiorari in another patentable subject matter case. *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 136 S. Ct. 2511 (2016).

mathematical formula.”¹⁹² In *Mayo*, the Court rejected patents directed to a system of measuring the toxicity of certain drugs used to treat Crohn’s disease as merely the application of “well-understood, routine, conventional activity previously engaged in by researchers in the field.”¹⁹³ In *Myriad*, the Court invalidated patents covering versions of several human genes as nothing but a “product of nature.”¹⁹⁴ And in *Alice*, the Court synthesized these cases as essentially encompassing a two-part test: “[f]irst . . . determine whether the claims at issue are directed to . . . patent-ineligible concepts [And second,] ask whether the additional [claim] elements ‘transform the nature of the claim’ into a patent-eligible application.”¹⁹⁵

Unfortunately, these opinions provide little concrete guidance on differentiating unpatentable abstractions from patentable embodiments.¹⁹⁶ What is a patent ineligible concept? For that matter, what is a “concept”? What is a “natural” product?¹⁹⁷ What are “additional” claim elements? What does “transform” mean? How *much* transformation is required to make a discovery simply *eligible* for patent protection? Courts have struggled mightily to apply these principles to the real world.¹⁹⁸ Academic and practitioner commentary on these cases has been withering,¹⁹⁹ and the PTO’s guidance on these cases has been less than illuminating.²⁰⁰

192. *Bilski*, 561 U.S. at 611.

193. *Mayo*, 566 U.S. at 73.

194. *Myriad*, 569 U.S. at 576.

195. *Alice*, 134 S. Ct. at 2355 (quoting *Mayo*, 566 U.S. at 72).

196. See John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1075–91 (2011) (discussing the problems with the Court’s “abstract idea” jurisprudence); Timothy R. Holbrook & Mark D. Janis, *Patent-Eligible Processes: An Audience Perspective*, 17 VAND. J. ENT. & TECH. L. 349, 352, 354–58 (2015) (raising similar questions).

197. See generally Sherkow, *supra* note 185, at 1144, 1155–66 (attempting to answer this question).

198. See Golden, *supra* note 196, at 1081 (“Given the lack of an applicable plain meaning for the term ‘abstract idea,’ a legal realist might hazard that characterization of patent claims as involving ‘abstract ideas’ really is just formal cover for a court’s conclusion that those claims are excessively ‘abstract’ in the sense that they are too broad to be socially justified by whatever innovative contribution has been made.”); Sherkow, *supra* note 185, at 1153 (noting that the Supreme Court’s “invocations of natural ‘laws,’ ‘phenomenon,’ and ‘products’ . . . provides no framework, no formula, and no list of factors to assess their construction”).

199. See, e.g., Bernard Chao, *Moderating Mayo*, 107 NW. U. L. REV. COLLOQUY 423, 424–425 (2012) (surveying the reaction to *Mayo*); Robert R. Sachs, *Punishing Prometheus: The Supreme Court’s Blunders in Mayo v. Prometheus*, PATENTLY-O (Mar. 26, 2012, 8:10 AM), <https://patentlyo.com/patent/2012/03/punishing-prometheus-the-supreme-courts-blunders-in-mayo-v-prometheus.html> [<http://perma.cc/3LHW-QVJ3>] (“Like so many pseudo-sciences in which every phenomenon can be rationalized and in which there is no

These difficulties pose particular problems for patents in the cancer space. Cancer research is a difficult, expensive, and long term enterprise, a substantial product of which is simply information about the natural world.²⁰¹ Where the promise of patents serve as motivation for practical research, ambiguity concerning whether patents in the area are even eligible for protection creates substantial risk for researchers and drug developers alike.²⁰² After *Myriad*, for example, it is unclear whether biopharmaceuticals derived from natural products—a significant component of many cancer therapies—can be patented.²⁰³ At an industry conference following

test that can show the theory to be incorrect, under *Prometheus* seemingly anything can be 'explained' as being unpatentable subject matter.”).

200. See Memorandum from Robert W. Bahr, Deputy Comm'r for Patent Examination Policy, U.S. Patent and Trademark Office, to Patent Examining Corps 6–7 (May 4, 2016), <http://www.uspto.gov/sites/default/files/documents/ieg-may-2016-memo.pdf> [https://perma.cc/8ESN-5EH4] (briefly discussing *Alice* and *Mayo* as examples, but failing to address their analytical process); Kevin E. Noonan, *The Recent PTO Guidance on Subject Matter Eligibility: Lessons*, PATENT DOCS (May 25, 2016), <http://www.patentdocs.org/2016/05/the-recent-pt-guidance-on-subject-matter-eligibility-lessons.html> [https://perma.cc/83B2-CS67] (“It is unclear why [the PTO’s] analysis should not arrive at patent eligibility for using a conventional method with a novel biomarker to produce a novel result The Office also seems to have conflated (or, more kindly, synthesized) the ‘routine, well-understood and conventional’ standard from *Mayo* into the *Myriad* product of nature analysis; while it may be likely that the Supreme Court will one day perform that synthesis, prudence suggests that we let the Court do it any [sic] not have the Office try to help.”).

201. See Abbasi, *supra* note 19, at 384 (“The GDC’s mission is to provide ‘the cancer research community with a unified data repository that enables data sharing across cancer genomic studies’”); Ayanian et al., *supra* note 19, at 2992 (introducing a “new model for studying cancer care,” the collection of “much more detailed data from patients, physicians, and medical records to support more comprehensive analyses of the reasons for variations in treatment and outcomes”); Bamford, et al., *supra* note 19, at 335 (containing an information source of data “extracted from information on 66,634 samples”); Saltz et al., *supra* note 19, at 1910 (“The complexity of cancer is prompting researchers to find new ways to synthesize information from diverse data sources and to carry out coordinated research efforts that span multiple institutions.”).

202. See Lisa Larrimore Ouellette, *Patentable Subject Matter and Non-Patent Innovation Incentives*, 5 U.C. IRVINE L. REV. 1115, 1116 (2015) (noting that some researchers may “find the patent incentive to be dulled by the persistent uncertainty that has plagued patentable-subject-matter doctrine in recent years”).

203. Dan L. Burk, *The Curious Incident of the Supreme Court in Myriad Genetics*, 90 NOTRE DAME L. REV. 505, 510 (2014) (“For thirty years prior to the *Myriad* decision, the Patent Office treated purified macromolecules the way they treated other purified chemicals, as the non-natural product of human ingenuity Overturning three decades of consistent administrative practice would be fairly disruptive.”); Donald Zuhn, *USPTO Issues Guidance for Analyzing Subject Matter Eligibility of Claims Reciting Laws of Nature/Natural Principles, Natural Phenomena or Natural Products*, PATENT DOCS (Mar. 4, 2014), <http://www.patentdocs.org/2014/03/uspto-issues-guidance-for-analyzing-subject-matter-eligibility-of-claims-reciting-laws-of-nature.html> [https://perma.cc/2EB7-FMVV] (discussing the difficulties in assessing “natural” products under the PTO’s § 101 guidance in light of *Mayo* and *Myriad*).

the Supreme Court decisions, Sherry Knowles, former Chief Patent Counsel at GlaxoSmithKline, noted that four out of six of front-line treatments for breast cancer contained Adriamycin (doxorubicin), an analog to a chemical produced in bacteria.²⁰⁴ Accordingly, the patentability of these treatments—and the appetite of their developers to usher similar therapies through clinical trials—is unclear.²⁰⁵

Similarly, diagnostics for assessing the nature of a patient's cancer, and the best treatments for it, are likely to fall afoul of patent eligibility after *Mayo* and *Alice*. Rebecca S. Eisenberg summarized this development as “increasingly clear that most important advances in [diagnostics] lie outside the boundaries of patent-eligible subject matter.”²⁰⁶ More specifically, Bernard Chao recently dissected several patent applications for cancer diagnostics that were rejected at the Patent Office for lacking patentable subject matter.²⁰⁷ These included methods for screening certain proteins associated with lethal cancers, selecting chemotherapy agents based on patients' genetic profiles, and assessing and enhancing an anti-cancer immune response using a sea sponge extract.²⁰⁸ Robert R. Sachs, too, has tabulated data on over 100 patent applications concerning cancer immunotherapies—cancer treatments utilizing the body's own immune system—abandoned in the wake of the Supreme Court decisions.²⁰⁹

204. Donald Zuhn, *Sherry Knowles Addresses Real World Impact of Myriad-Mayo Guidance at BIO Symposium*, PATENT DOCS (Oct. 15, 2014, 11:34 PM), <http://www.patentdocs.org/2014/10/sherry-knowles-addresses-real-world-impact-of-myriad-mayo-guidance-at-bio-symposium.html> [<https://perma.cc/AAT3-P9PY>].

205. *See id.*

206. Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 B.U. J. SCI. & TECH. L. 256, 256 (2015).

207. Bernard Chao & Lane Womack, *USPTO Is Rejecting Potentially Life-Saving Inventions*, LAW360 (Dec. 18, 2014), <http://www.law360.com.nyls.idm.oclc.org/articles/604808/print?section=health> [<https://perma.cc/AJ6K-TZPF> (staff-uploaded-archive)].

208. *Id.*

209. Robert R. Sachs, *Will the USPTO's "Patents 4 Patients" Program Even Make it off the "Cancer Moonshot" Launch Pad?*, BILSKI BLOG (June 30, 2016), <http://www.bilskiblog.com/blog/2016/06/will-the-usptos-patents-4-patients-program-even-make-it-off-the-launching-pad-1.html> [<https://perma.cc/2C7Y-T3W3>]. In connection with the Cancer Moonshot, and partly in response to these criticisms, the PTO has adopted a pilot program, the Cancer Immunotherapy Pilot Program, which fast-tracks certain cancer immunotherapy patent applications. *See, e.g.*, Cancer Immunotherapy Pilot Program, 81 Fed. Reg. 42,328, 42,328–32 (June 29, 2016). But it is unclear how such a program can salvage patent applications that would nonetheless continue to fall outside the scope of patentable subject matter. *See* John T. Aquino, *Attorneys Debate Risk of Cancer "Moonshot" Patent Claims Facing Rejection*, BLOOMBERG LIFE SCI. L. & INDUSTRY REP. (Aug. 30, 2016), <https://www.bna.com/attorneys-debate-risk-n73014447075/> [<https://perma.cc/K8EB-MC2X>] (discussing similar concerns raised by patent attorneys).

The Court's decision in *Alice* particularly obscures the patent eligibility of innovations derived from basic cancer research, even those that have specific, concrete clinical utility. Take, for example, *Esoterix Genetic Laboratories LLC v. Qiagen Inc.*,²¹⁰ a case concerning the patent eligibility of a method for determining whether, through genetic sequencing, certain lung cancers will respond to a particular treatment.²¹¹ In 2003 and 2004, the FDA approved two drugs to treat non-small cell lung cancer, Iressa (gefitinib) and Tarceva (erlotinib), both of which became the gold-standard therapy for the disease.²¹² A significant number of patients, however, developed resistance to the drugs after only short courses of treatment.²¹³ Determining which patients would develop resistance—and how to prevent it—remained an important but unsolved problem following the drugs' approval.²¹⁴ In 2004, researchers at Massachusetts General Hospital and Harvard Medical School determined that certain mutations in a single gene, *EGFR*, were primarily responsible for promoting resistance in patients treated with Iressa or Tarceva.²¹⁵ They also discovered that blocking mutant versions of *EGFR* may prolong patient survival.²¹⁶ The researchers, in turn, obtained a patent on a method to diagnose Iressa and Tarceva resistance: obtain a biopsy sample of a patient and perform genetic sequencing on the sample to determine whether it harbored one of three specific mutations.²¹⁷

Viewed through *Alice*'s looking glass, the patent could be construed both ways. On one side, the patent claimed a particular

210. 133 F. Supp. 3d 349 (D. Mass. 2015).

211. *Id.* at 356–59.

212. Letter from Robert Temple, Dir., Office of Drug Evaluation I, Ctr. for Drug Evaluation & Research, Dep't of Health & Hum. Servs., to Ronald Falcone, Regulatory Affairs Dir. AstraZeneca Pharm. (May 5, 2003), http://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/21-399_IRESSA_Approv.pdf [https://perma.cc/WZR2-8TMH] (determination of application approval); Letter from Robert Temple, Dir., Office of Drug Evaluation I, Ctr. for Drug Evaluation & Research, Dep't of Health & Hum. Servs., to Christine Boisclair, Senior Dir., Glob. Regulatory Affairs, OSI Pharm. (Nov. 18, 2004), http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/21743ltr.pdf [https://perma.cc/92FV-CHP6] (determination of application approval).

213. William Pao et al., *KRAS Mutations and Primary Resistance of Lung Adenocarcinomas to Gefitinib or Erlotinib*, 2 PLOS MED. 57, 58, 61 (2005).

214. *Id.*

215. Thomas J. Lynch et al., *Activating Mutations in the Epidermal Growth Factor Receptor Underlying Responsiveness of Non-Small-Cell Lung Cancer to Gefitinib*, 350 NEW ENG. J. MED. 2129, 2129–30 (2004).

216. Raffaella Sordella et al., *Gefitinib-Sensitizing EGFR Mutations in Lung Cancer Activate Anti-Apoptotic Pathways*, 305 SCI. 1163, 1163 (2004).

217. U.S. Patent No. 7,294,468 (filed Dec. 5, 2005).

diagnostic method for assessing drug resistance using a tangible process—the genetic sequencing of patient tumors for specific mutations—to produce a clinically actionable result. This appears to be an innovation beyond a mere “concept,” as articulated in *Alice*—and, in any event, transforms the information contained in the claim into a practical application of it.²¹⁸ But on the other side, the innovation could also be seen as being simply directed to the concept of genetically sequencing tumors to determine drug resistance. The specific sequences, drugs, and tumors recited in the claims do not, necessarily, turn that basic concept into a practical application. In *Esoterix*, the district court happened to adopt the latter view, concluding that the claims were “directed to a law of nature . . . the correlation between a naturally-occurring mutation in a cancer cell, and the likelihood that a particular type of known pharmaceutical compound will be effective in treating that type of cancer.”²¹⁹ And under *Alice*’s step two, “there was nothing ‘transformative’ . . . that amounts to a novel application of the natural law, or that otherwise warrants patent protection.”²²⁰ Legal analysis like this suggests that the now ambiguous nature of patentable eligibility makes protecting cancer diagnostics—and the information undergirding them—all the more uncertain.

2. The Statutory Bars

In an effort to goad inventors to the Patent Office—and to protect the public from unscrupulous late-comers—patent law requires inventors to timely file for patents on their inventions prior to or soon after disclosing them to the public.²²¹ Because several sections of the patent statute codify this requirement, these strictures are known as the “statutory bars.”²²² While the 2011 Leahy-Smith America Invents Act dramatically changed the textual structure of the statutory bars, their content has remained largely the same for over a century: the patent office will not award patents to inventors who have caused their inventions to be “patented, described in a

218. See *Alice Corp. Pty. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2351, 2630 (2014) (discussing the lack of invention beyond its mere concept).

219. *Esoterix Genetic Labs., LLC v. Qiagen, Inc.*, 133 F. Supp. 3d 349, 358 (D. Mass. 2015).

220. *Id.* at 359.

221. See 35 U.S.C. § 102(a) (2012) (barring patents if the underlying invention had been previously disclosed); Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 152 (2006) (discussing the statutory bars).

222. See Holbrook, *supra* note 221, at 152.

printed publication, or in public use, on sale, or otherwise available to the public” for more than a year prior to filing.²²³

Capturing the statutory bars’ prohibition of early public use within the hands of real-world research has proven slippery. An invention is not publicly used, for purposes of the statute, if it is used “by the inventor himself, or of any other person under his direction, by way of experiment, and in order to bring the invention to perfection”²²⁴ But determining whether a third-party has truly taken an inventor’s “direction” or whether the inventor’s efforts were genuinely for the purposes of “bringing an invention to perfection” are elusive inquiries.²²⁵ This is all the more difficult in today’s research environments, where collaboration is the norm and where technology transfer and non-disclosure agreements among sophisticated parties often obfuscate who, if anyone, acts under the direction of a mythical, sole inventor.²²⁶

In the cancer context, and in the drug-development context generally, the contours of public use comes to a head in clinical trials. Prior to the sale of a new drug in interstate commerce, the FDA requires its manufacturer to demonstrate the drug’s safety and provide “substantial evidence that the drug will have the effect it purports,” typically through clinical trials.²²⁷ The trials themselves, traditionally conducted in three phases of increasing size, are expensive, arduous, multiyear affairs: premarket cancer clinical trials cost, on average, \$39.8 million from start to finish and run between six-and-a-half to eight-and-a-half years.²²⁸ And even after approval, the FDA often requires its manufacturer to engage in “postmarket surveillance” of its product, to ensure its safe and efficacious deployment in the real world.²²⁹

223. 35 U.S.C. § 102(a)(1) (2012). Compare 35 U.S.C. § 102(a)(2) (2012) (awarding a patent to the first inventor to file, for patents filed after March 16, 2013), with 35 U.S.C. § 102(g)(2) (2006) (awarding a patent to the first inventor to invent).

224. *City of Elizabeth v. Pavement Co.*, 97 U.S. 126, 134 (1877).

225. See Mark A. Lemley, *Does “Public Use” Mean the Same Thing It Did Last Year?*, 93 TEX. L. REV. 1119, 1131–32 (2015) (discussing the paradox of “submarine patenting”); Ari Ezra Waldman, *Trust: A Disclosure Model for Patent Law*, 92 IND. L.J. 557, 559, 563–64, 566 (2017) (discussing various difficulties with public use’s “control” element).

226. See Eisenberg, *supra* note 23, at 226–29 (discussing the difficulties conjoining scientific collaboration and statutory bars’ disclosure requirement); cf. Stuart J.H. Graham & Ted Sichelman, *Why Do Start-Ups Patent?*, 23 BERK. TECH. L.J. 1063, 1082 (2008) (discussing the difficulty in detecting breaches of non-disclosure agreements).

227. 21 U.S.C. § 355(d) (2012).

228. Sertkaya et al., *supra* note 90, at 3–3.

229. See Lars Noah, *Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority*, 1997 WIS. L. REV. 873, 879–82 (describing several instances of the FDA’s postmarket surveillance system).

The main product of all of this work is information. Specifically, data on the drug's toxicity to humans and at what dosages; data on how the human body receives and metabolizes the drug; data on whether the drug poses dangers to any special patient populations; data on whether the new drug will interact with any other medications patients are likely take; and importantly, data—volumes and volumes of data—on how clinical treatment groups fared in their diseases' prognoses relative to any control groups.²³⁰ Eisenberg has called this production of information the “structural role” of the FDA: the development of credible information about the effects of drugs.”²³¹

In this sense, experimental clinical trials can be conceived as just that: experiments. Like hypothesis testing, whether a new drug, in fact, works in any scientifically rigorous sense is largely unknown until after clinical trials—the experiments—have been performed.²³² One could therefore be forgiven for thinking that clinical trials necessarily fall under the public-use exception for “experiment[s] in order to bring the invention to perfection.”²³³ But this is not always so. In several cases, courts have invalidated patents covering new drugs because the drugs were deployed in clinical trials for more than a year prior to their patent applications.²³⁴ In *Pronova Biopharma Norge AS v. Teva Pharmaceuticals USA, Inc.*,²³⁵ for example, the U.S. Court of Appeals for the Federal Circuit invalidated Pronova's patent covering

230. See 21 C.F.R. § 314.50(d) (2011) (enumerating the technical data required for a New Drug Application).

231. Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 347 (2007).

232. See generally S.J. Cutler et al., *The Role of Hypothesis Testing in Clinical Trials*, 19 J. CHRONIC DISEASE 857 (1965) (establishing this experimentalist view of clinical trials).

233. *City of Elizabeth v. Pavement Co.*, 97 U.S. 126, 134 (1877).

234. See, e.g., *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1375 (Fed. Cir. 2017) (concluding that future sale agreement of finished pharmaceutical product then in clinical trials constituted an “on sale bar” to patentability); *Dey, L.P. v. Sunovion Pharm., Inc.*, 715 F.3d 1351, 1360 (Fed. Cir. 2013) (reversing the district court and concluding that a triable issue of fact remained on whether Sunovion's studies were, in fact, confidential); *Pronova Biopharma Norge AS v. Teva Pharm. USA, Inc.*, 549 F. App'x 934, 942–43 (Fed. Cir. 2013) (reversing the district court and holding the patents invalid); *In re Natures Remedies, Ltd.*, 315 F. App'x 300, 305 (Fed. Cir. 2009) (affirming the patent office rejection of a patent application due to statutory bars raised from the invention being listed in clinical trials); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1374–75 (Fed. Cir. 1998) (affirming the invalidation of patents covering biopsy needles due to the statutory bar triggered by clinical trials). *But see* *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 471 F.3d 1369, 1380–81 (Fed. Cir. 2006) (concluding that the experimental nature of Eli Lilly's testing did not raise a statutory bar); *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1335 (Fed. Cir. 2005) (affirming the district court rejection of Apotex's statutory bars defense while invalidating the patents on other grounds).

235. 549 F. App'x 934 (Fed. Cir. 2013).

Lovaza (omega-3-acid ethyl esters) because its predecessor provided samples of the drug to a clinical hospital for analytical testing with “no agreement restricting use of batches to clinical trials or experiments.”²³⁶ Such preclinical work was an invalidating public use, according to the court: where “a compound is provided without restriction to one highly skilled in the art, that compound’s formulation is disclosed in detail, and the formulation is subject to confirmatory testing, no other activity is needed to render that use an invalidating one.”²³⁷

To be clear, there are numerous cases to the contrary. The Federal Circuit’s decision in *SmithKline Beecham v. Apotex Corp.*²³⁸ offered some clarity to the intersection of these two areas of law, and has provided substantial guidance in the area.²³⁹ But the consequence of decisions like *SmithKline* is unpredictability for pharmaceutical developers.²⁴⁰ Recounting the development of Eli Lilly & Co.’s Straterra (atomoxetine), Christopher M. Holman discussed the difficult choices the company faced in filing its patents in light of uncertainty about the drug’s performance and the public use bar.²⁴¹ In assessing whether to conduct more tests to perfect its claims or to file early on thinner and less scientifically rigorous data, Lilly “had no way of knowing whether the clinical trials would later be construed as

236. *Id.* at 942.

237. *Id.* at 943. With this said, it is unclear whether inventions derived from the *data* of clinical testing are, themselves, subject to patent law’s statutory bars beginning with the clinical trials themselves. That question likely turns on resolving the tension between the data’s confidential nature and patent law’s inherency doctrine, an issue beyond the scope of this discussion. See generally Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM. & MARY L. REV. 371 (2005) (discussing inherency).

238. 365 F.3d 1306, 1316–17 (Fed. Cir. 2004), *vacated en banc*, 403 F.3d 1331 (Fed. Cir. 2004).

239. *Id.* at 1316–17 (rejecting its prior invalidating public use decision and reaffirming that the experiment use exception to the statutory bars only applies where the inventor is testing claimed aspects of the invention); see also *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1381 (Fed. Cir. 2006) (concluding that the patents were not invalid because the patent holder “restricted access to the facility and provided full-time security . . . closely monitored and confined the movements of the volunteers . . . [did] not use the [patented] drugs to treat schizophrenic patients, but merely to test the safety and efficacy of the drug [sic]”); *Janssen Pharmaceutica, N.V. v. Eon Labs Mfg., Inc.*, 134 F. App’x 425, 431 (Fed. Cir. 2005) (concluding patent was not invalid, because “the [clinical] trials were closely monitored by [the patent holder]; there was a strict protocol that was to be followed[;] . . . participating physicians were not able to dispense [the patented] capsules to anyone they wished[;] . . . any unused drug had to be returned to [the patent holder]; . . . [the patent holder] received no money for these trials[;] and there were only twenty-eight people involved in the study”).

240. See Christopher M. Holman, *Unpredictability in Patent Law and Its Effect on Pharmaceutical Innovation*, 76 MO. L. REV. 645, 657–61 (2011).

241. *Id.*

public use invalidating their patent.”²⁴² It ultimately chose the latter—and then ironically lost its patent in future challenges for failing to include *enough* experimental data.²⁴³

Like Lilly’s case with Straterra, the standard practice in the pharmaceutical industry is to file for patents as early as possible, specifically to avoid the statutory bars.²⁴⁴ Ideally, however, this practice seems undesirable in the cancer context. Early, preclinical experimental data in the cancer context is notoriously unreliable.²⁴⁵ And in several notable instances, patent claims covering certain cancer drugs or diagnostics have been, literally, scientifically disproven in later clinical trials.²⁴⁶ Early patents covering Avastin (bevacizumab), for example, claim its use in treating breast cancer, either alone, or in combination with other therapies.²⁴⁷ But without the benefit of robust clinical trials, these patents relied on genetic linkage studies or preclinical mouse models.²⁴⁸ When actual clinical trials on Avastin and breast cancer were completed in 2008, the results were either statistically insignificant—or, for one trial, actually demonstrated a *decrease* in patient survival.²⁴⁹

Avastin demonstrates that the statutory bars encourage expansive patents on methods of and drugs for cancer treatment that may not necessarily work. More broadly, this rush to patent essentially irreproducible science bears “numerous social costs affecting drug research, scientific integrity, and patient safety.”²⁵⁰ But beyond these costs, the specter of clinical trials raising patent law’s statutory bars dissuades cancer researchers from perfecting their innovations—or even testing to see whether they work—before patenting. Indeed, a patent system that works in this manner is antagonistic, not complementary, to the regulatory system: if the purpose of requiring clinical trials is “the development of credible information about the effects of drugs,”²⁵¹ the need for early patenting

242. *Id.* at 659.

243. *Id.* at 661.

244. Sherkow, *supra* note 21, at 883 (discussing this phenomenon).

245. See C. Glenn Begley & Lee M. Ellis, *Raise Standards for Preclinical Cancer Research*, 483 NATURE 531, 532 (2012) (describing some of the difficulties with preclinical cancer research).

246. Sherkow, *supra* note 21, at 886–89 (discussing Avastin).

247. *Id.* at 896.

248. *Id.* at 883–84.

249. *Id.* at 896–97.

250. *Id.* at 899.

251. Eisenberg, *supra* note 231, at 347.

in areas like cancer actively dissuades it.²⁵² A patent system that mandates cheap and easy patenting in the early stages of research fails to encourage the development of that most important aspect of cancer research: information.

3. Patent Expiration

Cancer is a disease of time. It often takes years to kill its victims.²⁵³ In other instances, it lurks until old age.²⁵⁴ And knowing whether one has, in fact, survived often takes years of waiting.²⁵⁵ Cancer research, too, has a fundamental problem of time: how long should researchers wait until they have determined that something does, or does not, cause cancer? How long of a window should be used to assess whether a treatment has worked? Simply measuring the survival rates of cancer sufferers under a particular treatment poses particularly difficult questions—scientific questions concerning statistics and methodology.²⁵⁶ For example, diagnosing cancer earlier may lead to the erroneous conclusion that a given treatment prolongs survival.²⁵⁷ Similarly, simply measuring “overall mortality,” may incorporate age related biases: “[a] nation with a larger fraction of older citizens will seem more cancer-ridden than a nation with younger citizens, even if actual cancer mortality has not changed.”²⁵⁸ With appropriate statistical adjustments to measuring mortality rates, a robust analysis of treatments takes years, and sometimes, decades worth of data.

But patents don't last forever. Since 1995, they only last from when they were issued until twenty years after the date they were filed.²⁵⁹ And because patents on biopharmaceuticals are often filed at

252. See Budish et al., *supra* note 22, at 2045–46 (discussing the role of the patent term on research incentives).

253. See *SEER Stat Fact Sheets: Cancer of Any Site*, NAT'L CANCER INST., <http://seer.cancer.gov/statfacts/html/all.html> [<http://perma.cc/AV6L-AKJK>] (noting that 66.9% of cancer patients survive at least five years after diagnosis).

254. MUKHERJEE, *supra* note 12, at 44 (“Cancer is an age-related disease—sometimes exponentially so.”).

255. *Id.* at 148 (“[Childhood leukemia patients] remained in remission not just for weeks or months, but for years. They came back, year after year, and sat nervously in waiting rooms at trial centers all around the nation.”).

256. See *id.* at 229–30 (describing some of these difficulties).

257. *Id.* at 230.

258. *Id.*

259. Uruguay Round Agreements Act, Pub. L. No. 103-465, Sec. 532, § 154(a)(2), 108 Stat. 4809, 4984 (1994) (codified as amended at 35 U.S.C. § 154(a)(2) (2012)) (“Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States . . .”).

their genesis—not after thorough clinical trials have been conducted—patents often begin to expire during the drug discovery–approval process, before the treatment’s manufacturer can sell its product in the marketplace.²⁶⁰ Since it takes, on average, ten to fifteen years for a biopharmaceutical developer to discover and move a new treatment through regulatory approval,²⁶¹ there is the possibility that little of a patent’s twenty-year lifespan will be left by the time the drug reaches patients.²⁶² In 1984, Congress recognized this difficulty in the Drug Price Competition and Patent Term Restoration Act (more popularly known as the Hatch-Waxman Act), which granted some term extensions to patents covering drugs that are the subject of clinical trials.²⁶³ Nonetheless, the Hatch-Waxman Act limits these extensions to a total of fourteen years of patent life—on average, three years shorter than their nonregulated counterparts.²⁶⁴

This system of early patent filing, combined with limited term extensions, encourages research and development companies to reorient their clinical trials around expediting their drugs’ approval times.²⁶⁵ This has only been exacerbated by patent law’s recent move to a “first to file” regime, further encouraging researchers—or, more appropriately, the attorneys in researchers’ intellectual property departments—to file for patents as soon as they become apprised of even nascent discoveries.²⁶⁶ This presents some particular problems in the cancer context given the long times needed to otherwise measure

260. See Eisenberg, *supra* note 231, at 351–52.

261. REBECCA A. ENGLISH, YEONWOO LEBOVITZ & ROBERT B. GIFFIN, TRANSFORMING CLINICAL RESEARCH IN THE UNITED STATES: CHALLENGES AND OPPORTUNITIES: WORKSHOP SUMMARY 12 (2010).

262. See Eisenberg, *supra* note 231, at 352 (noting that the average effective life of a patent covering an invention subject to clinical trials is 11.7 years).

263. Pub. L. No. 94-417, sec. 201, § 156, 98 Stat. 1585, 1598–4602 (1984) (codified as amended at 35 U.S.C. § 156 (2012)); see also Eisenberg, *supra* note 231, at 352.

264. Eisenberg, *supra* note 231, at 352 (parsing 35 U.S.C. §§ 156(c), (g)(1)(B), (g)(6) (2012)).

265. Ian Ayres & Lisa Larrimore Ouellette, *A Market Test for Bayh-Dole Patents*, 102 CORNELL L. REV. 271, 278 (2017) (“[T]he need for a lengthy exclusivity period skews medical research toward diseases for which clinical trials can be conducted more quickly.”); Budish, Roin & Williams, *supra* note 22, at 2044 (discussing that firms attempt to maximize patent terms in “cancer research, where clinical trials—and hence, project durations—are shorter for late-stage cancer treatments relative to early-stage treatments or cancer prevention”); Vertinsky, *supra* note 26, at 1523 (“Strong patent rights at early stages of the discovery and development process reinforce the model of placing early and secret bets on potential drug candidates that are pushed through a proprietary development process.”).

266. Timothy R. Holbrook, *Patent Disclosures and Time*, 69 VAND. L. REV. 1459, 1466 (2016) (discussing this race to patent following the 2011 Leahy Smith America Invents Act).

mortality rates. For cancer clinical trials, therefore, biopharmaceutical developers often rely not on mortality endpoints but on so-called surrogate endpoints, or physiological proxies that are “*reasonably likely* to predict clinical benefit.”²⁶⁷ These include a reduction in tumor size, the amount of time it takes for a cancer to progress to a later “stage,” the amount of time until the average patient discontinues treatment, or the continuing presence or absence of cancer-related biomarkers.²⁶⁸

Unfortunately, however, measuring many of these surrogate endpoints within the context of rapidly expiring patents is only practically feasible in late-stage cancers.²⁶⁹ As a result, pharmaceutical developers tend to focus their efforts on clinical trials that can be deployed among longer—and more hopeless—sufferers of the disease.²⁷⁰ This has the pernicious consequence of encouraging “private firms [to] invest more in late-stage cancer drugs—and *too little* in early-stage cancer and cancer prevention drugs—because late-stage cancer drugs can be brought to market comparatively quickly.”²⁷¹ A 2015 study in the *American Economic Review* calculated the effect of these incentives on short-termism in cancer research: a roughly 8.7% decrease in R&D funding for every ten percent *increase* in five-year survival rates.²⁷² Furthermore, from 1973 to 2011, there appeared to be *no* privately-funded clinical trials with investigations of longer than twenty years—that is, beyond the patent term.²⁷³ Research-and-development patterns accordingly skew toward later-stage cancer drugs and speedier clinical trials.²⁷⁴ And the

267. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CLINICAL TRIAL ENDPOINTS FOR THE APPROVAL OF CANCER DRUGS AND BIOLOGICS 2 (May 2007), <http://www.fda.gov/downloads/Drugs/Guidances/ucm071590.pdf> [<https://perma.cc/3UDP-DZPX>]; see also Budish et al., *supra* note 22, at 2081 (discussing the incentive distortions of surrogate endpoints).

268. See U.S. FOOD & DRUG ADMIN., *supra* note 267, at 6–11.

269. See Thomas R. Fleming, *Surrogate Endpoints and FDA's Accelerated Approval Process*, 24 HEALTH AFFAIRS 67, 68 (2005) (discussing difficulties in using surrogate endpoints for earlier stage diseases); Victor G. De Gruttola et al., *Considerations in the Evaluation of Surrogate Endpoints in Clinical Trials: Summary of a National Institutes of Health Workshop*, 22 CONTROLLED CLINICAL TRIALS 485, 487 (2001) (discussing advanced stage diseases as “situations where trials using clinical endpoints are not feasible or cannot be carried out efficiently”); Ross L. Prentice, *Surrogate Endpoints in Clinical Trials: Definition and Operational Criteria*, 8 STAT. MED. 431, 434–36 (1989) (describing this effect on “advanced” breast cancer).

270. Budish et al., *supra* note 22, at 2045.

271. *Id.*

272. *Id.* at 2068.

273. *Id.* at 2074.

274. *Id.*

magnitude of the effect is enormous: for “US cancer patients diagnosed in 2003 [for example the] longer commercialization lags required for non-hematologic cancers generated around 890,000 lost life-years.”²⁷⁵

Viewed from a greater altitude, this focus on later-stage cancer with shorter clinical trials fails to generate some of the most important information about cancer—specifically, long-term data on how to slow, stop, or prevent early stage cancer from progressing into later stages of the disease. With the dramatic differences in survival rates between early and late stage cancer, information about early cancers is likely to have a greater clinical benefit to larger numbers of people.²⁷⁶ And given cancer’s predilection to mutate and evolve over time, and through different courses of treatment, information concerning halting early stage cancers is likely to produce more information about cancer, generally.²⁷⁷ Patents’ time constraints also discourage longer-term research into preventing cancer—likely the most effective strategy in “curing” the world of the disease.²⁷⁸ Instead, the rapidly expiring patent grant has encouraged development about only surrogate endpoints, which may not be clinically valid.²⁷⁹ While

275. *Id.* at 2081. That is, that the clinical detriment of studying late stage—and more likely untreatable cancers—as opposed to early stage ones, could have improved aggregate clinical outcomes by 890,000 life years. *Id.*

276. See J.J. Ott, A. Ullrich & A.B. Miller, *The Importance of Early Symptom Recognition in the Context of Early Detection and Cancer Survival*, 45 *EURO. J. CANCER* 2743, 2743 (2009) (reviewing the medical literature for the benefit of early cancer detection).

277. See, e.g., Ding et al., *supra* note 98, at 506 (deriving clinical information from tumor evolution in leukemia); Siân Jones et al., *Comparative Lesion Sequencing Provides Insights Into Tumor Evolution*, 105 *PROC. NAT’L ACAD. SCI. USA* 4283, 4286 (2008) (“Mutations thereby act as a clock, providing information similar to that obtained through the use of sequence divergence to assess the relatedness of organisms or cells during evolution or development.”); Fumiaki Sato, Shigehira Saji & Masakazu Toi, *Genomic Tumor Evolution of Breast Cancer*, 23 *BREAST CANCER* 4, 6 (2016) (noting that a “series of genomic aberrations would occur in the early stage of mammary carcinogenesis”).

278. Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 *UCLA L. REV.* 672, 752 (2014) (“Indeed, there are certain types of drugs that firms will rarely develop because the twenty-year patent term is too short given the amount of time it takes to complete their R&D—including early-stage and preventative treatments for cancer and Alzheimer’s disease.”).

279. See TOMASZ BURZYKOWSKI, GEERT MOLENBERGHS & MARC BUYSE, *THE EVALUATION OF SURROGATE ENDPOINTS 2–3* (2005) (“More than ever is there a strong drive to search for and evaluate potential surrogate markers and surrogate endpoints for randomized clinical trials.”); Fleming, *supra* note 269, at 68; Thomas R. Fleming & John H. Powers, *Biomarkers and Surrogate Endpoints in Clinical Trials*, 31 *STAT. MED.* 2973, 2982 (2012) (“Using biomarkers as surrogate endpoints often is motivated by interests to reduce the size and duration of definitive clinical trials However, a rigorous evidence based justification should be provided in any setting where use of biomarkers as surrogate

validating these endpoints or providing better ones through public research is likely to produce large social returns, the time-limited nature of patents is not likely to encourage private investment in their validation.²⁸⁰

B. Trade Secrets

As the name suggests, trade secrets comprise confidential information important in business or trade.²⁸¹ Once solely creatures of state law, trade secrets as instruments of intellectual property recently became federal causes of action with the 2016 enactment of the Defend Trade Secrets Act.²⁸² Nonetheless, the substantive differences between the bulk of state trade secret laws and their federal counterpart are relatively few.²⁸³ Today, broadly generalized, trade secret law protects “financial, business, scientific, technical, economic, or engineering information” that “derives independent economic value . . . from not being generally known to . . . the public,”²⁸⁴ and for which the owner has taken “reasonable measures to keep such information secret.”²⁸⁵ The public is free to attempt to identify trade secrets through public means—by, for example, reverse engineering a proprietary product—but owners of trade secrets are protected

endpoints is proposed because the scientific evaluation of benefit and risk needs to be not only timely but also valid and reliable.”); *FDA Facts: Biomarkers and Surrogate Endpoints*, U.S. FOOD & DRUG ADMIN. (July 22, 2016), <http://www.fda.gov/AboutFDA/Innovation/ucm512503.htm> [<http://perma.cc/6PBT-BGFE>] (“Biomarkers and surrogate endpoints alone do not give us the total picture of benefit and risk of a therapy. . . . Despite such caveats, as science and technology advance, it is hoped that the increased use of biomarkers and surrogate endpoints will facilitate the more efficient development of safe and effective medical products.”).

280. See Roin, *supra* note 278, at 752.

281. See 18 U.S.C. § 1839(3) (2012) (defining a trade secret as “all forms and types of financial, business, scientific, technical, economic, or engineering information . . . [that] derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public”).

282. See Defend Trade Secrets Act of 2016, Pub. L. No. 114-153, 130 Stat. 376; Dennis Crouch, *Implementing and Interpreting the Defend Trade Secrets Act*, PATENTLY-O (Apr. 27, 2016), <http://patentlyo.com/patent/2016/04/implementing-interpreting-secrets.html> [<http://perma.cc/QM2Z-632C>] (describing the Defend Trade Secrets Act’s implementation).

283. John Carson & Cameron Cushman, *DTSA Versus UTSA: A Comparison of Major Provisions*, LAW360 (June 8, 2016), <http://www.law360.com/articles/803049/dtsa-versus-utsa-a-comparison-of-major-provisions> [<https://perma.cc/CR5N-7M2F>] (“The DTSA [(Defend Trade Secrets Act)] is modeled in many respects after the UTSA [(Uniform Trade Secrets Act)]. Accordingly, the substantive provisions governing federal actions under the DTSA bear many similarities with those of state laws modeled after the UTSA.”).

284. 18 U.S.C. § 1839(3)(B).

285. *Id.* at § 1839(3)(A).

against confidants disclosing them to others.²⁸⁶ And unlike patents, trade secrets essentially last forever—that is, as long as they remain secret.²⁸⁷

Trade secrets serve as enormously powerful incentives in the development of cancer information. Biopharmaceutical developers often protect entire “libraries” of synthetic molecules as trade secrets, along with preliminary data about the compounds’ molecular targets.²⁸⁸ These libraries “vastly increase[] the scope of potentially useful information available to scientists,”²⁸⁹ including uncovering several fundamental properties of cancer, such as information about certain cellular pathways common in many cancers²⁹⁰ and genetic mutations in others.²⁹¹ Companies developing large, complex biopharmaceuticals as cancer treatments will also frequently guard their manufacturing methods as trade secrets.²⁹² Viewed as protocols—like kitchen recipes—trade secret protection in this area has encouraged the development of information about best practices in a variety of manufacturing processes.²⁹³ In the clinical trial space,

286. See Eisenberg, *supra* note 23, at 194 (“Once [a trade secret] becomes generally known to other scientists through independent discovery, the first discoverer loses protection.”); Reichman & Samuelson, *supra* note 23, at 60 (explaining that reverse-engineered scientific information fits poorly within trade secret law as it “provide[s] innovators and investors with no exclusive property rights”); David A. Rice, *Public Goods, Private Contract and Public Policy: Federal Preemption of Software License Prohibitions Against Reverse Engineering*, 53 U. PITT. L. REV. 543, 557 (1992) (“Other advances in science and technology may gain more limited protection, but cannot be wholly withdrawn from the public domain as a matter of proprietary right. Trade secrets, for example, are not protected against independent discovery or against being ascertained with the aid of reverse engineering.”).

287. Christopher D. Stone, *What to Do About Biodiversity: Property Rights, Public Goods, and the Earth’s Biological Riches*, 68 S. CAL. L. REV. 577, 605 n.76 (1995) (“Distinct from patents, trade secrets protection potentially lasts forever.”).

288. Arti K. Rai et al., *Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery*, 8 YALE J. HEALTH POL’Y L. & ETHICS 1, 4, 7 (2008).

289. *Id.* at 7.

290. See, e.g., A. Lavecchia, C. Di Giovanni & E. Novellino, *STAT-3 Inhibitors: State of the Art and New Horizons for Cancer Treatment*, 18 CURRENT MED. CHEMISTRY 2359, 2359 (2011) (reviewing libraries’ use in discovering role of *STAT3* in cancer).

291. See Denise A. Chan & Amato J. Giaccia, *Harnessing Synthetic Lethal Interactions in Anticancer Drug Discovery*, 10 NATURE REV. DRUG DISCOVERY 351, 352–54 (describing screening for genetic lethality in cancer, generally).

292. See Price & Rai, *supra* note 25, at 1028 (“[T]rade secrecy [is] pervasive in the field of biologics manufacturing.”).

293. See Peter Lee, *Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer*, 100 CAL. L. REV. 1503, 1531–33 (2012) (discussing two case studies of the importance of tacit knowledge); Price & Rai, *supra* note 25, at 1031 (highlighting the importance of tacit information about biologics

potential marketers of cancer treatments also universally treat the raw data from their trials as confidential.²⁹⁴ This practice bears several public health and policy concerns, discussed below,²⁹⁵ but it does encourage sponsors of clinical trials to be expansive—that is, information seeking—about their trials' design and conduct.²⁹⁶ Lastly, the FDA's requirements to engage in post-market surveillance for many cancer therapies may generate additional safety and efficacy data often protected as trade secrets.²⁹⁷ While biopharmaceutical marketers involved in such surveillance have strong incentives not to reveal too much information to the FDA²⁹⁸—lest their drugs be removed from the marketplace—confidentiality imposed on such data invites, at least, a greater measure of candor in its reporting.²⁹⁹

At the same time, trade secrets poorly protect other forms of information—potentially valuable and expensive-to-uncover information—about cancer. Basic information about a cancer treatment's intended—and unintended—molecular mechanisms is virtually impossible to keep as a trade secret once the treatment is disclosed.³⁰⁰ As a result, biopharmaceutical developers have little incentive to engage in further mechanistic research of any treatments once the treatments have been approved by the FDA.³⁰¹ Further, for a

manufacturing); *cf.* HAROLD MCGEE, ON FOOD AND COOKING (2004) (systematically reviewing the best practices of various methods of cooking).

294. Jorge L. Contreras & Liza Vertinsky, *Pre-Competition*, 95 N.C. L. REV. 67, 120 n.279 (2016) (“[T]he vast majority of clinical trials data remains private.”); *see also* Erika Lietzan, *A New Framework for Assessing Clinical Data Transparency Initiatives*, 18 MARQ. INTELL. PROP. L. REV. 33, 37 (2014) (discussing the biopharmaceutical industry's expectation that clinical data information be kept confidential); W. Nicholson Price II & Timo Minssen, *Will Clinical Trial Data Disclosure Reduce Incentives to Develop New Uses of Drugs?*, 33 NATURE BIOTECHNOLOGY 685, 685 (2015) (discussing market disincentives to disclosing clinical trial data).

295. *Infra* notes 305–17 and accompanying text.

296. *See* Richard Simon, *New Challenges for 21st Century Clinical Trials*, 4 CLINICAL TRIALS 167, 168 (2007).

297. *See* Trudo Lemmens & Shannon Gibson, *Decreasing the Data Deficit: Improving Post-Market Surveillance in Pharmaceutical Regulation*, 59 MCGILL L.J. 943, 961–63 (2014) (describing this, in the U.S. and Canada, in the context of adverse event reporting).

298. *See* Price & Minssen, *supra* note 294, at 685 (“[C]linical trial disclosure severely limits the patentability of new uses in both the United States and the European Union.”).

299. *See id.* at 685 (noting the “increased exposure to litigation owing to trolling of [raw clinical trial] data by class-action tort lawyers”); Sherkow, *supra* note 21, at 886–89 (noting the Prempro litigation).

300. Eisenburg, *supra* note 23, at 194 (describing this in the biotechnology context); Reichman & Samuelson, *supra* note 23, at 60 (discussing this in the context of scientific information, generally).

301. Benjamin P. Falit, *Curbing Industry Sponsors' Incentive to Design Post-Approval Trials That Are Suboptimal for Informing Prescribers but More Likely Than Optimal Designs to Yield Favorable Results*, 37 SETON HALL L. REV. 969, 998 (2007) (“When

variety of reasons—including intellectual property reasons—*negative* information about a treatment’s safety and effectiveness gets purposely underdeveloped.³⁰² In particular, developers often intentionally overlook nuances about dosing information for specific patient subgroups—a potentially critical facet of cancer information.³⁰³ And even after approval, marketers of cancer treatments may nonetheless voluntarily disclose important, previously confidential information about their products to medical practitioners and clinicians to inform (and sell) them on the relative superiority of their treatments.³⁰⁴

But apart from trade secrets’ effectiveness, or lack thereof, in promoting the development of information about cancer, they pose several worrisome public health problems. Keeping secret too much information about cancer threatens physicians’ ability to fully understand the treatments they provide to their patients.³⁰⁵ As an example, Myriad Genetics, a breast cancer-gene testing company, has developed a proprietary database of its customers’ DNA sequences, including a repository of “variants of unknown significance” (“VUSs”)—individual mutations in certain genes with no known clinical importance.³⁰⁶ This large storehouse of information, were it

conducting voluntary, non-label-seeking post-approval studies, pharmaceutical companies may have an incentive to use a control that is cheap and provides the best chance of obtaining favorable results, even though a different comparator would be more medically informative.”); *see also* Eisenberg, *supra* note 23, at 194 (discussing the incentive to withhold public disclosure of information to prevent reverse engineering that may terminate the right to a trade secret claim).

302. *See* Sean B. Seymore, *The Null Patent*, 53 WM. & MARY L. REV. 2041, 2051–54 (2012) (discussing reasons why negative information arising from scientific research is underreported); Nicola Jones, *Half of US Clinical Trials Go Unpublished*, NATURE (Dec. 3, 2013), <http://www.nature.com/news/half-of-us-clinical-trials-go-unpublished-1.14286#/b1> [<https://perma.cc/T4MF-Y45W>] (“For those trials that were also published in journals, complete reporting of negative side effects of the drugs—rather than just mentioning common events, for example—occurred 73% of the time in the trials database but only 45% of the time in the publications.”).

303. *See* Sherkow, *supra* note 21, at 892–95 (discussing Plavix’s trials’ as overlooking an important gene variant in patients).

304. *See* Ryan Abbott & Ian Ayres, *Evidence and Extrapolation: Mechanisms for Regulating Off-Label Uses of Drugs and Devices*, 64 DUKE L.J. 377, 391–92 (2014) (discussing pharmaceutical marketers’ promotion of off-label uses supported by clinical trials to physicians).

305. *See* Conley et al., *supra* note 24, at 600; Eisenberg, *supra* note 24, at 720.

306. Conley et al., *supra* note 24, at 599–600; Jacob S. Sherkow & Christopher Thomas Scott, Commentary, *CASE STUDY: Myriad Stands Alone*, 32 NATURE BIOTECHNOLOGY 620, 620 (2014). While Myriad has kept its database secret since 2004, some of its strategy stems from the 2013 loss of many of its important gene-sequence patents in *Ass’n for Molecular Pathology vs. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013). *See id.* at 620. While such a result may seem to normatively promote the patenting of genetic information, data-

public, could be easily mined by clinicians to preliminarily assess the prognoses of patients' with VUSs.³⁰⁷ But its protection as a trade secret means that clinicians treating VUS-harboring patients must labor largely in the dark, and at their patients' risk.³⁰⁸ Similarly, the protection of raw clinical trial data as trade secrets often means a lack of information about rare but significant side effects.³⁰⁹ Allowing clinicians access to this data, especially those treating patients with rare or complex cancers for which data is especially hard to come by, would undoubtedly help their service.³¹⁰

Apart from these public health concerns, trade secrets in the cancer context may also be undesirable for public policy reasons. First, because trade secrets are, by their nature, secret, coordinating research among biopharmaceutical developers is unfeasible.³¹¹ As a result, encouraging the discovery of cancer information through trade secrets runs the risk of producing irreproducible or duplicative research.³¹² Second, because much cancer research is federally funded, trade secrets may be a less-than-appropriate intellectual property incentive for taxpayers: without a transfer of information to the public, private subsidies of trade secrets operate as pure wealth

generating inventions have long allowed their owners to claim patent protection on their devices while secreting away the information their machines create. Brenda Simon & Ted Sichelman, *Data-Generating Patents*, 111 Nw. U. L. REV. 377, 377 (2017).

307. See Conley et al., *supra* note 24, at 613.

308. *Id.* Typically, access to secret databases can be solved through licensing combined with non-disclosure agreements. But Myriad, at least currently, has refused to license its database to others, even on confidential terms. See *id.* at 615 (explaining that Myriad has asymmetrical access to information, such that Myriad may access public databases, but outsiders may not access Myriad's database).

309. See Jones, *supra* note 302 (noting that “[s]erious adverse events were mentioned in 99% of trials on the database but in only 71% corresponding articles”).

310. See Conley et al., *supra* note 24, at 618.

311. See Spencer Phillips Hey & Aaron S. Kesselheim, *Countering Imprecision in Precision Medicine*, 353 SCI. 448, 448–49 (2016) (discussing research coordination issues when IP, like trade secrets, are unknown or diffused across industry); Rai et al., *supra* note 288, at 34 (“For the most part, only limited *inter-firm* R&D coordination or exchange of information would occur—largely confined to contexts where complementary assets had to be deployed in order to maximize research potential.”).

312. See Price, *supra* note 24, at 447–48 (“Secrecy slows cumulative innovation and promotes duplicative investment—though of course it also encourages *ex ante* investment.”); Rai et al., *supra* note 288, at 21 (arguing that proprietary molecular databases encourage duplicative research); Vertinsky, *supra* note 26, at 1558 (“Sharing of information about which drug candidates are being studied and tested, along with knowledge derived from clinical trial failures, can be a critical part of reducing duplicative discovery efforts and avoiding later stage drug candidate failures.”). For a discussion of this argument in relation to Edmund Kitch's prospect theory of patents, see Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 509 n.14 (2009).

transfers.³¹³ Third, given cancer's enormous burden on public resources, the public may have a viable claim that it simply has a right to know basic information about cancer's molecular machinery, whether uncovered through private research or otherwise.³¹⁴ And fourth, trade secrets covering negative results from clinical trials may be important to the development of new information about cancer.³¹⁵ Allowing companies to confidentially retain this data may hamper future research efforts.³¹⁶ The availability of trade secrets, for example, may crimp efforts to create a data commons for cancer research, one of the tools widely believed to be integral to larger efforts—like the Cancer Moonshot—to stymie the disease.³¹⁷

C. Regulatory Exclusivities

Treatments for cancer approved by the FDA often bear another form of intellectual property: regulatory or data exclusivities.³¹⁸ Regulatory exclusivities protect the data generated by therapeutic developers during clinical trials: generic or biosimilar manufacturers may not rely on developers' clinical trial data in their regulatory submissions for a set period of time after the original therapies'

313. See Sheldon Krinsky, *The Profit of Scientific Discovery and Its Normative Implications*, 75 CHL.-KENT L. REV. 15, 36–37 (1999) (“It may be difficult for some to understand how turning federal research funds into discoveries that are privately controlled, how classifying scientific results of therapeutic significance as trade secrets, and how a publicly funded research enterprise in which conflicts of interest are endemic can serve the public interest.”).

314. See R. Adorno, *The Right Not to Know: An Autonomy Based Approach*, 30 J. MED. ETHICS 435, 437 (2004) (“Public health interests may in particular circumstances justify limitations on the right to ignore one’s genetic make up as they may justify limitations to confidentiality, for instance, in the case of infectious diseases.”); Lemmens & Gibson, *supra* note 297, at 973 (“[T]he driving force behind an invigorated debate over data access has been the issue of wasteful spending of public funding.”); Fiona Murray & Siobhán O’Mahony, *Exploring the Foundations of Cumulative Innovation: Implications for Organization Science*, 18 ORG. SCI. 1006, 1011 (2007) (describing this as the principle animating the public release of data from the Human Genome Project).

315. See Falit, *supra* note 301, at 998 (discussing the use of suboptimal comparators in post-approval medical studies to increase the chance of obtaining favorable test results); Seymore, *supra* note 302, at 2051–54 (discussing reasons why negative information arising from scientific research is underreported).

316. See Seymore, *supra* note 302, at 2050–56.

317. See Abbasi, *supra* note 19, at 384; Grossman et al., *supra* note 135, at 1111; Lowy & Collins, *supra* note 171, at 1902–03.

318. See generally Robin Feldman, *Regulatory Property: The New IP*, 40 COLUM. J.L. & ARTS 53 (2017) (describing regulatory exclusivities as forms of property); Anna B. Laakmann, *A Property Theory of Medical Innovation*, 56 JURIMETRICS 117, 199 (2016) (describing these exclusivities as forms of property). *But see* Heled, *supra* note 25, at 287 (describing the same as a regulatory entitlement, rather than property).

approval.³¹⁹ Due to the cost of running separate, confirmatory clinical trials, this unavailability of the pioneer's data typically bars generic entrants until the exclusivity period ends.³²⁰ Anna B. Laakmann terms this form of exclusivity "regulatory property": a property right that "governs information generated to satisfy a regulatory standard and appropriate to include in a submission to a regulatory agency."³²¹

The length of these data exclusivities varies depending on several factors, including a treatment's molecular identity, its disease indication and prevalence in the population, and whether its developer conducted pediatric testing during clinical trials.³²² A "new chemical entity," for example—that is, a drug that "contains no active [chemical] moiety that has been approved by FDA in any other application"³²³—receives five years of data exclusivity from generic competition.³²⁴ For diseases occurring in less than 200,000 people in the United States³²⁵—"orphan indications"—the FDA awards seven years of exclusivity.³²⁶ And conducting clinical trials in pediatric populations rewards applicants with an additional six months of exclusivity on top of the exclusivities already granted.³²⁷ Data exclusivities for larger molecule biologics parallel and lengthen these time periods.³²⁸

These exclusivities serve as important incentives—and policy levers—for drug development.³²⁹ But they do a poor job encouraging the development of basic information about complex diseases, like cancer.³³⁰ Data exclusivities, in all their iterations, cover only

319. Laakmann, *supra* note 318, at 120–21.

320. *See generally* Heled, *supra* note 25 (discussing regulatory shelters in medicine and their legal implications).

321. Laakmann, *supra* note 318, at 119.

322. Thomas, *supra* note 25, at 42 n.40 (enumerating the various exclusivities and their legal bases).

323. 21 C.F.R. § 314.108(a) (2017).

324. *Id.* § 314.108(b)(2).

325. *Id.* § 316.29(c).

326. *Id.* § 316.31.

327. 21 U.S.C. § 355a(b)–(c) (2012).

328. *See* Thomas, *supra* note 25, at 42 n.40 (describing the exclusivity regimes for biologics).

329. Erika Lietzan, *The Myths of Data Exclusivity*, 20 LEWIS & CLARK L. REV. 91, 94 (2016) ("The well-accepted narrative of data exclusivity is that it is provided by the government as an incentive to perform the research necessary to obtain the marketing authorization in question.").

330. *See* Laakmann, *supra* note 318, at 129 (describing this tension); Lietzan, *supra* note 329, at 118 n.107 ("Second, a new drug is never fully understood when approved, nor has it been proven safe and effective in any absolute sense."); Kristina M. Lybecker, *When Patents Aren't Enough: Why Biologics Necessitate Data Exclusivity Protection*, 40 WM. MITCHELL L. REV. 1427, 1438 (2014) (noting that, as opposed to patents, "data protection

approved therapeutics used for treatment—the *molecules* themselves—and new indications to use them.³³¹ They do not, however, encourage the development of information about new molecular targets, cellular signaling pathways, or tumor stage progression.³³² Importantly, they are similarly agnostic about the content of the clinical trials used for approval, including dosing information, differential effects on certain subpopulations, or comparative results with current standard therapies.³³³ Eisenberg, in considering similar problems for patents in this regard, notes that these informational goods

do not necessarily correspond to product markets. Many inventions feed into drug development, including research platform technologies like genomic information and databases, newly identified (or characterized) drug targets, genetically engineered animal models, and new laboratory techniques, instruments, and reagents. These “upstream” inventions . . . help to explain disease pathways and mechanisms and to identify potential targets for therapeutic interventions³³⁴

Unsettlingly, data exclusivities for orphan drugs have, at times, encouraged regulatory gamesmanship at the expense of further developing cancer information.³³⁵ Knowing that physicians will often prescribe orphan drugs for broader and more grossly profitable disease indications, therapeutics developers have tailored their clinical trials around smaller, more manageable orphan indications to

incentivizes the costly and time-consuming development work, which is required to establish safety and efficacy and to secure regulatory approval of a new product”); Maxwell R. Morgan, *Regulation of Innovation Under Follow-on Biologics Legislation: FDA Exclusivity As an Efficient Incentive Mechanism*, 11 COLUM. SCI. & TECH. L. REV. 93, 105 (2010) (“FDA exclusivity, by contrast, better tailors incentives for firms to bear these downstream development, regulatory approval, and commercialization costs for any socially valuable new drug, regardless of whether it meets the standards of patentability.”). At the same time, such exclusivities do serve to promote trade secrets regarding the manufacturing of these compounds—its own problem in the field. Price & Rai, *supra* note 25, at 1028 (discussing trade secrets covering manufacturing methods of biologics).

331. Lybecker, *supra* note 330, at 1438 (discussing the distinction in legal protections for “small molecule” generics and biosimilars).

332. *Cf.* Morgan, *supra* note 330, at 107.

333. The FDA’s clinical trial requirements mandate only that a new drug be demonstrated to be “safe and effective” relative to its clinical benefit. *See* 21 C.F.R. § 314.2 (2017). Assuming that requirement is met, the regulations do not further specify that the drug operate within specific dosage ranges, populations, or adjuvant therapies.

334. *See* Eisenberg, *supra* note 231, at 355–56.

335. *See generally* Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 687 (2009) (defining “regulatory gaming” as “private behavior that harnesses procompetitive or neutral regulations and uses them for exclusionary purposes”).

maximize their exclusivity periods.³³⁶ In 2004, Amgen's Sensipar (cinacalcet), for example, was approved for two indications: secondary hyperparathyroidism in patients on dialysis with chronic kidney disease and hypercalcemia of parathyroid carcinoma, the latter being an orphan condition so rare it is diagnosed on average in only twenty-eight patients each year.³³⁷ Following approval, however, physicians began to use the drug off label—that is, for diagnoses other than the drug label's listed indication—for a variety of conditions.³³⁸ Indeed, off-label uses were so extreme as to constitute 98.8% of prescriptions for a two-year period following approval.³³⁹

While it is true that oncology practice tends to be responsible for a large portion of off-label uses, this enormous ratio of off- to on-label use (494:1) strongly suggests a disconnect between Sensipar's actual, real-world use and the information developed during its clinical trials. Rather, it appears—as is often the practice—that Sensipar's orphan indication (parathyroid carcinoma) was used as a vehicle for approval, knowing that off-label prescriptions in only tangentially related diseases would account for the bulk of the drug's profits.³⁴⁰

To be clear, such behavior has virtues as well as vices. Seeking approval for succeeding and broader indications may put a developer's product on the market sooner, to the great benefit of patients who may then obtain it off label if needed. And providing treatment to sufferers of rare diseases that, absent the orphan drug program, would remain untreated should be praised, as Amgen indeed deserves for its investigations in parathyroid carcinoma. But where clinical resources are limited, and where broader clinical trials serve to produce more therapeutically useful information to more

336. See André Côté & Bernard Keating, *What Is Wrong with Orphan Drug Policies?*, 15 VALUE IN HEALTH 1185, 1187 (2012) (listing “blockbuster” orphan drugs); John W. Peabody, Allen Ruby & Peter Cannon, *The Economics of Orphan Drug Policy in the US: Can the Legislation Be Improved?*, 8 PHARMACOECONOMICS 374, 374 (1995) (noting the problem with the same).

337. Elizabeth Shane, *Parathyroid Carcinoma*, 86 J. CLINICAL ENDOCRINOLOGY & METABOLISM 485, 485 (2001); Letter from Robert Meyer, Dir. Office of Drug Evaluation II, to Pamela Danaher, Manager of Regulatory Affairs, Amgen Inc. (March 8, 2004), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/21-688.pdf_Sensipar_Approv.pdf [<https://perma.cc/8S2S-FHPB>]; see Christina H. Wei & Avital Harari, *Parathyroid Carcinoma: Update and Guidelines for Management*, 13 CURRENT TREATMENT OPTIONS IN ONCOLOGY 11, 11 (2012) (discussing the incidences of hypercalcemia of parathyroid carcinoma as being extraordinarily rare).

338. See Aaron S. Kesselheim et al., *The Prevalence and Cost of Unapproved Uses of Top-Selling Orphan Drugs*, 7 PLOS ONE e31894, 2–3 (2012).

339. *Id.* at 3.

340. *See id.* at 6.

patients, the orphan drug exclusivity regime may encourage gamesmanship over substance.

At the same time, data exclusivities fail to capture more benevolent investigations of cancer therapies, notably combination therapies.³⁴¹ Many cancer therapies—and chemotherapies in particular—are combinations of several drugs, either taken in specific sequences or under very controlled dosages in rapid succession.³⁴² Developing the information required to identify these combinations from a virtually limitless array of permutations is arduous and expensive.³⁴³ Yet, none of the data exclusivities definitively answer how the FDA will consider combination therapy for data exclusivity purposes.³⁴⁴ As a result, there are relatively few commercial investigations into combination therapies of older drugs—even though the information produced by such trials would be enormously valuable.³⁴⁵ To its credit, the FDA has recently issued new guidance suggesting a limited data exclusivity regime for therapeutic combinations that contain a new chemical entity.³⁴⁶ But these do little to promote the production of information concerning combinations of old drugs.³⁴⁷

Data exclusivities also fail to cover several cutting-edge technologies in cancer treatment, notably personalized cancer immunotherapy. In personalized immunotherapy, clinicians reengineer a patient's white blood cells to elicit the patient's own

341. See U.S. FOOD & DRUG ADMIN., NEW CHEMICAL ENTITY EXCLUSIVITY DETERMINATIONS FOR CERTAIN FIXED-COMBINATION DRUG PRODUCTS GUIDANCE FOR INDUSTRY 1 (Oct. 2014), <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm386685.pdf> [<https://perma.cc/7P73-4QGJ>] (“Historically, FDA has interpreted these provisions such that a fixed-combination was ineligible for 5-year NCE exclusivity if it contained a previously approved active moiety, even if the product also contained a new active moiety (i.e., an active moiety that the Agency had not previously approved).”).

342. MUKHERJEE, *supra* note 12, at 455 (describing advances in combination therapy).

343. *Id.* at 126.

344. See U.S. FOOD & DRUG ADMIN., *supra* note 341, at 1.

345. See Johannes Koch, *Pairing New Cancer Drugs With Older Ones Bolsters Roche Profit*, BLOOMBERG (July 21, 2016), <http://www.bloomberg.com/news/articles/2016-07-21/roche-first-half-profit-rises-7-as-cancer-drugs-get-combined> [<http://perma.cc/MK87-P9C3>] (describing some of the difficulties in this approach); Peter Loftus, *Combination Drug Therapies for Cancer Show Promise at Higher Potential Cost*, WALL ST. J. (June 5, 2016) <https://www.wsj.com/articles/combination-drug-therapies-for-cancer-show-promise-at-higher-potential-cost-1465141936> [<https://perma.cc/62DM-ZAYK> (staff-uploaded archive)] (discussing recent developments of cancer combination therapies using older drugs).

346. See U.S. FOOD & DRUG ADMIN., *supra* note 341, at 2.

347. *Id.* at 1.

immune system to fight against cancerous cells.³⁴⁸ This usually takes one of two forms: either priming the white blood cells to the patient's specific cancer or genetically modifying the white blood cells to recognize the cancer.³⁴⁹ Afterwards, the modified white blood cells are reinjected into the patient.³⁵⁰ By their nature, these therapies are unique to each patient and each cancer—a therapeutic platform that presents a host of serious regulatory challenges.³⁵¹ At the same time, clinical trials for these therapies provide wells of general information about cancer and its often-complex relationship with the immune system.³⁵² A regulatory property system grounded in encouraging the production of generalizable information like this should, ideally, encourage these sorts of trials. Nonetheless, in the absence of a certain data exclusivity regime, it is wholly unclear what will encourage the development of information concerning these personalized immunotherapies.

Perhaps as a function of history—for simpler diseases with simpler treatments—data exclusivities ultimately promote products rather than information.³⁵³ Where complex diseases, like cancer, are concerned, this perversely encourages the development of “me too” therapies—therapies modeled on existing ones, already approved by the FDA, or, more subtly, treatments that target the same cellular pathways of approved products. In one particularly astonishing example, three of the current top-ten selling biologic products are all

348. See Meghana Keshavan, *Experimental Cancer Therapy Holds Great Promise—But at Great Cost*, STAT (Aug. 23, 2016), <https://www.statnews.com/2016/08/23/cancer-car-t-side-effects/> [<https://perma.cc/UM3Z-28AL>] (describing CAR-T therapy).

349. *Id.*

350. *Id.* (“The therapy itself consists of an infusion: The Frankensteinian T cells are fed back into the patient’s bloodstream, where they proliferate and work furiously to kill tumor cells.”).

351. Chizuru Ogi & Atsushi Aruga, *Clinical Evaluation of Therapeutic Cancer Vaccines*, 9 HUM. VACCINES & IMMUNOTHERAPIES 1049, 1049 (2013) (explaining that as of 2013, Provenge, was the only therapeutic cancer vaccine to have earned approval by the FDA).

352. See Jennifer Couzin-Frankel, *Cancer Immunotherapy*, 342 SCI. 1432, 1432–33 (2013) (describing individual immunotherapies as marking a shift where “the anecdotes coalesce into data . . . a sense of paradigms shifting”).

353. See generally Laakmann, *supra* note 318 (noting that public health regulation pushes developers to move discoveries downstream along innovation pathways); Lybecker, *supra* note 330 (describing the different incentives created by patents and data exclusivity with respect to the development of biologic medicines); Morgan, *supra* note 330 (arguing that the adoption of a market-exclusivity rather than data-exclusivity regime would promote efficient disclosure of information); Price & Rai, *supra* note 25 (observing that under the current regulatory regime for biologic medicine manufacturing there are high barriers to both entry into the market and to the disclosure of basic knowledge about biologics functions and optimal products).

monoclonal antibodies directed to a specific protein, tumor necrosis factor alpha.³⁵⁴ To be clear, new products—that is, new drugs and biologics—are truly important in any broader fight against cancer. But as tools, these products are only as useful as the depth of information about when, and in what circumstances, to deploy them. In her conception of data exclusivities as regulatory property, Laakmann idealizes data exclusivities as belonging to a “process through which administrative oversight gives rise to the production of new information resources.”³⁵⁵ As currently structured, however, this oversight fails to encourage the most robust and useful information in the fight against cancer.

III. INFORMATION AND IP FOR CANCER RESEARCH

The Cancer Moonshot may fail for numerous scientific, administrative, or even political reasons.³⁵⁶ But just getting the Moonshot off the ground—or, for that matter, other complex, public-private partnerships—will require tailoring the current intellectual property regime to fit the informational production desired from such a project. Giving private industry enough incentives to participate—but on terms that comport with a long-term, publicly funded project with serious public health implications—remains key. This is, of course, easier said than done. Balancing IP incentives with public health and policy concerns persists as one of the more intractable problems in innovation policy.³⁵⁷

354. The current biologics landscape strongly demonstrates this point: of the top ten selling biologics in 2014, three are monoclonal antibodies directed against one protein, tumor necrosis factor alpha. Peter Ubel, *The Best-Selling Biologic Drugs*, FORBES (Oct. 16, 2014), <http://www.forbes.com/sites/peterubel/2014/10/16/the-best-selling-biologic-drugs/> [<https://perma.cc/TRT9-WQE5>] (listing anti-TNF biologics, Humira, Enbrel, and Remicade, among the top ten).

355. Laakmann, *supra* note 318, at 119.

356. Sharon Begley, *DNA Pioneer James Watson: The Cancer Moonshot Is ‘Crap’ But There Is Still Hope*, STAT (July 20, 2016), <https://www.statnews.com/2016/07/20/james-watson-cancer/> [<https://perma.cc/HE86-FHY2>] (“The depressing thing about the ‘cancer moonshot’ is that it’s the same old people getting together, forming committees, and the same old ideas, and it’s all crap.”); Breivik, *supra* note 6, at A21 (“Confronted with these forces, there is little incentive for our democratically elected leaders to question the goal of the ultimate cure. Yet, they should be aware of the rhetorical spin that drives the cancer enterprise and how it obstructs a clear understanding of the issue.”); Bruce Zetter & Lara Maggs, *What the Cancer ‘Moonshot’ Needs to Fix*, POLITICO (Apr. 20, 2016), <http://www.politico.com/agenda/story/2016/04/biden-cancer-moonshot-needs-to-fix-000109> [<https://perma.cc/WP6L-KGHC>] (tasking the NCI with proportional imbalances in research funding for specific types of cancers).

357. Peter Lee, *Toward a Distributive Commons in Patent Law*, 2009 WIS. L. REV. 917, 920 (“The debate is one of the most intractable in intellectual property law, and it is no exaggeration to say that lives hang in the balance. In the realm of health technologies,

Recognizing that the product of the Cancer Moonshot is informational may ease these difficulties. Cancer information derived from the Moonshot can be considered as a public good: a resource that is both nonrivalrous, in that one's use does not deplete the resource for others, and nonexcludable, in that it "cannot be privately provided or traded in markets."³⁵⁸ A vast literature documents that the development of public goods are most rewarding where there are limited encumbrances to both public access and commercial use.³⁵⁹ A public forest, for example, may best serve a public nonetheless interested in environmental preservation even where some clear-cut logging is allowed.³⁶⁰ This applies in even greater force to informational public goods, the commercial development of which does not diminish the public's access to the good procured.³⁶¹

Today, establishing informational public goods often revolves around "data sharing": the collection of, and access to, standardized sets of information pliable to statistical or empirical analysis.³⁶² This has most notably included the Human Genome Project ("HGP"), the effort to provide a "template" sequence of all of the DNA contained within a human cell.³⁶³ Although the HGP functioned as a public-private partnership, its researchers nonetheless adhered to the "Bermuda Principles," a "require[ment] that all DNA sequences generated by the HGP be released to the public a mere twenty-four hours after generation."³⁶⁴ And while portions of the human genome were originally patented, since the project's completion in 2003, non-profit, academic, and commercial researchers have freely plumbed its

advancing innovation through strict exclusive rights often appears to conflict with the ideal of promoting distributive justice.").

358. Romer, *supra* note 9, at S74; *see also* Contreras, *supra* note 10, at 99.

359. *See* Daniel J. Hemel & Lisa Larrimore Ouellette, *Knowledge Goods and Nation States*, 101 MINN. L. REV. 167, 192–99 (2016) (documenting this literature of knowledge as a public good); Romer, *supra* note 9, at S76 (listing prior discussions in the economic literature of this concept); *see also* Contreras, *supra* note 10, at 100 (describing these rewards for the Human Genome Project).

360. *See* Kenneth J. Arrow & Anthony C. Fisher, *Environmental Preservation, Uncertainty, and Irreversibility*, 88 Q.J. ECON. 312, 314 (1974) (modeling commercial development of environmentally preserved areas by taking into account the irreversibility of some commercial development).

361. *See* Hemel & Ouellette, *supra* note 359, at 170–171 (discussing the nonrivalrous nature of information).

362. *See* Stodden, *supra* note 30, at 2 (discussing data sharing and statistical replication).

363. Contreras, *supra* note 10, at 101.

364. *Id.* at 101.

depths, contributing to an additional \$65 billion in economic output.³⁶⁵ Conceiving the Cancer Moonshot as less like the space race and more like the HGP suggests that its success will depend on encouraging data sharing in the shadow of intellectual property.

The remainder of this Section provides some concrete suggestions for achieving data sharing for the Cancer Moonshot and later provides some general thoughts about how data-sharing can illuminate some of the academic literature on similar public-private partnerships and IP. First, this Section focuses on historical and current data-sharing efforts in cancer research, and some of the intellectual property issues they raise. Second, this Section explores ways to encourage data sharing for the Moonshot—specifically, ways to encourage the production of desirable information, its disclosure in a data sharing agreement, and its ultimate use by participants. Finally, this Section ties these findings to the academic literature on IP, information, and public-private partnerships for large-scale research projects.

A. *Data and Data-Sharing Efforts in Cancer Research*

Data sharing in cancer research is not new; physicians have been trading information about their patients' successes and failures of treatment since the disease was identified in antiquity.³⁶⁶ On a broader scale, however, the National Cancer Institute's Clinical Trials Cooperative Group Program, established in 1955, was likely the first major effort to share information about experimental therapies in cancer across institutions.³⁶⁷ The Cooperative Group Program's main effort lay in running large-scale, multi-institutional clinical trials, mainly to assess the effectiveness of new anti-cancer compounds.³⁶⁸ But the Program also established a cross-disciplinary network of cancer researchers in the hopes of bringing a diversity of scientific experience to bear on fighting cancer.³⁶⁹ Since 2014, the Program has been rechristened the National Clinical Trials Network ("NCTN") and focuses more on providing support, oversight, and funding to

365. *Id.* at 100 (citing BATELLE TECH. P'SHIP PRACTICE, *THE IMPACT OF GENOMICS ON THE U.S. ECONOMY* (2013), <http://www.unitedformedicalresearch.com/wp-content/uploads/2013/06/The-Impact-of-Genomics-on-the-US-Economy.pdf> [<https://perma.cc/WA8P-FKJ3>]).

366. MUKHERJEE, *supra* note 12, at 39–40 (discussing the Edwin Smith Papyrus, an ancient Egyptian manuscript that contains the first recorded observations about cancer).

367. SHARYL J. NASS, HAROLD L. MOSES & JOHN MENDELSON, *A NATIONAL CANCER CLINICAL TRIALS SYSTEM FOR THE 21ST CENTURY* 43 (2010).

368. *Id.* at 43–44.

369. *Id.* at 44.

clinical trials run by academic cancer centers and community hospitals.³⁷⁰ Importantly, all of the NCTN's current programs contain a Statistics and Data Management component.³⁷¹

As the complexity of cancer research has evolved, so too have the types of data subject to collection. Data concerning cancer's underlying molecular biology—genetic mutations found in tumors, cellular signaling pathways that contribute to the disease, and molecular markers of tumors—comprise a leviathan source of data for cancer research. Several platforms house this data: CGHub, COSMIC, and cBioPortal are but a few of the larger cancer “omics” databases.³⁷² The FDA, meanwhile, houses an enormous quantity of raw, clinical trial data, much of which has recently been organized into the Janus Clinical Trials Repository, “a data repository and nonclinical study for subject-level clinical trial data submitted to the FDA as part of regulatory submissions.”³⁷³ And the NCI, through its Surveillance, Epidemiology, and End Results Program (“SEER”), manages a variety of databases concerning cancer patients’ treatments and longitudinal outcomes.³⁷⁴ A recent review of cancer databases groups them in roughly six categories: (1) data concerning DNA mutations in tumors; (2) data concerning whether certain genes have been copied multiple times in tumors; (3) data on gene expression, i.e., whether a gene is turned “on” or “off” within a tumor databases; (4) epigenetic databases, i.e., databases concerning the chemical profile of tumors’ DNA beyond just their sequence; (5) integrative databases, or databases combining the information of several databases and providing a platform for analysis; and (6) a catch-all “other” category, including data on the proteins involved in cancer progression.³⁷⁵

Realizing the true benefits of cancer databases, however, requires access to them by researchers and clinicians; through data

370. *An Overview of NCI's National Clinical Trials Network*, NAT'L CANCER INST. (May 29, 2015), <https://www.cancer.gov/research/areas/clinical-trials/nctn> [<https://perma.cc/PVB6-WJQS>].

371. *Id.*

372. See Yadong Yang et al., *Databases and Web Tools for Cancer Genomics Study*, 13 GENOMICS, PROTEOMICS & BIOINFORMATICS 46, 46–47, 49 (2015).

373. *Janus*, U.S. FOOD & DRUG ADMIN. (March 17, 2017), <http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/ucm155327.htm> [<https://perma.cc/S62A-J83J>].

374. *Surveillance, Epidemiology, and End Results Program*, NAT'L CANCER INST., <http://seer.cancer.gov> [<https://perma.cc/QGN7-FWZ4>].

375. Charoentong et al., *supra* note 45, at 1886–87.

sharing, not merely a gross aggregation of data.³⁷⁶ In a 2003 policy statement concerning data sharing and funding, the NIH concluded “that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health.”³⁷⁷ This is especially true for datasets in cancer research, which require “increase[d] sample sizes and available statistical power, as well as . . . [a] diversity of samples, which allows more robust subgroup analyses.”³⁷⁸ Data sharing is so important—for cancer research and beyond—that the NIH now requires it for all federally funded studies of \$500,000 per year or more.³⁷⁹ The scientific journals, *Nature*, *Science*, and *Cell*—considered the three most prestigious life science journals—all require some form of data sharing for any articles they publish.³⁸⁰

Despite this, there are numerous difficulties with data sharing in the cancer context.³⁸¹ One of those difficulties is, essentially, a legal one: each database requires different terms of use and is protected by a variety of different intellectual property regimes. The Cancer Care Outcomes Research & Surveillance Consortium (“CanCORS”), for example—a dataset of roughly 10,000 patients diagnosed with lung or colorectal cancer—is strictly proprietary.³⁸² Researchers looking for

376. See *id.* at 1886 (“Thus, a cancer researcher can address today a specific question and not only by generating proprietary high-throughput data but also by accessing and mining available datasets.”); *id.* at 1899 (“The current bottleneck in whole-exome sequencing projects is not the sequencing of the DNA itself but lies in the structured way of data management and the sophisticated computational analysis of the experimental data.”).

377. NAT’L INSTS. HEALTH, FINAL NIH STATEMENT ON SHARING RESEARCH DATA (2003), <http://grants.nih.gov/grants/guide/notice-files/not-od-03-032.html> [<https://perma.cc/TH6V-Y5SQ>].

378. Tatiana Perrino et al., *Advancing Science Through Collaborative Data Sharing and Synthesis*, 8 PERSP. PSYCHOL. SCI. 433, 433 (2013).

379. NAT’L INSTS. HEALTH, *supra* note 377.

380. *Availability of Data, Material and Methods*, NATURE, <http://www.nature.com/authors/policies/availability.html> [<https://perma.cc/T6VQ-LULA> (dark archive)]; *Information for Authors*, CELL, <http://www.cell.com/cell/authors> [<https://perma.cc/YK2H-VS2P>]; *Science: Editorial Policies*, SCIENCE, <http://www.sciencemag.org/authors/science-editorial-policies> [<https://perma.cc/HVG3-E5YG>].

381. See Margaret A. Stone et al., *Sharing Patient Data: Competing Demands of Privacy, Trust and Research in Primary Care*, 55 BRIT. J. GEN. PRACTICE 783, 783–84, 787 (2005) (discussing concerns of patient confidentiality, researcher conflict of interest, and clinical diminishment).

382. CANCER CARE OUTCOMES RESEARCH AND SURVEILLANCE: CANCORS PROJECT OVERVIEW 1, (2014), <https://www.cancors.org/public/servlets/open/home/home.cmd?itab=0> [perma.cc/N7XX-J7AK]; See *Forms to Request Data Access or to Propose a Manuscript*, CANCORS, <https://www.cancors.org/public/servlets/open/home/home.cmd?itab=4> [perma.cc/3EFH-ABSV]; NCIP/cagrid-core, GITHUB, <https://github.com/NCIP/cagrid-core> [perma.cc/Y7KX-EGMV].

access to CanCORS data must partner with a CanCORS member and are subject to a Data Use Agreement: a contract limiting the type, manner, and content of data sharing with other institutions.³⁸³ By contrast, caGrid—a clinical trial data sharing platform—runs on completely free and open source licenses, namely the Berkeley Software Distribution 3-clause license (“BSD-3”).³⁸⁴ The BSD-3 license places no restrictions on access or use of the underlying data, or its use in the creation of new intellectual property derived from it.³⁸⁵ COSMIC—a database of mutations present in over 370,000 tumors—strikes somewhat of a middle ground, requiring paid-up, agreed-upon licenses for all researchers, but charging large fees for only commercial companies and large academic institutions.³⁸⁶ This variety in cancer databases and licensing regimes almost parallels the complexity in the disease itself.

Cancer investigators looking to conduct research across platforms—or looking to deposit their data in multiple fora—are therefore required to navigate the twists and turns of these licensing regimes. Performing cross-platform cancer research may consequently run aground on conflicting licensing terms.³⁸⁷ In extreme cases, owners of proprietary datasets may refuse access to their underlying data if it is combined with other, open-source datasets.³⁸⁸ For commercial developers, attempting to link data across multiple, proprietary, fee-based datasets may significantly increase the cost of research, a problem akin to “stacking” multiple IP royalties to use a single product.³⁸⁹ And, ultimately, conflicting licensing terms across

383. See *Forms to Request Data Access or to Propose a Manuscript*, *supra* note 382.

384. *NCIP/cagrid-core*, *supra* note 382; see also Margaret Rouse, *BSD (Berkeley Software Distribution)*, TECHTARGET, <http://searchdatacenter.techtarget.com/definition/BSD-Berkeley-Software-Distribution> [perma.cc/MLV5-RMVB] (describing the Berkeley Software Distribution system).

385. See *The BSD 3-Clause License*, OPEN SOURCE INITIATIVE, <https://opensource.org/licenses/BSD-3-Clause> [perma.cc/92XQ-EV25].

386. Simon A. Forbes et al., *COSMIC: Exploring the World's Knowledge of Somatic Mutations in Human Cancer*, 43 NUCLEIC ACIDS RES. 805, 805 (2014) (“Our latest release (v70; Aug 2014) describes 2,002,811 coding point mutations in over one million tumor samples and across most human genes.”); *Licensing - Frequently Asked Questions (FAQ)*, COSMIC, <http://cancer.sanger.ac.uk/cosmic/license/faq> [perma.cc/RP3N-PRCD].

387. See Jennifer C. Molloy, *The Open Knowledge Foundation: Open Data Means Better Science*, 9 PLOS BIOLOGY 1, 4 (2011) (“Drawing together diverse datasets for reuse in this manner becomes complicated where their terms of use are restrictive or not interoperable, making openness a valuable attribute.”).

388. See, e.g., Oxenham, *supra* note 30, at 16 (describing this phenomenon in the context of the development of Hetionet).

389. Cf. Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 1993 (2007) (“Royalty stacking refers to situations in which a single product potentially infringes on many patents, and thus may bear multiple royalty burdens.”).

datasets are likely to hinder, if not wholly prevent, the redistribution—or further protection—of newly created cross-platform datasets to other researchers.³⁹⁰

These difficulties are especially problematic in encouraging research into longitudinal data analysis: statistical linkages of tumor mutations, cancer treatment, and clinical outcomes.³⁹¹ A recent report from *Nature* highlighted these difficulties in the development of Hetionet, a “free online resource that melds data from 28 public sources on links between drugs, genes and diseases.”³⁹² The principal investigator responsible for the project was required to negotiate separate licenses for each original data source—but was refused in one case, and failed to come to terms in three others.³⁹³ This resulted in a platform of unclear legality.³⁹⁴ This “confusion has the power to slow down science . . . because researchers will be discouraged from combining data sets into more useful resources,” and runs the risk of “good data . . . going to waste because their creators could not clarify whether [one] could republish them.”³⁹⁵

To its credit, the Cancer Moonshot has attempted to overcome some of these difficulties. To focus its efforts, the Moonshot project initially divided itself into seven “Working Groups” of interest, including the Enhanced Data Sharing Working Group, which seeks to bring down technological and structural barriers to data sharing.³⁹⁶ A portion of that effort seeks to expand the NCI’s Genomic Data Commons (“GDC”), a “unified data repository that enables data sharing across cancer genomic studies in support of precision

390. See Oxenham, *supra* note 30, at 16–17 (“The European Union assigns specific database rights, independent of copyright, that aim to protect the investment made in compiling a database. Legally speaking, these rights prevent researchers . . . from republishing data sets created by scientists in EU states without their consent [E]ven in jurisdictions such as the United States, where no separate rights exist to govern databases, there is still room for confusion. Although facts don’t qualify for copyright, the way they are compiled arguably might—if the act of making that compilation requires sufficiently creative expression.”); Stodden, *supra* note 30, at 14 (“Evolving community standards and peer review cannot be relied upon to solve all dissemination issues, as some, such as licensing for code and data, require coordinated action to ensure that goals such as interoperability are met.”).

391. See Stodden, *supra* note 30, at 3–4 (describing this in several case studies of cancer genetics data); Strausberg et al., *supra* note 82, at 470–72 (discussing the need for such tools to assess clinical utility).

392. Oxenham, *supra* note 30, at 16.

393. *Id.*

394. *Id.* at 16–17.

395. *Id.* at 17.

396. CANCER MOONSHOT BLUE RIBBON PANEL REPORT 2016, *supra* note 163, at 3.

medicine.”³⁹⁷ On a smaller scale, the Cancer Moonshot has supported several ad hoc cancer data sharing initiatives. The Applied Proteogenomics Organizational Learning and Outcomes consortium (“APOLLO”), for example, combines data from 8,000 lung cancer patients under the care of the Departments of Defense and Veterans Affairs.³⁹⁸ APOLLO data focuses on gene expression within tumors, i.e., which genes are turned “on” and “off” as a neoplasm is subjected to treatment.³⁹⁹ Recently, APOLLO has become an international consortium with the inclusion of four Australian institutions, and that country’s own data-sharing efforts, the Australian Proteome of Human Cancer.⁴⁰⁰ Relatedly, the Human Cell Atlas (“HCA”)—“comprehensive reference maps of all human cells . . . as a basis for both understanding human health and diagnosing, monitoring, and treating disease”⁴⁰¹—have made determined gains to coordinate data sharing on both institutional and technological levels.⁴⁰² In June 2017, the U.C. Santa Cruz Genomics Institute, one of the pioneer institutions in the Human Genome Project, announced its participation in the HCA—specifically to build the project’s data coordination platform.⁴⁰³ U.C. Santa Cruz researchers note that the HCA is “not only a fascinating and important biology project, it’s also a very large computational and engineering project that is leading the way in terms of how to organize big data.”⁴⁰⁴

397. *The Next Generation Cancer Knowledge Network*, NAT’L CANCER INST. <https://gdc.cancer.gov> [perma.cc/N9C5-WB5P].

398. Adam Bonislawski, *APOLLO Initiative Aims to Make Proteogenomics Routine Part of Cancer Treatment at VA, DoD*, GENOMEWEB (July 26, 2016), <https://www.genomeweb.com/proteomics-protein-research/apollo-initiative-aims-make-proteogenomics-routine-part-cancer-treatment> [perma.cc/64MZ-UDJU].

399. *APOLLO – Proteogenomically Zeroing in on Cancer*, HUPO (July 11, 2016), <https://www.hupo.org/2016/07/news/apollo-proteogenomically-zeroing-in-on-cancer/> [perma.cc/L545-T3R7] (“Applied Proteogenomics Organizational Learning and Outcomes—will look at both a patient’s genes (genomic analysis) and the expression of these genes in the form of proteins (proteomic analysis) to create the nation’s first system in which cancer patients are routinely screened for genomic abnormalities and proteomic information to match their tumor types to targeted therapies.”).

400. Press Release, The White House Office of the Vice President, *supra* note 174.

401. *Human Cell Atlas*, HUM. CELL ATLAS, <https://www.humancellatlas.org> [perma.cc/M6HV-DF4H].

402. *Data Coordination*, HUM. CELL ATLAS, <https://www.humancellatlas.org/data-sharing> [perma.cc/YL6J-HG57].

403. *UC Santa Cruz Genomics Institute Joins Human Cell Atlas Initiative*, GENOMEWEB (June 1, 2017), https://www.genomeweb.com/informatics/uc-santa-cruz-genomics-institute-joins-human-cell-atlas-initiative?utm_source=Sailthru&utm_medium=email&utm_campaign=GWDN%20Mon%20PM%202017-06-19&utm_term=GW%20Daily%20News%20Bulletin [perma.cc/6JBK-4ZAF].

404. *Id.*

But, thus far, the Moonshot effort has not tackled the IP and licensing issues at the core of these data-sharing agreements. Access to the GDC is under tight controls and subject to a complicated licensing policy tied to NIH grants.⁴⁰⁵ The policy requires, among other things, “that basic sequence and certain related data made available through NIH-designated data repositories and all conclusions derived from them will be freely available.”⁴⁰⁶ At the same time, “[i]t discourages patenting of ‘upstream’ discoveries . . . while it encourages the patenting of ‘downstream’ discoveries,” without defining, precisely, what those terms mean.⁴⁰⁷ Furthermore, the NIH Data Access Committee controls access to GDC’s data, tranching it “through a tiered model involving unrestricted- and controlled-data access mechanisms.”⁴⁰⁸ Were that not enough, the policy seems only to apply to NIH-funded research, making unclear what policies, if any, apply to private researchers.⁴⁰⁹ Resolving these issues will remain at the core of successfully implementing any of the Moonshot’s data-sharing efforts.

B. Encouraging Data Sharing and IP for Cancer

For the Cancer Moonshot to be successful, it needs to implement a workable data-sharing plan in the shadow of intellectual property protections. Participants in the Moonshot will likely need to commit to generating and sharing data concerning cancer research, treatment, and outcomes—but are unlikely to participate without some form of incentive guaranteeing their investment in research.⁴¹⁰ The solution

405. See *NIH Genomic Data Sharing Policy, NIH Notice No. NOT-OD-14-124*, NAT’L INSTS. HEALTH (Aug. 27, 2014), <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html> [perma.cc/M2LS-827K] (structuring restrictions on genomic data sharing).

406. *Id.*

407. *Id.*

408. *Id.*

409. See *id.*

410. See Lietzan, *supra* note 329, at 94 (“The well-accepted narrative of data exclusivity is that it is provided by the government as an incentive to perform the research necessary to obtain the marketing authorization in question.”); Price & Minssen, *supra* note 294, at 685 (raising this issue in the context of sharing clinical trial data); Vertinsky, *supra* note 26, at 1517 (“[Policymakers] need to find ways of mitigating the negative effects of market incentives on cooperation without removing market incentives altogether from this process. This requires strategies for confronting and reducing the tensions between private and public incentives to create and share knowledge.”); see also Memorandum, *supra* note 5 (discussing incentives for the Moonshot).

It is important to note that this regime may appear to parallel—but is ultimately orthogonal—to similar regimes used to encourage the production of chemical toxicity data. Like programs such as the Moonshot, data on industrial chemicals’ toxicity in humans is underproduced and underused, despite its value. Mary L. Lyndon, *Information*

likely lies in tailoring intellectual property protections to encourage the level, type, and terms of data sharing the Moonshot ultimately requires.

Like many things, developing a working model of private ordering against legal backdrops consists of breaking its essential questions into elements.⁴¹¹ Here, the essential questions concerning the success of the Cancer Moonshot can be thought of as comprising three parts: producing valuable cancer information; disclosing that information through data-sharing programs; and using that data to develop cancer treatments or further information.

1. Production

Tailoring IP policies to encourage the production of cancer information ultimately depends on the type of information sought to be produced and the organization likely to produce it. For starters, basic information about cancer—the genes, proteins, and cellular features found prominently in tumors—has been typically uncovered by academic researchers funded by federal grants.⁴¹² In this way, at least for academic researchers in the cancer space, the NIH/NCI grant-funding system strongly functions as a research incentive for the immediate production of basic cancer information. Academic scientists study the basic molecular trappings of cancer, publish that information in scientific journals, and apply for more grants.⁴¹³ This occurs even though many NIH grants restrict researchers' ability to protect, through the traditional means of intellectual property, their

Economics and Chemical Toxicity: Designing Laws to Produce and Use Data, 87 MICH. L. REV. 1795, 1796 (1989). Several laws have, consequently, been enacted to encourage chemical manufacturers to disclose the toxicity of their products to regulators and the public. *Id.* at 1832–33. At the same time, the cost of such studies—like the cost of clinical trials in the cancer context—have dissuaded manufacturers from doing just that. *See id.* at 1810–13. The difference here, however—and an important one, at that—is that the toxicity information sought to be produced is ultimately *harmful* to the manufacturer in that it is designed to be used for restrictive regulation or as the basis for private tort lawsuits. *Id.* at 1817–25. The solutions proposed to remedy these problems—right-to-know laws, environmental tort liability, agency enforcement—are therefore inapposite to similar information production regimes used in the Moonshot. *See id.* at 1854–60.

411. Cf. Robert H. Mnookin & Lewis Kornhauser, *Bargaining in the Shadow of the Law: The Case of Divorce*, 88 YALE L.J. 950, 959 (1979) (analyzing private ordering in divorce by recognizing that “[l]egal doctrine separates the potential consequences of divorce into four distributional questions”).

412. *See* Eckhouse et al., *supra* note 92, at 24 (showing the breakdown of cancer research funding).

413. *See* Brian A. Woodcock, “*The Scientific Method*” as Myth and Ideal, 10 SCI. & EDUC. 2069, 2070 (2014) (“Scientists apply for grants, supervise employees, prepare budgets, and much more.”).

basic discoveries.⁴¹⁴ Tailoring IP laws to further encourage the *academic* development of *basic* cancer information may therefore have little practical effect.

This hinges, of course, on the availability of NIH funding for certain areas of research. Where NIH funding is scant—for, say, scientific, ethical, or political reasons—private research may fill in that gap. And there, the availability of some form of intellectual property to protect basic discoveries may encourage research in that area.⁴¹⁵ Prior to the developments in *Mayo*, *Myriad*, and *Alice*, some of this basic research was disclosed by pharmaceutical developers in patent applications, both to preserve potentially lucrative claims in future, continuing applications, but also as a defensive strategy.⁴¹⁶ After the Supreme Court’s recent patent-ineligibility turn, however, more of this information is likely to be the subject of trade secrets.⁴¹⁷ Dan L. Burk has recently noted the information-draining quality of this shift: “if the unpatentable invention is kept as a trade secret, it may beget further trade secrets.”⁴¹⁸

This turn towards secrecy poses particular problems for public-private partnerships. The information derived from them can be thought of as part of the “public infrastructure”—publicly-available resources created or subsidized by the public sector.⁴¹⁹ Subsidizing the

414. See *NIH Genomic Data Sharing Policy*, *supra* note 405.

415. One area in which this has been prominent is stem cell research. Since the 1990s, public funding of stem cell research has been difficult and thin. As a consequence, prominent researchers in the area have turned to patents and licensing fees to fund further research. See John M. Golden, *WARF’s Stem Cell Patents and Tensions between Public and Private Sector Approaches to Research*, 38 J.L. MED. & ETHICS 314, 314–15 (2010) (describing stem cell patents held by the Wisconsin Alumni Research Foundation); Jacob S. Sherkow & Christopher Thomas Scott, *Stem Cell Patents After the America Invents Act*, 16 CELL STEM CELL 461, 461–63 (2015) (discussing the history of stem cell patents).

416. See Contreras & Vertinsky, *supra* note 294, at 85–89 (discussing defensive patenting from a genomics consortium); Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 69 (2004) (“Continuations are a major part of patent practice. They are especially important in certain industries, particularly pharmaceuticals and biotechnology.”).

417. See Derek E. Bambauer, *Secrecy is Dead - Long Live Trade Secrets*, 93 DENV. L. REV. 833, 833 (2016) (“[I]nnovators will shift to using trade secret law to safeguard advances, rather than filing for patent protection or using contractual and technological self-help to keep inventions confidential . . . [because] obtaining a patent has become more difficult and less certain with recent doctrinal developments.”).

418. Dan L. Burk, *Patents as Data Aggregators in Personalized Medicine*, 21 B.U. J. SCI. & TECH. L. 233, 245 (2015).

419. Brett M. Frischmann, *Infrastructure Commons*, 2005 MICH. ST. L. REV. 121, 126–29 (defining public infrastructure); David S. Levine, *Secrecy and Unaccountability: Trade Secrets in Our Public Infrastructure*, 59 FLA. L. REV. 135, 140–45 (2007) (describing information as public infrastructure).

creation of these resources and then locking them behind trade secrecy's private gates moves such information from *public* infrastructure to *private* property, with little recourse for appeal.⁴²⁰ In short, it would be a twenty-first century version of enclosure: "a plain enough case of class robbery."⁴²¹

Besides basic scientific information about cancer, encouraging the production of clinical information about the disease would also be significantly useful. Typically, that information is produced by therapeutics developers in connection with bringing a particular therapeutic treatment to market.⁴²² For a variety of reasons, developers have little incentive in producing more clinical information than minimally required for regulatory approval.⁴²³ But because IP protections largely influence the green-lighting and structuring of clinical trials, tailoring those protections may spur the development of more clinical trials.⁴²⁴ Significant changes to patent systems solely to encourage therapeutics' developers to test more of their products may be too blunt of an instrument for both political and policy reasons.⁴²⁵

One smaller, and potentially easier, fix would be a statutory clarification that the use of a drug during clinical trials does not raise

420. See 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, 857–59 (1980) (discussing agencies' duty to assess when to move "proprietary information" to public disclosure).

421. Donald N. McCloskey, *The Economics of Enclosure: A Market Analysis*, in EUROPEANS PEASANTS AND THEIR MARKETS: ESSAYS IN AGRARIAN ECONOMIC HISTORY 123 (William N. Parker & Eric L. Jones eds., 1975). "Enclosure" refers to the process, enacted between the fifteenth to nineteenth centuries in England, of aggregating smaller, communal village farms into a single, larger space, owned privately by a single landowner. *Id.* Because enclosure operated as a "redistribution of wealth from the poor to the rich," historians and economists alike have likened it to "a plain enough case of class robbery." *Id.* at 142.

422. See Contreras & Vertinsky, *supra* note 294, at 120; see also Lietzan, *supra* note 294, at 37; Price & Minssen, *supra* note 294, at 685.

423. See Falit, *supra* note 301, at 988–89.

424. See Lietzan, *supra* note 294, at 94–95; Prince & Minssen, *supra* note 294, at 685–66; Vertinsky, *supra* note 26, at 1517–18; Memorandum, *supra* note 5.

425. Roin, *supra* note 278, at 751–53 (articulating a patent system based on time to market—and its difficulties); Roin, *supra* note 312, at 508–10 (proposing the narrowing of the nonobviousness requirement for drugs and its difficulties). Despite the persuasiveness of these proposals, they may violate major intellectual property treaties, including TRIPS, the Agreement on Trade-Related Aspects of Intellectual Property Rights. See General Agreement on Tariffs and Trade – Multilateral Trade Negotiations (the Uruguay Round): Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods art. 27.1, Dec. 15, 1993, 33 I.L.M. 81 (requiring patents to be available for inventions that include "an inventive step").

one of patent law's statutory bars.⁴²⁶ Doing so may encourage therapeutics developers to at least pull more promising compounds off the shelf for early stage clinical work, without the threat of penalizing them—and barring the patentability of derivative compounds—if their experiments fail. Encouragingly, Congress has taken a similar tack before with respect to infringement in the clinical trial context. Section 271(e) of the patent statute excepts from patent infringement “uses [of a patented invention] reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.”⁴²⁷ This provision, in turn, has been interpreted broadly by the courts—despite a buffet of exceptions⁴²⁸—and is now a core plot of the landscape for therapeutics' developers IP strategy.⁴²⁹

Lastly, standardizing the IP licensing regime for cancer databases could also promote the development of new cancer information. Licensing interoperability—rather than infringement liability—often precludes meta-analyses of large datasets.⁴³⁰ And researchers undertaking such analyses do so for a variety of reasons and with a variety of applications in mind.⁴³¹ Perfectly harmonizing interoperability to meet these diverse concerns will likely remain impossible.⁴³² But centering on a default licensing scheme—much like FRAND (fair, reasonable, and non-discriminatory) licensing in a standard setting organization—that both protects the original data and recognizes its diverse for-profit and non-profit uses may be a workable solution. At the same time, creating a uniquely-tailored licensing regime just for cancer data will almost certainly prove problematic, if for no other reason than the difficulties in predicting

426. See *supra* Section II.A.2 (discussing the statutory bars).

427. 35 U.S.C. § 271(e)(1) (2012).

428. These exceptions include new animal drugs, veterinary biological products, and patents on processes used to submit routine manufacturing information to the FDA. See *id.*; *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1072 (Fed. Cir. 2011).

429. See *Classen Immunotherapies, Inc. v. Elan Pharm., Inc.*, 786 F.3d 892, 893–94 (Fed. Cir. 2015) (concluding that Elan did not infringe Classen's patents by engaging in clinical research on its own drug, Skelaxin (metaxalone)). Because, prior to *Classen*, it was unclear whether § 271(e) would apply to brand manufacturers—and not just generics—its full effect is only beginning to be seen.

430. See Simon Oxenham, *Legal Maze Threatens to Slow Data Science*, 536 NATURE 16, 16–17 (2016); Victoria Stodden, *Reproducing Statistical Results*, 2 ANN. REV. STAT. & APPLICATION 1, 14 (2015).

431. See Oxenham, *supra* note 30, at 17.

432. See Molloy, *supra* note 387, at 4 (discussing the unrequited virtues of interoperability); Stodden, *supra* note 30, at 14 (discussing interoperability difficulties including “a conflict between openness for the replication of computational results and traditional methods of privacy protection via data sequestration”).

how such data will be used in the future.⁴³³ To these ends, off-the-shelf licenses like the GNU Lesser General Public License (“GNU LGPL”) may prove effective. The GNU LGPL specifically contemplates the use of earlier datasets for the purpose of combining them into a larger work.⁴³⁴ It also operates automatically; researchers wishing to use GNU LGPL protected datasets would not need to secure permission from individual owners for their use.⁴³⁵ Whether GNU LGPL or another licensing scheme is best positioned as a default for cancer datasets will almost certainly require more careful investigation. But centering on a common standard for licensing would promote the analysis of our current repository of cancer information and encourage its further development.

2. Disclosure

While producing cancer information is an important goal of the Cancer Moonshot, its ultimate disclosure remains paramount. Indeed, the Moonshot’s participants’ concerns about the siloing of cancer information centers around what is, essentially, a disclosure problem: finding ways of encouraging the producers of cancer information to share it.⁴³⁶ Tailoring intellectual property incentives around disclosure may ultimately promote the activity.

First, the disclosure of previously secret information is one of the core functions of the patent system. Perhaps ironically, it may therefore appear that encouraging the patenting of cancer information would consequently encourage its disclosure.⁴³⁷ But the reality, of course, is more nuanced than that. A number of scholars have recently pointedly out—both doctrinally and empirically—that patents’ disclosure function as a source of technical information is relatively minimal.⁴³⁸ Furthermore, what does tend to be disclosed is often wrapped not in technically useful language or the argot of legal certainty, but a peculiar pidgin of “patentese” useful, sadly, only to

433. Judith Swan et al., *Cancer Surveillance in the U.S.: Can We Have a National System?*, 83 *CANCER* 1282, 1282–83 (1998) (“Although significant steps have been taken to move toward the use of a uniform data set, differences in data collection, analysis, and reporting place an extra burden on registries that report to more than one surveillance program. In addition, the inconsistencies of data sets present obstacles to their compilation for collaborative use.”).

434. *GNU Lesser General Public License (Version 3)*, GNU OPERATING SYSTEM (June 29, 2007), <https://www.gnu.org/licenses/lgpl-3.0.en.html> [<https://perma.cc/A6D7-A52V>] (containing provisions for combined works in section 4 of the license).

435. *Id.* (requiring some sharing of code).

436. *See supra* Section III.A.

437. *See* Sherkow, *supra* note 21, at 847–48 (discussing this disclosure paradigm).

438. *Id.* at 867–68.

other patent attorneys.⁴³⁹ Efforts to fix this disclosure regime in patents would, obviously, prove meaningful. But they have been attempted many times, and in many different contexts, without much success.⁴⁴⁰ The problems in aligning patent drafting to scientific discovery are products of law, history, and philosophy, more than scientific ones.⁴⁴¹ In other words, “it may simply be impossible to cleanly map words to things.”⁴⁴²

Second, trade secrets are, by their nature, anti-disclosure regimes. Indeed, for trade secrets to remain protectable, their owners *must* engage in efforts to keep them secret.⁴⁴³ Encouraging the protection of cancer information through trade secrets would simply run counter to the purpose of the Cancer Moonshot, and would contribute to an increasing compartmentalization of information.⁴⁴⁴ To mitigate against this, any information created as part of the Cancer Moonshot should be legally excepted from its protection as a trade secret or confidential business information. This has several advantages, not the least of which is that information derived from the Moonshot that is eventually submitted to the FDA would be subject to disclosure through the Freedom of Information Act.⁴⁴⁵ Furthermore, disclosure as a condition of participation circumvents the problem of “regulatory blocking”: obtaining, and then delaying or failing to use, regulatory exclusivities for anticompetitive purposes.⁴⁴⁶ After all, a regime that mandates information disclosure provides no benefit to those who are slack to use their own—or their competitors’—information. To be sure, forced disclosure like this would only eliminate trade secrets *de jure* as opposed to *de facto*:

439. Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 633–34 (2010) (“A crucial step in [the claiming drafting] process is transforming the inventor’s plain English into patentese, the specialized language that patents are written in.”).

440. See Sherkow, *supra* note 21, at 905 (discussing the lack of prior success in aligning science to patents’ disclosure function).

441. See Dan L. Burk & Mark A. Lemley, *Fence Posts or Sign Posts? Rethinking Patent Claim Construction*, 157 U. PA. L. REV. 1743, 1745–47 (2009).

442. *Id.* at 1745.

443. 18 U.S.C. § 1839(3)(A) (2012) (requiring a trade secret owner to have “taken reasonable measures to keep such information secret”).

444. See *supra* notes 23–24 and accompanying text.

445. Cf. *Pub. Citizen Health Research Grp. v. FDA*, 704 F.2d 1280, 1290–91 (D.C. Cir. 1983) (determining that confidential business information submitted to the FDA from clinical trials is not subject to FOIA requests).

446. Cf. C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 949–50 (2011) (promoting a “use it or lose it” approach to generic exclusivity earned through the Hatch-Waxman Act pharmaceutical patent litigation).

even without legal protection, nothing will prevent participants in the Cancer Moonshot from keeping information to themselves. But removing legal protections from information developed under the auspices of a federally-funded information-*sharing* program would provide appropriate and legal avenues for the disclosure of such information for future projects.

Lastly, mandating disclosure brings with it the ancillary, but important, benefits of standardizing data structure. That is, the FDA could require data disclosed by Moonshot participants to be submitted in certain formats, be coded in particular ways, or contain specific structured data elements.⁴⁴⁷ This is significantly important for follow-on research programs like Hetionet. Data standardization facilitates future research through interoperability, allows for “reliable comparisons” across studies, and eases data management, among other benefits.⁴⁴⁸ Agreeing on uniform data standards has been a task typically left to industry but has experienced severe balkanization in the clinical context.⁴⁴⁹ Putting this role in the hands of the FDA, or at least with some FDA oversight, has had much more success.⁴⁵⁰

Mandating disclosure in a way palatable to industry, however, remains a challenge. With patents ineffective and trade secrets unwanted, regulatory exclusivities—tied to the disclosure of information—may prove fruitful. Private participation in the Moonshot could be structured around bonus regulatory exclusivities for future therapies in return for the disclosure of certain types of information. These could be structured along a continuum of the data's value: a smaller number of years for the disclosure of datasets identifying new molecular targets or chemical screen products, and a longer regulatory exclusivity period for the disclosure of robust longitudinal data from human trials. This is not entirely unprecedented. Currently, the FDA grants an additional six-month

447. ENGLISH ET AL., *supra* note 261, at 34–35 (discussing the FDA's role in data standardization). *See generally* Roy B. Jones, Dianne Reeves & Charles S. Martinez, *Overview of Electronic Data Sharing: Why, How, and Impact*, 14 CURRENT ONCOLOGY REP. 486 (2012) (discussing these terms in the oncology data context).

448. *See* Christopher P. Cannon et al., *American College of Cardiology Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients with Acute Coronary Syndromes: A Report of the American College of Cardiology Task Force on Clinical Data Standards (Acute Coronary Syndromes Writing Committee)*, 38 J. AM. COLL. CARDIOLOGY 2114, 2116 (2001) (listing these and other benefits).

449. *See* ENGLISH ET AL., *supra* note 261, at 34–35.

450. *See id.* at 35 (discussing some “big data” successes, like the cancer Biomedical Informatics Grid (“caBIG”)).

exclusivity period for therapeutic developers' completion of pediatric clinical trials.⁴⁵¹ This operates whether the pediatric trials were, themselves, a success: developers that engaged in, and failed, pediatric trials for their drugs are still entitled to the six-month exclusivity benefit.⁴⁵² This six-month exclusivity award—worth, in some cases, hundreds of millions of dollars—therefore functions as an informational disclosure incentive. A company that conducts pediatric clinical trials receives an exclusivity bonus on its product for essentially *disclosing* that information to the agency.⁴⁵³

One could easily envision such a system for the Cancer Moonshot, where disclosure of discrete datasets—raw data from clinical trials, for instance, or information concerning chemical screens against tumors—entitle their owners to a regulatory exclusivity period bonus applied to a future therapeutic product approved by the FDA. Industry has signaled approval for such bounties as promising more certainty than other forms of intellectual property that may only poorly protect the information disclosed.⁴⁵⁴ And the exclusivity bonus for conducting pediatric trials, for example, has been, in many ways, a success.⁴⁵⁵ If the program is successful, taxpayers will likely pay for these bonuses in the form of higher prices, at least in the short term.⁴⁵⁶ But society can hope for the long-

451. 21 U.S.C. § 355a(b)–(c) (2012). This exclusivity is often thought of as an extension of the patent term because pediatric exclusivities are listed alongside patents in the FDA's *Orange Book*; however, it's a six-month exclusivity bonus applied in addition to *all* other exclusivities—patents or other regulatory exclusivities. *Frequently Asked Questions on Patents and Exclusivity*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm> [<https://perma.cc/893G-LURK>] (“When pediatric exclusivity is obtained, a 6-month period of exclusivity is added to all existing patents and exclusivity on all applications held by the sponsor for that active moiety.”).

452. *See* 21 U.S.C. § 355a(b)(1) (requiring only that the “studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted”—not that the pediatric indication is ultimately approved).

453. *Cf.* Eisenberg, *supra* note 231, at 347 (“If a century ago the goal of drug regulation was to protect people from poisons, today drug regulation guides the development of information that turns poisons, used advisedly, into drugs Information about drug effects is an extremely valuable resource for guiding sound therapeutic choices, as well as for guiding the development of better products in the future.”).

454. *See* Thomas, *supra* note 25, at 42–47 (describing the rise and success of regulatory exclusivities).

455. Jennifer S. Li et al., *Economic Return of Clinical Trials Performed Under the Pediatric Exclusivity Program*, 297 JAMA 480, 480 (2007) (describing the pediatric-exclusivity regime as “creating incentives for studies in children” and a “windfall” for pharmaceutical developers).

456. Michael Dickson & Jean Paul Gagnon, *Key Factors in the Rising Cost of New Drug Discovery and Development*, 3 NATURE REVIEWS DRUG DISCOVERY 417, 418 (2004) (tethering regulatory exclusivities to drug prices).

term benefits designed in the program's favor. Besides, structuring disclosure incentives around regulatory exclusivity bonuses would not require a separate appropriation from Congress, making a bonus system perhaps more politically feasible than direct subsidies.⁴⁵⁷

Alternatively, a different form of regulatory property could be used as an incentive: priority review vouchers ("PRVs"). Generally, PRVs allow an agency to expedite review of a time-limited asset, such as FDA approval for a drug protected by rapidly expiring patents.⁴⁵⁸ But as the "voucher" in PRV suggests, the property is alienable and can be sold to others on the open market.⁴⁵⁹ This encourages a broad variety of stakeholders to participate in neglected research, even if their immediate needs do not contemplate priority review. Indeed, PRVs were originally implemented to spur the development of treatments for neglected diseases affecting impoverished parts of the world.⁴⁶⁰ And recently, the 21st Century Cures Act expanded the PRVs to include drugs used to treat agents of bioterrorism.⁴⁶¹ Further, like regulatory exclusivities, PRVs do not necessarily require separate congressional appropriations, similarly making them politically feasible incentives.⁴⁶² For the Moonshot, PRVs could be implemented as bonuses to companies for disclosing valuable cancer datasets. A PRV incentive would be strong: in other contexts they have sold for over \$300 million on the open market, with AbbVie recently purchasing one for \$350 million.⁴⁶³

457. Cf. Roin, *supra* note 312, at 507 ("[U]nlike a government-run drug-development program, Congress could easily implement the proposed FDA-administered exclusivity periods because current law already provides for certain short delays in the approval process for generics.")

458. 21 U.S.C. § 360n(a)(2) (2012). Priority review vouchers were originally proposed in a 2006. David Ridley, Henry G. Grabowski & Jeffrey L. Moe, *Developing Drugs for Developing Countries*, 25 HEALTH AFFS. 313, 313 (2006). In an amazing alliance between academia and Congress, the system of priority review vouchers was enacted into law shortly thereafter. Kyle Wamstad, Note, *Priority Review Vouchers – A Piece of the Incentive Puzzle*, 14 VA. J.L. & TECH. 126, 127 (2009).

459. 21 U.S.C. § 360n(b)(2) ("The sponsor of a tropical disease product that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher . . .").

460. See *id.* § 360n(a)(2) (limiting priority review vouchers to drug applications for "tropical diseases"); Ridley et al., *supra* note 458, at 313 ("To receive a voucher, a therapy must . . . treat neglected diseases such as African trypanosomiasis, Chagas disease, leishmaniasis, or dengue fever . . .").

461. 21st Century Cures Act, Pub. L. No. 114-255, Sec. 3086, § 565A, 130 Stat. 1033, 1144–47 (2016).

462. 21 U.S.C. § 360n(c)(5) (funding the administration of priority review vouchers through existing appropriations).

463. John Carroll, *That Priority Review Voucher Program? The FDA Hates It*, FIERCE BIOTECH (Mar. 3, 2016), <http://www.fiercebiotech.com/r-d/priority-review-voucher->

This is not to say that these exclusivity incentives—and PRVs in particular—are without problems. With respect to neglected tropical diseases, PRVs have been criticized by health scholars as being ineffective—generating a meager total of *four* drugs developed under its auspices from 2007 to 2016.⁴⁶⁴ In addition, there is some evidence to suggest that awarding PRVs encourages the purchase and sale of smaller pharmaceutical companies by larger ones, rather than the outsized R&D spending contemplated by the program.⁴⁶⁵ The FDA itself has been critical of PRVs administrative burden as detracting from other “important public health work.”⁴⁶⁶ And there is, of course, the potential for perpetual price increases that come with such monopoly provisioning.⁴⁶⁷ These are important criticisms of PRVs that should not be taken lightly. Nonetheless, they seem to be more related to the ineffectiveness of using PRVs as *drug* development tools rather than—as contemplated here—information-sharing regimes.

Squatting, rather, seems more problematic in this context: developers sitting on exclusivity periods earned as a result of disclosing information, without using such information to bring therapies to market.⁴⁶⁸ Several scholars have recognized analogous problems in a variety of other contexts. In 2011, Michael Abramowicz highlighted this problem for “orphan business models”: “business models previously conceived and disclosed that no one has had

program-fda-hates-it [<https://perma.cc/ZA9Z-NPG2>] (“AbbVie (\$ABBV) plunked down \$350 million for its review voucher back in the spring of 2015. And there’s plenty of evidence that the industry sees significant value in the vouchers, looking for four added months of marketing for their top prospects.”).

464. Ana Santos Rutschman, *The Priority Review Voucher Program at the FDA: From Neglected Tropical Diseases to the 21st Century Cures Act*, ANNALS OF HEALTH L. SUMMER 2017, at 71, 80.

465. Aaron S. Kesselheim, *Drug Development for Neglected Diseases: The Trouble with FDA Review Vouchers*, 359 NEW ENG. J. MED. 1981, 1981 (2008).

466. Peter Loftus, *Drug Makers Buy Pricey Vouchers to Speed Products to Market*, WALL ST. J. (Nov. 1, 2015), <https://www.wsj.com/articles/drug-firms-buy-pricey-vouchers-to-speed-products-to-market-1445333403> [<https://perma.cc/K256-LLWG> (staff-uploaded archive)].

467. Kesselheim, *supra* note 465, at 1982.

468. See Nicholson W. Price II, *Regulating Secrecy*, 91 WASH. L. REV. 1769, 1809–10 (2016) (“Voluntary disclosure could be driven by incentives provided to firms, most likely in the form of regulatory benefits such as agency-enforced exclusivity. . . . Such exclusivity would have a limited duration and be explicit, resolving some of the problems with secrecy. . . . However, firms would be expected to game the system; those secrets worth more than the exclusivity would be kept secret, and those of lesser value would be disclosed, leading to a socially suboptimal outcome.”).

sufficient incentives to implement.”⁴⁶⁹ In Abramowicz’s account, government-issued exclusivities for orphan business models—patents, regulatory exclusivities, and even royal prerogatives—suffer from a lack of “institutional capability to determine which business models will need legal exclusivity in order to be commercialized.”⁴⁷⁰ Granting exclusivities to such business models is plainly inefficient.⁴⁷¹ Similarly, Ian Ayres and Lisa Larrimore Ouellette have recently explored this phenomenon in the context of university-developed patents.⁴⁷² Ayres and Ouellette note that many university-developed patents are licensed exclusively, narrowing their ambit of commercialization.⁴⁷³ Given that some university-developed patents are broadly commercialized using *nonexclusive* licenses, they argue that “a nonexclusive license is *prima facie* evidence that the invention ought not to have been patented at all.”⁴⁷⁴ And even more broadly, Ted Sichelman has documented that “[a]s an empirical matter . . . less, probably much less, than half of all patented product inventions are commercialized.”⁴⁷⁵

Interestingly, each of these scholars support analogous market-based solutions—essentially, auctions—to solve the problem of regulatory squatting. Abramowicz, for example, proposes several creative auction schemes designed to either grant only the shortest period of exclusivity the market would bear or to encourage competitors to disclose *further* information in an attempt to thwart the first-discloser’s exclusivity period entirely.⁴⁷⁶ Ayres and Ouellette, in their study of university patents, do essentially the same.⁴⁷⁷ And while Sichelman finds that such auctions have some drawbacks in encouraging the patenting of commercialized productions, as opposed to “embryonic inventions,” he appears largely supportive.⁴⁷⁸ One of

469. Michael Abramowicz, *Orphan Business Models: Toward a New Form of Intellectual Property*, 124 HARV. L. REV. 1362, 1365 (2011).

470. *Id.* at 1368–69.

471. See generally Paul E. Schaafsma, *An Economic Overview of Patents*, 79 J. PAT. & TRADEMARK OFF. SOC’Y 241 (1997) (discussing, *inter alia*, the efficiency concerns of early royal letters patent).

472. See Ayres & Ouellette, *supra* note 265.

473. *Id.* at 271.

474. *Id.* at 275–76.

475. Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341, 362 (2010).

476. See Abramowicz, *supra* note 469, at 1396–1407, 1419–20.

477. See Ayres & Ouellette, *supra* note 265, at 301–05.

478. See Sichelman, *supra* note 475, at 391, 401 (“In sum, while patent extension auctions could potentially cure many under-commercialization problems, given the possible asymmetries between original patentees and third-party bidders that do not arise from the benefits of development during the term, implementation could be quite difficult and could lead to marked increases in deadweight losses.”).

the many virtues of these proposals is the employment of market-based initiatives to counteract decidedly anti-market regimes. And in doing so, these proposals leverage what was previously dispersed, and in some cases, confidential information to decide not only on the worthiness, but also on the extent of such regulatory monopolies. In other words, exclusivity auctions as rewards for disclosure indirectly promote the disclosure of information itself. In writing about these auctions, Ayres and Ouellette emphasize that “the purpose of [an] exclusivity auction is not to identify the lowest bidder with the lowest commercialization cost . . . [It] is to harness *knowledge* of the lowest-cost commercializer.”⁴⁷⁹ Ultimately, programs like these are tailored to avoid—especially for public projects like the Cancer Moonshot—giving up too much of the public’s goodwill for too little information in return.

Despite their faults, regulatory exclusivities do appear to be the best options for promoting the disclosure and use of cancer information. According to John R. Thomas—a qualified skeptic of the practice—regulatory exclusivities nonetheless “provide a far more robust and reliable exclusion mechanism than do patents for rights holders,” are self-enforcing, are less susceptible to challenge, and are more aligned with specific products than other traditional forms of intellectual property.⁴⁸⁰

3. Use

Lastly, although the primary goals of the Cancer Moonshot center on the production and disclosure of information, the project should also further the actual *use* of this information in the development of new therapies—what many researchers have described as “translational medicine.”⁴⁸¹ Ideally, the information developed through a program like the Cancer Moonshot would be used to create new drugs, biologics, and medical devices for treating cancer itself, not to mention information about how to best use such therapies, on which patients, and under what circumstances. While these may not be the Moonshot’s primary aim—indeed, part of the Moonshot is preventing such narrow thinking towards products as to seemingly discourage them⁴⁸²—concrete therapies should be at least some of the fruits of that labor.

479. See Ayres & Ouellette, *supra* note 265, at 304.

480. Thomas, *supra* note 25, at 42–43.

481. See, e.g., PRESIDENT’S COUNCIL OF ADVISORS ON SCI. & TECH., *supra* note 141, at 2.

482. See *supra* notes 168–72 and accompanying text.

Patents and trade secrets, of course, will likely play their traditional—or at least, current—roles in ushering these new products to market. To the extent that commercial developers of therapeutics see immediate value in the public information developed as a result of the Cancer Moonshot, they will likely engage in such activity without further intervention. Indeed, one of the goals of the Moonshot is to enable the profitable development of newer therapies without perpetual assistance.⁴⁸³ To be sure, the laws governing patents and trade secrets in this space could be substantially better aligned to produce those goods.⁴⁸⁴ But that realignment is likely to have significant effects in those regimes beyond the mere encouragement of using Cancer Moonshot data to develop therapies. Whether sharpening patent and trade secret law to achieve that makes an appropriate cut or is too blunt of an instrument for serious consideration will likely depend on how valuable the information produced by a project like the Moonshot ends up being.

Similar to the context of the disclosure of cancer data, regulatory incentives may too have a role to play in enhancing the data's use. Indeed, regulatory exclusivities already play an extensive role in encouraging private investment in the development of new therapies.⁴⁸⁵ Such exclusivities could easily be tailored to give preference to therapies developed from Cancer Moonshot data, such as data made available to the Genomic Data Commons or for participants in the project to be used in future applications to the FDA. These kind of exclusivity rewards may spark enough encouragement for private industry to produce, disclose, and *use* cancer information as a profitable enterprise. Further, this seems tacitly supported by those scholars, like Abramowicz, who have advocated for exclusivity procurement auctions: auctions for regulatory exclusivities for treatments based on cancer data that produce few bidders signal a lack of utility of the data disclosed; auctions that produce many, active bidders signal a higher level of utility in the data.⁴⁸⁶ Whether such incentives are tailored around bonus exclusivity periods, PRVs, or some other form of regulatory property merits further investigation. But holding out additional incentives to develop the data uncovered by a program like the Cancer Moonshot is likely to best serve the effort's goals.

483. See Simon, *supra* note 7.

484. See *supra* notes 305–10 and accompanying text.

485. See Thomas, *supra* note 25, at 42–47.

486. See Abramowicz, *supra* note 469, at 1399–1400.

C. *Public-Private Partnerships, Intellectual Property, and Information Policy*

In some ways the Cancer Moonshot, at least in its ideal form, is unique in that it is a public-private partnership to uncover information about a complex disease, a true understanding of which has eluded physicians for millennia.⁴⁸⁷ But the project also illuminates broader difficulties with public-private research in general, namely problems of intellectual property and information policy. Examining these difficulties provides several broader lessons about the purpose and limits of public-private partnerships.

1. Data Privacy

First, the Cancer Moonshot sheds light on public-private partnerships' challenges concerning data privacy. The Moonshot, conceived as an information-sharing regime, immediately raises several issues concerning the security of patient's data, an especially sensitive reality in cancer research.⁴⁸⁸ Cancer information derived from human tumors is essentially information about cancer patients' (ill) health.⁴⁸⁹ A patient's tumor type may inform an observer about the patient's private behavior, such as a history of smoking or sexual activity.⁴⁹⁰ And genetic information derived from that tumor may contain more health information—such as parentage or dispositions to diabetes or Alzheimer's—than just a cancer diagnosis.⁴⁹¹ Safeguarding patients' health data remains one of the more difficult challenges—both technical and legal—in the privacy world today.⁴⁹² Public-private partnerships dedicated to sharing personal information

487. Time will tell whether it will be a worthy endeavor. In the meantime, skepticism abounds. See Peter Lee, *Toward a Distributive Commons in Patent Law*, 2009 WIS. L. REV. 917, 919–920.

488. Jane Kaye, *The Tension Between Data Sharing and the Protection of Privacy in Genomics Research*, 13 ANN. REV. GENOMICS & HUM. GENETICS 415, 415 (2012) (“Next-generation sequencing and global data sharing challenge many of the governance mechanisms currently in place to protect the privacy of research participants. These challenges will make it more difficult to guarantee anonymity for participants, provide information to satisfy the requirements of informed consent, and ensure complete withdrawal from research when requested.”).

489. See Julien Mancini et al., *Consent for Biobanking: Assessing the Understanding and Views of Cancer Patients*, 103 J. NAT'L CANCER INST. 154, 158 (2011) (noting that cancer information is subject to the Genetic Information Nondiscrimination Act (GINA)).

490. See, e.g., Janet R. Daling et al., *Human Papillomavirus, Smoking, and Sexual Practices in the Etiology of Anal Cancer*, 101 CANCER 270, 270 (2004).

491. See Robert C. Green et al., *ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing*, 15 GENETICS IN MED. 565, 565 (2013).

492. See Kaye, *supra* note 488, at 415.

must therefore recognize these challenges despite their mandates to disseminate it broadly. In some instances, the threat of political reprisal and current market forces favoring privacy will be enough to ensure the security of patients' data.⁴⁹³ But that does not mean that private enterprise can be simply deputized to safeguard the broader citizenry's health data.⁴⁹⁴ However well-intentioned, public-private partnerships' efforts to structure information sharing about health data should give us pause.

2. Scientific Reproducibility

Second, the Moonshot counsels forward thinking concerning scientific reproducibility. Its encouragement to produce and disclose large *quantities* of cancer information makes no guarantees about the *quality* of such data. Recently, numerous meta-analyses have decried the lack of reproducibility of much cancer research.⁴⁹⁵ A review in *Nature* of this problem noted that the effort "to translate cancer research to clinical success has been remarkably low," and blamed this lack of success, at least in part, on "the quality of published preclinical data."⁴⁹⁶ But cancer research is not the only field touched by recent accusations of irreproducibility; much of the life sciences, in fact, have come under questioning for producing volumes of essentially irreproducible results.⁴⁹⁷ Whether this is truly a crisis in the making or simply a routine part of the scientific method remains to be seen.⁴⁹⁸

But public-private partnerships, like the Cancer Moonshot, should take special efforts to ensure that the information produced as a result of their programs is, at a minimum, reproducible by others. This is because public-private partnerships have a public obligation to produce such data and are likely more susceptible to encourage the creation of irreproducible. The public funds the public part of the public-private partnership in the first instance—by providing government resources needed to conduct the enterprise—and also in

493. See Ryan Calo, *Privacy and Markets: A Love Story*, 91 NOTRE DAME L. REV. 649, 651 (2015) (developing "a novel account of the relationship between privacy and markets, positioning the two concepts as sympathetic instead of antithetical").

494. Wilbanks & Topol, *supra* note 24, at 346–47.

495. See, e.g., Begley & Ellis, *supra* note 245, at 532.

496. *Id.* at 531–32.

497. See Sherkow, *supra* note 21, at 855–60 (reviewing the literature surrounding irreproducibility).

498. See Christie Aschwanden, *Science Isn't Broken*, FIVETHIRTYEIGHT (Aug. 19, 2015), <http://fivethirtyeight.com/features/science-isnt-broken/> [http://perma.cc/7TTZ-GSOC] (arguing that irreproducible results is a normal function of the scientific method).

the marketplace, if the endeavor is successful. At the same time, the prizes offered for private participation in the project create conflicts for companies to produce data of the highest quality.⁴⁹⁹ The success of any information-seeking public-private partnership, therefore, hinges on ensuring that the data produced is, in fact, valid.

3. Overprivatization

Third, as much as some form of intellectual property may be a necessary incentive for participation in public-private partnerships, too much protection may ultimately be counterproductive. Numerous scholars have written at length about the role that stringent IP protections play in stymieing information production in burgeoning fields.⁵⁰⁰ To chose just one example in a galaxy of others, Fiona Murray and Siobhán O'Mahony recently recounted how intellectual property protection shaped the use of the Oncomouse, a genetically engineered mouse with a predisposition to cancer, "widely recognized as an important building block for further innovations in cancer biology and drug discovery."⁵⁰¹ After DuPont purchased and began to enforce the patent rights to the cancer tool, "the use of Oncomice in drug discovery slowed and . . . [a]cademic research was inhibited as follow-on innovators turned to different animal models."⁵⁰² This problem of patent enforcement creating hurdles for future research can be particularly salient for public-private partnerships that invest the power (and often, money) of the government in private hands. One potential solution may be to look toward using public-private partnerships to facilitate the organization of a knowledge commons, an institutional design created to facilitate the "*sharing* of knowledge and information resources to produce innovation and creativity."⁵⁰³ Several scholars, especially Jorge L. Contreras, have written considerably about using commons frameworks in the context of genetic data.⁵⁰⁴ But whether this strategy is enough to encourage

499. Vertinsky, *supra* note 26, at 1517 ("[Policymakers] need to find ways of mitigating the negative effects of market incentives on cooperation without removing market incentives altogether from this process. This requires strategies for confronting and reducing the tensions between private and public incentives to create and share knowledge.").

500. See, e.g., Burstein, *supra* note 178, at 232–33; Eisenberg, *supra* note 23, at 178; Rai, *supra* note 178, at 126.

501. Murray & O'Mahony, *supra* note 314, at 1012.

502. *Id.*

503. Brett M. Frischmann, Michael J. Madison & Katherine J. Strandburg, *Introduction, in GOVERNING KNOWLEDGE COMMONS*, *supra* note 10, at x.

504. See, e.g., Contreras, *supra* note 10, at 99–100; Jorge L. Contreras, *Bermuda's Legacy: Policy, Patents, and the Design of the Genome Commons*, 12 MINN. J.L. SCI. &

private investment in public-private partnerships remains to be seen. Suffice it to say that public-private partnerships need to take special care in tailoring their intellectual property incentives to promote the dissemination of information even potentially at the cost of profitable private ownership.

4. Transaction Costs

Fourth, even if public-private partnerships can perfectly align intellectual property rights and information policies in theory, there may be significant transaction costs to putting them on paper. Tania Bubela, Jenilee Guebert, and Amrita Mishra have recently discussed some of the difficulties in creating material transfer agreements (“MTAs”)—contracts that “set the terms under which [institutions’] materials and associated data may be obtained and used by others”—in the context of preclinical research.⁵⁰⁵ MTAs are a necessary part of preclinical research; they “provide a mechanism to protect the interests of the owners of discoveries and inventions, while promoting data and material sharing in the research community.”⁵⁰⁶ But their negotiation, interpretation, and enforcement often create significant burdens for researchers—so much so, that in several high-profile cases, they have functioned to halt research rather than ease it.⁵⁰⁷ Similarly, Jorge L. Contreras and Liza Vertinsky have written about the Accelerating Medicines Partnership, a public-private partnership devoted to studying Alzheimer’s, diabetes, arthritis, and lupus.⁵⁰⁸ Simply creating the partnership—to speak nothing of the research conducted under its auspices—“took more than two years of intense negotiations to conclude,” and include intellectual property provisions among participants that remain confidential.⁵⁰⁹ This is not to say that public-private partnerships should abandon their efforts because the transaction costs are often enormously high. Rather, as Bubela, Guebert, and Mishra’s work broadly suggests, large, multi-

TECH. 61, 63 (2011); Jorge L. Contreras, *Prepublication Data Release, Latency, and Genome Commons*, 329 SCI. 393, 393–94 (2010); Jorge L. Contreras, *Data Sharing, Latency Variables, and Science Commons*, 25 BERK. TECH. L.J. 1601, 1641–52, 1657–58 (2010).

505. Tania Bubela, Jenilee Guebert & Amrita Mishra, *Use and Misuse of Material Transfer Agreements: Lessons in Proportionality from Research, Repositories, and Litigation*, 13 PLOS BIOLOGY 1, 1 (2015).

506. *Id.*

507. *Id.* at 6–7 (discussing *United States v. Kurtz*, No. 04-CR-0155A, 2008 WL 1820903 (W.D.N.Y. Apr. 21, 2008) and *United Univ. Professions v. New York*, 966 N.Y.S.2d 350 (N.Y. Sup. Ct. 2013) (unpublished table decision), 2013 WL 203402).

508. Contreras & Vertinsky, *supra* note 294, at 92–93.

509. *Id.* at 93–95.

institutional agreements among partnership participants “should be kept as simple as possible, so that institutions can realistically monitor and enforce the terms.”⁵¹⁰

5. Political Challenges

Fifth, the Cancer Moonshot provides some broader, synoptic perspective to why, and under what circumstances, public-private partnerships tend to arise in the first instance. The Moonshot arose where neither the market, regulation, nor simple government largess produced the sort of information or public goods demanded by the marketplace—namely, a substantial cure for cancer.⁵¹¹ But this does not necessarily explain why the government sees it fit to intervene here, as opposed to the many other areas where market demand is left unfulfilled. Commenting on the short-termism of private investment, venture capitalist Peter Thiel once quipped, “We wanted flying cars, instead we got 140 characters.”⁵¹² And yet, no one has proposed a public-private partnership between the Federal Aviation Administration and Boeing dedicated to producing a flying car. This suggests that public-private partnerships, like the Moonshot, are more than solutions to simple market failures; they are an encapsulation of naked public policy (and political) preferences as to how both the public and private sectors should allocate research and development funds. It is not just that the polity demands a cancer cure—it is also that the polity disagrees with the direction, manner, and effort of current cancer research.⁵¹³ The Cancer Moonshot is, essentially, a political rebuke of therapeutic developers’ current efforts to produce cancer therapies.⁵¹⁴

6. Health Care Costs

At the same time, this rebellion, like others, may eventually devour its children.⁵¹⁵ A successful cancer moonshot may create

510. Bubela et al., *supra* note 505, at 8.

511. See notes 135–42 and accompanying text.

512. George Packer, *No Death, No Taxes*, NEW YORKER, Nov. 28, 2011, at 44–45.

513. See Daniel Engber, *Cancer Research Is Broken*, SLATE (Apr. 19, 2016, 9:21 AM), http://www.slate.com/articles/health_and_science/future_tense/2016/04/biomedicine_facing_a_worse_replication_crisis_than_the_one_plaguing_psychology.html [https://perma.cc/85EQ-2QBA (staff-uploaded archive)] (chastising the cancer research model).

514. See Address Before a Joint Session of the Congress on the State of the Union, *supra* note 4.

515. Cf. DEBORAH KENNEDY, HELEN MARIA WILLIAMS AND THE AGE OF REVOLUTION 113 (2002) (quoting Mallet du Pan on the French Revolution that “the Revolution devours its children”).

therapies so expensive for the public to purchase, they constitute a drain on the public health coffers. This is, in fact, what has recently occurred for a set of drugs curing hepatitis C that so “severely stress budget-constrained programs like Medicaid and the Veterans Health Administration[,] . . . their aggregate cost would [if widely deployed] overwhelm budgeted resources.”⁵¹⁶ But perhaps even more frighteningly, a successful cancer moonshot may extend the average citizen’s lifespan to such a degree that we will need to rethink a variety of social constructions grounded in what we previously perceived as an average lifespan, including sentences in criminal law, insurance policies, and the social safety net for elders.⁵¹⁷ Whether political constituencies that bargained for public-private partnerships recognize the perils of their success remains to be seen. But, in thinking about the real fruits of projects like the Cancer Moonshot—informational or otherwise—we should be careful what we wish for.

CONCLUSION

The Cancer Moonshot is ultimately an effort to uncover information about cancer, the complexity of which is, perhaps, unrivaled. Yet, the cost, time, and effort of producing cancer information is enormous—too great of a burden to place on public resources alone. The Moonshot, like other efforts to study costly, informationally complex phenomena, has therefore turned to a public-private partnership as a solution to marshaling resources and expertise to achieve its goals. At the same time, the attractiveness of incentives for private participation—namely, intellectual property in these areas—is unclear. Patents, once the gold standard for cancer research, face numerous difficulties: subject matter concerns loom over recent advances; the statutory bars require early, ineffective disclosures; and patents’ twenty-year term discourages important, long-term research. Trade secrets and some regulatory exclusivities harbor similar problems.

Aligning the Cancer Moonshot with intellectual property incentives requires explicitly recognizing that the project is informational in nature. To that end, the practical goal of the Moonshot should be the implementation of a data-sharing regime.

516. Austin Frakt, *We Can’t All Have It All: The Economic Limits of Pharmaceutical Innovation*, JAMA FORUM (Apr. 6, 2016), <https://newsatjama.jama.com/2016/04/06/jama-forum-we-cant-all-have-it-all-the-economic-limits-of-pharmaceutical-innovation/> [<http://perma.cc/8U2A-ZQCH>].

517. See Govind Persad, *Lifetimes in the Law* 6–13 (unpublished manuscript) (on file with the North Carolina Law Review).

More specifically, the Moonshot should encourage the production, disclosure, and use of cancer information developed from its partnership. Encouraging private participation, however, will likely require tailoring various components of the current IP regime. The production of cancer data, for example, could be encouraged by formally shielding preclinical and clinical trials from patent law's statutory bars, as well as encouraging participants to ensure interoperability—both legal and technical—among datasets. Private companies could be encouraged to disclose their data to other participants by rewarding them with regulatory exclusivity bonuses. And encouraging therapeutics developers to use the information generated from such a project could be furthered by doling out priority review vouchers for their products. To be sure, some of these solutions would require statutory fixes—not an easy task given the myriad public health priorities Congress currently faces. But each of these items is relatively cheap, easy to administer, and—importantly—politically viable.

More broadly, the Cancer Moonshot sheds light on some of the difficulties of the phenomenon of information seeking public-private partnerships. Using the power of the government to encourage private development of, essentially, public goods is a delicate game. Information developed under these auspices raises issues concerning data privacy and scientific reproducibility, not to mention greater concerns about the role of IP rights for publicly-funded projects, generally, and the transaction costs required to bring such projects to fruition. Cancer's *IP*, therefore, is equal parts *intellectual property* and *information policy*. But these difficulties aside, the Cancer Moonshot, like its namesake effort to put a man on the moon, represents the endurance of the human spirit in attempting to conquer frontiers unknown. As a quest for information, the Cancer Moonshot strives to boldly fill the common kitty of human understanding—to “set sail on this new sea because there is new knowledge to be gained.”⁵¹⁸

518. Address at Rice University in Houston on the Nation's Space Effort, 1962 PUB. PAPERS 668 (Sept. 12, 1962).